Localised Cancer Treatment

PCI Biotech

Second Quarter and First Half 2010 Results

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– 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; high cancer specificity; complete clinical regression
- Screening studies suggest a large number of alternative drug combinations
  - *In vitro* studies indicate that up to 20% of relevant drugs may be enhanced by PCI
- 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
  - Successful completion of 90 MNOK rights issue

Highlights

- Completed inclusion of fourth dose group in the PC-A11 Phase I/II study
  - Preliminary results suggest that further dose escalation may not be needed
  - Third dose group successfully completed – continued good response with complete clinical tumour regression and no serious adverse reactions deemed drug related by the investigators
- Completed rights issue of NOK 90 million
  - Fully guaranteed by largest shareholders and oversubscribed by ~50%
- Produced Active Pharmaceutical Ingredient (API) for next clinical trials
  - Have invested in API that will cover for the planned clinical trials
- Received inconclusive data from preclinical bladder cancer studies
  - The results are not conclusive, but still indicate a lack of significant treatment effects at the applied conditions
- Accelerated identification of additional indications & combination products
  - Engaged international advisors to review KOL data and analyse market opportunities

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PCI Technology

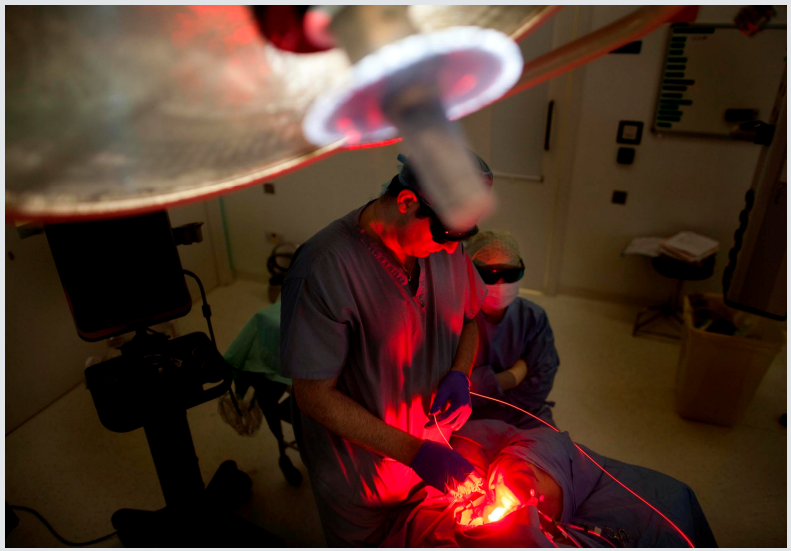
Photochemical Internalisation – a new technology for localised cancer treatment

- Light-induced chemistry for local enhancement of the effect of various drugs, using a unique and patented photosensitiser, Amphinex® to induce the enhancement

- Initial regulatory interactions suggest that ‘combination pack’ is a feasible regulatory route, opening up for PCI-based multiproduct opportunities

- Targeted light-directed delivery of effective cancer drugs to solid tumours is feasible for most cancers and locations in the body

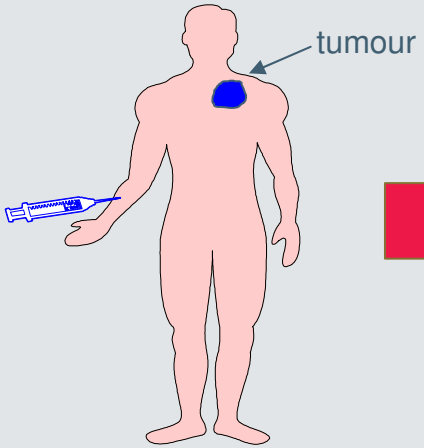
- First clinical PCI study with the combination product PC-A11, based on Amphinex® and the well established generic cytotoxic bleomycin, at University College Hospital in London



