



Localised Cancer Treatment

PCI Biotech

Fourth Quarter and Preliminary 2011 Results

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February 2012

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Highlights 2011

- Completion of Phase I/II study of Amphinex®
- Design of Phase II study determined after extensive expert and regulatory consultation
- CHMP opinion that Amphinex should be developed as single product rather than a combination pack
- CE mark for the PCI 652nm medical laser, with PCI Biotech approved as manufacturer and supplier
- Positive pre-clinical efficacy results with 3 widely used cancer drugs: docetaxel, gemcitabine and erlotinib
- NOK 10.85 million awarded in BIA grant from The Research Council of Norway
- Winner of DNB's 2011 Innovation prize

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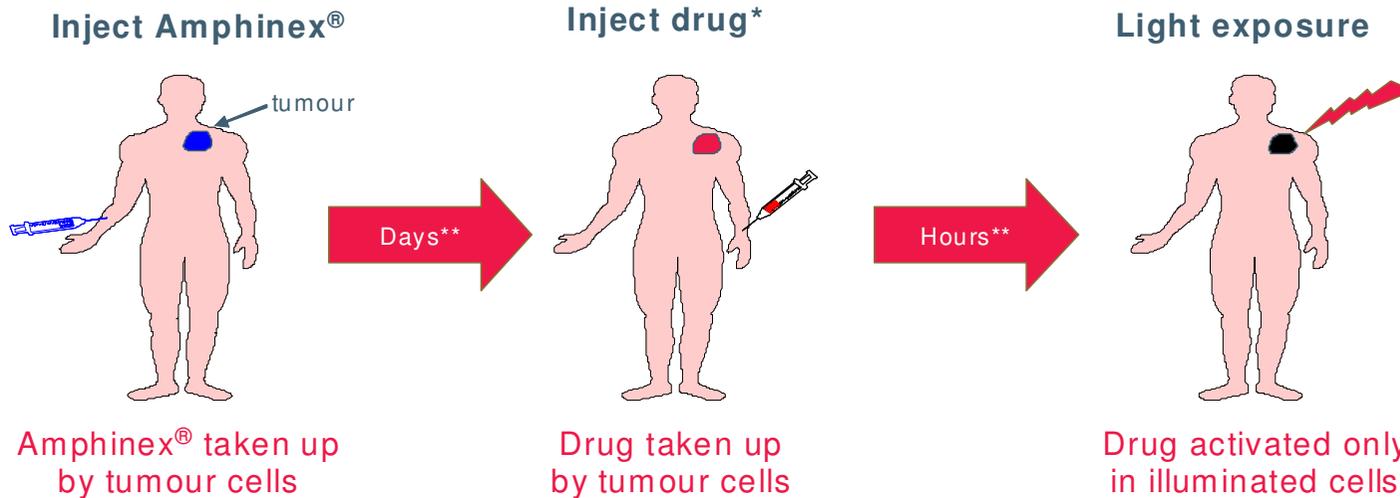
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Photochemical Internalisation – a new technology for localised cancer treatment



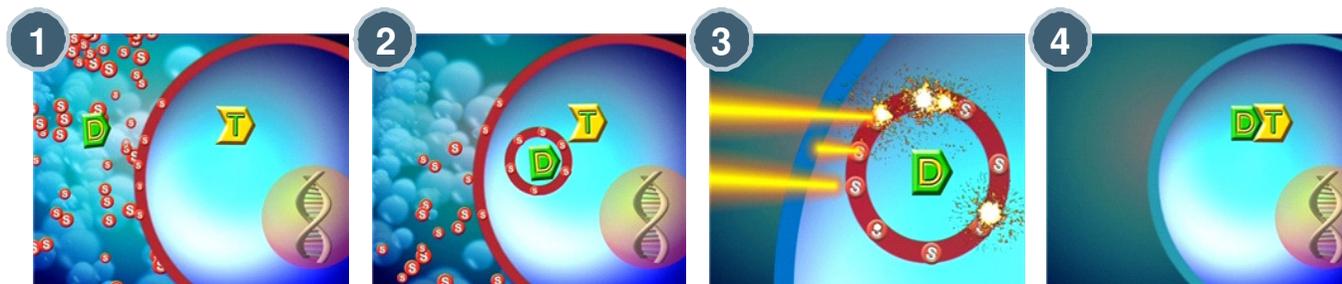
- Light-induced enhancement of various drugs, using a unique and patented photosensitiser, Amphinex[®] to induce the enhancement
- PCI Biotech is developing Amphinex[®] for local enhancement of marketed cancer drugs
- First clinical PCI study with Amphinex[®] for enhancement of the generic cytotoxic bleomycin
 - Included patients with some of the most difficult tumours to treat; osteosarcoma and squamous cell carcinoma of the head and neck, and skin metastases from breast cancer
 - 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

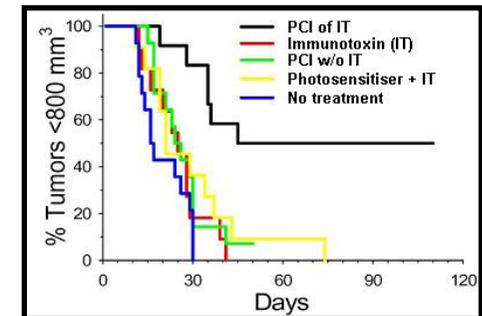
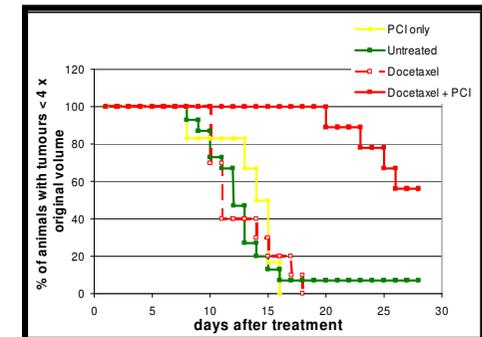
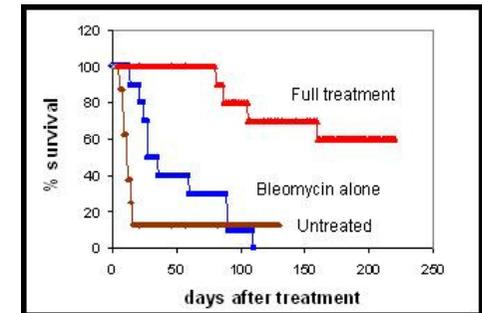
Enabling drugs to reach intracellular therapeutic targets



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 docetaxel
- Effective delivery of macromolecules
 - Proven effective delivery of several types of macromolecules, including targeted immunotoxins