Significantly enhancing the local effect of cancer drugs

Amphinex®: patented molecule (photosensitiser) making cells sensitive to light

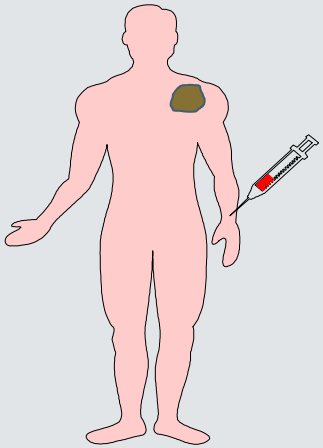
Inject Amphinex®



Amphinex® taken up by tumour cells

Days**

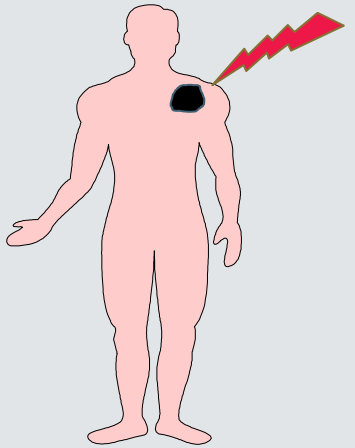
Inject drug*



Drug taken up by tumour cells

Hours**

Light exposure



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

PCI induces endosomal drug delivery through light exposure

Amphinex® (S) and the drug (D) are injected into the body and carried by the blood stream to the cancer cell

Amphinex® and the drug are taken up by the cell, but the drug is unable to reach the target (T), as it is encapsulated in an endosome

Light activates Amphinex® in the membrane of the endosome. The membrane is destroyed and the drug is released

The drug can now bind to its target and initiate the therapeutic response

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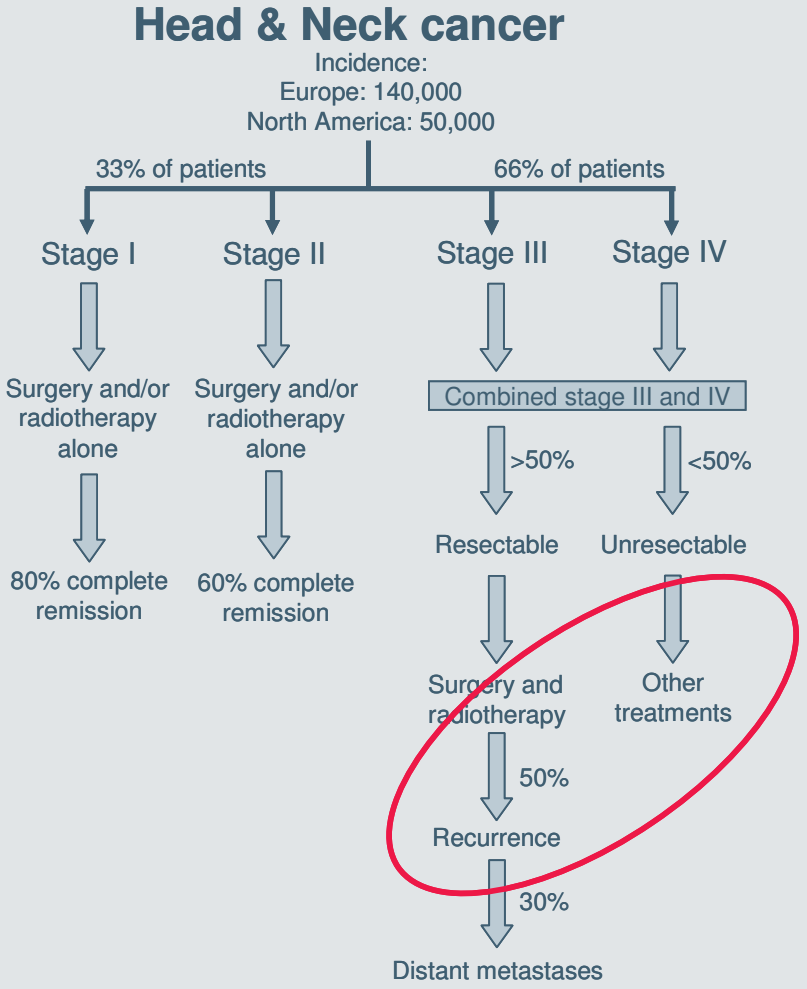
PC-A11

PC-A11: Local Treatment of H&N Cancer

PC-A11
Head & Neck Cancer

PCI has the potential to solve localised treatment challenges

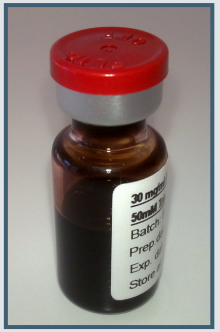
- Globally >640,000 new cases annually, and >140,000 in Europe
- Often not diagnosed until at advanced stage
- Current treatments expensive, and often associated with functional and cosmetic impairments
- Recurrence is common (20-30%) and problematic, as prior treatments often compromise treatment of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

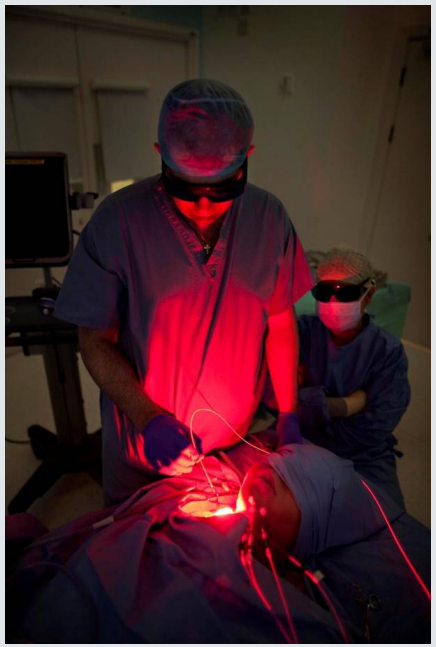
PC-A11: Key clinical results

- 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



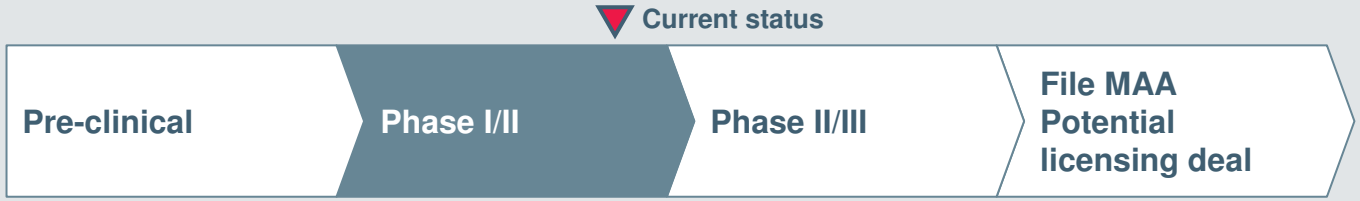
Amphinex®

- 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
  - 14 patients in total so far across 4 dose groups
- Phase I/II study on schedule to finish in 2010
  - Preliminary results indicate good safety and efficacy
  - Complete clinical regression of almost all target tumours with good tolerability in the first three dose groups
  - Preliminary safety results from the 4th dose group suggest that further dose escalation may not be necessary – starting to see significant skin photosensitivity



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 meeting scheduled for 2010
  - FDA interaction being planned
- Aim to apply for Marketing Authorisation if Phase II/III results are sufficiently positive
- Size, comparator, timing, etc to be determined depending on indication and regulatory discussions
- Potential licensing deal after filing for Marketing Authorisation
- Light source: Medical lasers currently available in EU, new laser needed for US

* MAA: Marketing Authorisation Application

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PC-A22

PC-A22

- Preclinical bladder cancer studies have been performed at Radboud University of Nijmegen and Norwegian University of Science & Technology
- Received inconclusive data from both preclinical bladder cancer studies
  - The results are not conclusive, but still indicate a lack of significant treatment effects at the applied conditions
- Some further experimental preclinical data needed to conclude
  - Limited experiments with altered dosing conditions will be performed in a few follow-up experiments, to elucidate whether the lack of effect is due to inherent factors or the applied dosing conditions