*Berg, K. *et al.* (2005) *Clin. Cancer Res.* 11, 8476

**Unpublished results

***Selbo, *et al.* (2009). *PLoS ONE*, 4, e6691

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Strategy

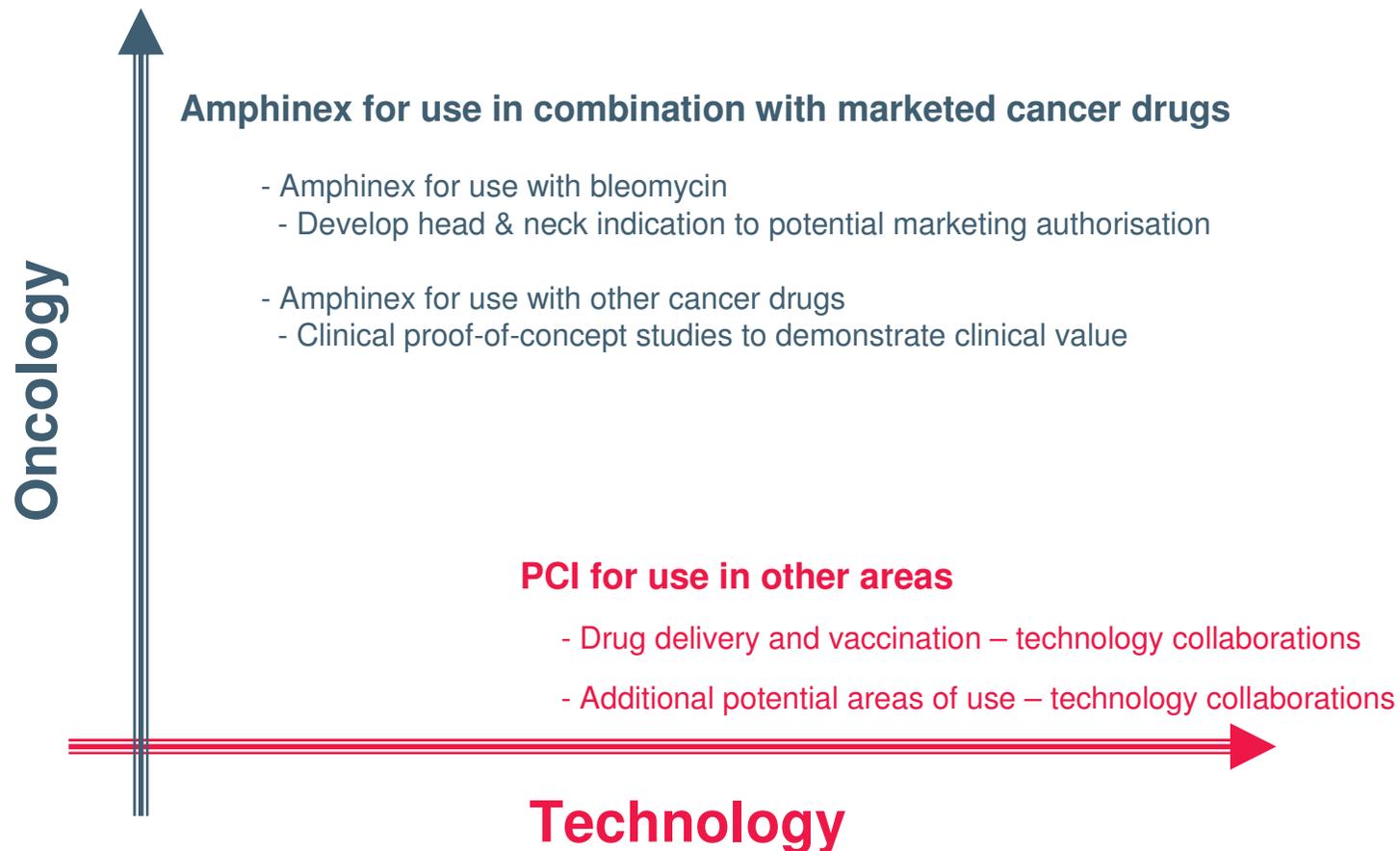
Localised cancer treatment – need for selective tumour ablation and improved local control



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



Growth of PCI Biotech via 2 axes



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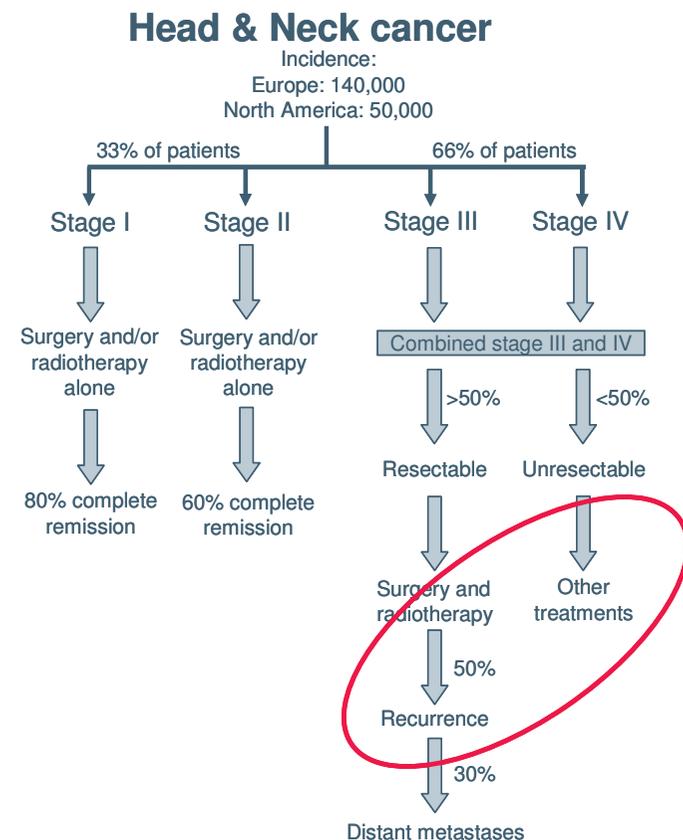