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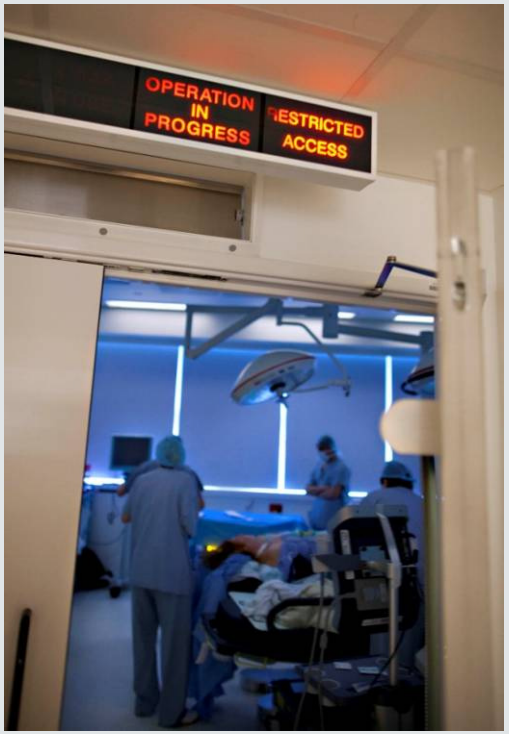
New combinations

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**
  - Engaged International advisors to assess KOL input and provide market analyses
  - Identify most promising combinations and indications and initiate additional Proof of Concept studies
  - Further cancer indication 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



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Amphinex®

Manufacturing of Amphinex®

- Developed a new and improved formulation of Amphinex®
- Completed bridging studies between new and old formulation. All future clinical trials with the new formulation of Amphinex®
- Produced a large stock of the Active Pharmaceutical Ingredient (API) for Amphinex®
- Formulation of 2,000 vials of Amphinex® based on new formulation during 2H 2010

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Financial results

Financial key figures 2010 and 2009

P&L (TNOK)	Q2 2010	Q2 2009	1H 2010	1H 2009	2009
Grants	1 789	1 723	3 151	3 439	8 612
Research and development costs	5 561	4 099	10 816	9 059	19 319
General and administrative costs	2 620	1 944	4 429	3 947	6 979
Total operating costs	8 181	6 043	15 245	13 006	26 298
Operating results	-6 392	-4 320	-12 094	-9 566	-17 686
Profit before tax	**-6 222**	**-3 662**	**-11 751**	**-8 084**	**-15 015**
Cash flow (TNOK)					
Net cash flow from operations	-2 215	-3 892	-5 867	-8 203	-14 206
Net cash flow from investments		-39		-113	-113
Net cash flow from financials	83 369		83 369		0
Net cash flow	**81 154**	**-3 931**	**77 502**	**-8 316**	**-14 319**

Financial key figures 2010 and 2009

Balance (TNOK)	30.06.2010	30.06.2009	31.12.2009
Fixed assets	115	247	181
Short term receivables	3 859	3 306	5 017
Cash & cash equivalents	**113 325**	**41 826**	**35 823**
Equity	107 255	41 531	35 077
Long term debt	0	0	0
Short term debt	10 044	3 849	5 944

Rights issue completed during Q2 2010

- Rights issue of 2,250,000 new shares with a subscription price of NOK 40 per share completed during Q2
- Fully guaranteed by largest shareholder. Strong support from existing shareholders. Oversubscribed by 50%.
- Gross proceeds NOK 90 million, net proceeds NOK 83.4 million
- Rights issue registered in Foretaksregisteret on 21 June.
- Number of shares following rights issue: 7,666,390

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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 • On track to finish the Phase I/II study in 2010 • Regulatory discussions for Phase II/III scheduled
PC-A22	• Received inconclusive data from preclinical bladder cancer studies • Some further studies required to conclude whether to proceed with this indication
New products	• Accelerated process to identify new product combinations and cancer indications • Preclinical results for additional products and indications with attractive development prospects • Engaged international advisors to analyse KOL data and market opportunities
Amphinex®	• Produced a large stock of the Active Pharmaceutical Ingredient (API) for Amphinex® • Well documented and patented product for the proprietary PCI platform
Finance	• Good financial position for further development of PC-A11 and the PCI platform

2010 - 2011

- Preclinical bladder cancer evaluation finished (PC-A22)
- 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

Enquiries

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