H&N cancer

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



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 (Erbix) most relevant price comparator
 - Approximately 20% of head & neck cancer patients eligible for Amphinex

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Amphinex[®]

CHMP opinion that Amphinex should be developed as a stand alone agent



- The CHMP opinion has provided a clear regulatory development route for Amphinex
 - Amphinex should be developed as a single drug for use in combination with bleomycin for head and neck cancer
- Has no direct impact on the design of the clinical development programme for head & neck cancer
- Amphinex's value will be further demonstrated through clinical proof of concept studies with other cancer drugs in additional indications
- Should have little impact on the justifiable price for the treatment, as the drug is a minor cost component in the PCI treatment
- It is not yet clear how the FDA will relate to this issue



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



- Patient inclusion 2012 – 2013
- 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 5-8 sites in 4-5 European countries

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

- Start of patient inclusion expected Q1 2012
 - Extensive discussions with investigators and head & neck cancer experts to optimise the study procedure and protocol
 - Regulatory and ethics approvals and hospital contract negotiations in process
- Further hospitals (2-3) in countries where the study protocol is already approved are being approached and will be considered for site selection to speed up patient inclusion into the study



PCI 652 Laser – designed for PCI treatment

- Prototyped, produced, and received CE marking for the PCI 652 nm medical laser
- PCI Biotech approved as manufacturer and supplier of the laser
- Designed for PCI treatment with Amphinex[®]
- One channel (5W) for superficial and 6 channels (0.5W) for interstitial light application
- Will be used in the Phase II study of Amphinex[®] in combination with bleomycin in head and neck cancer

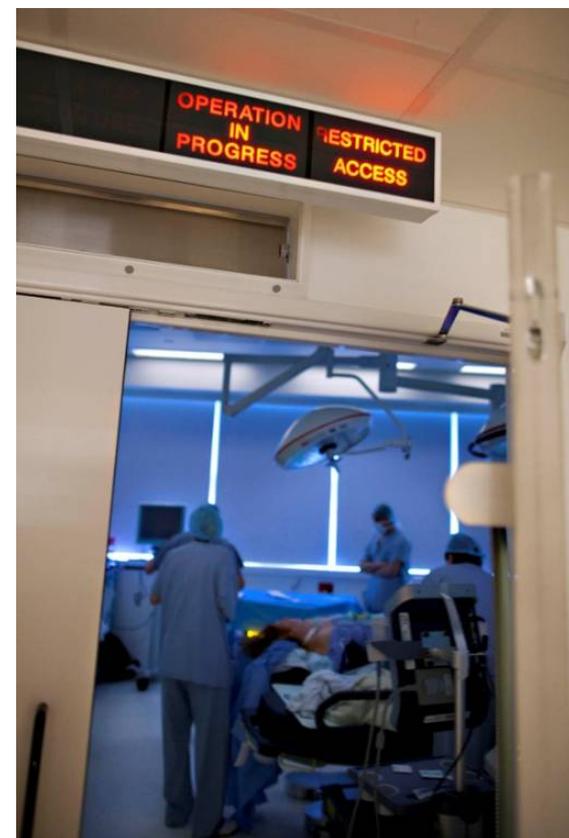


Further clinical Proof of Concept studies to be initiated to broaden the use of Amphinex

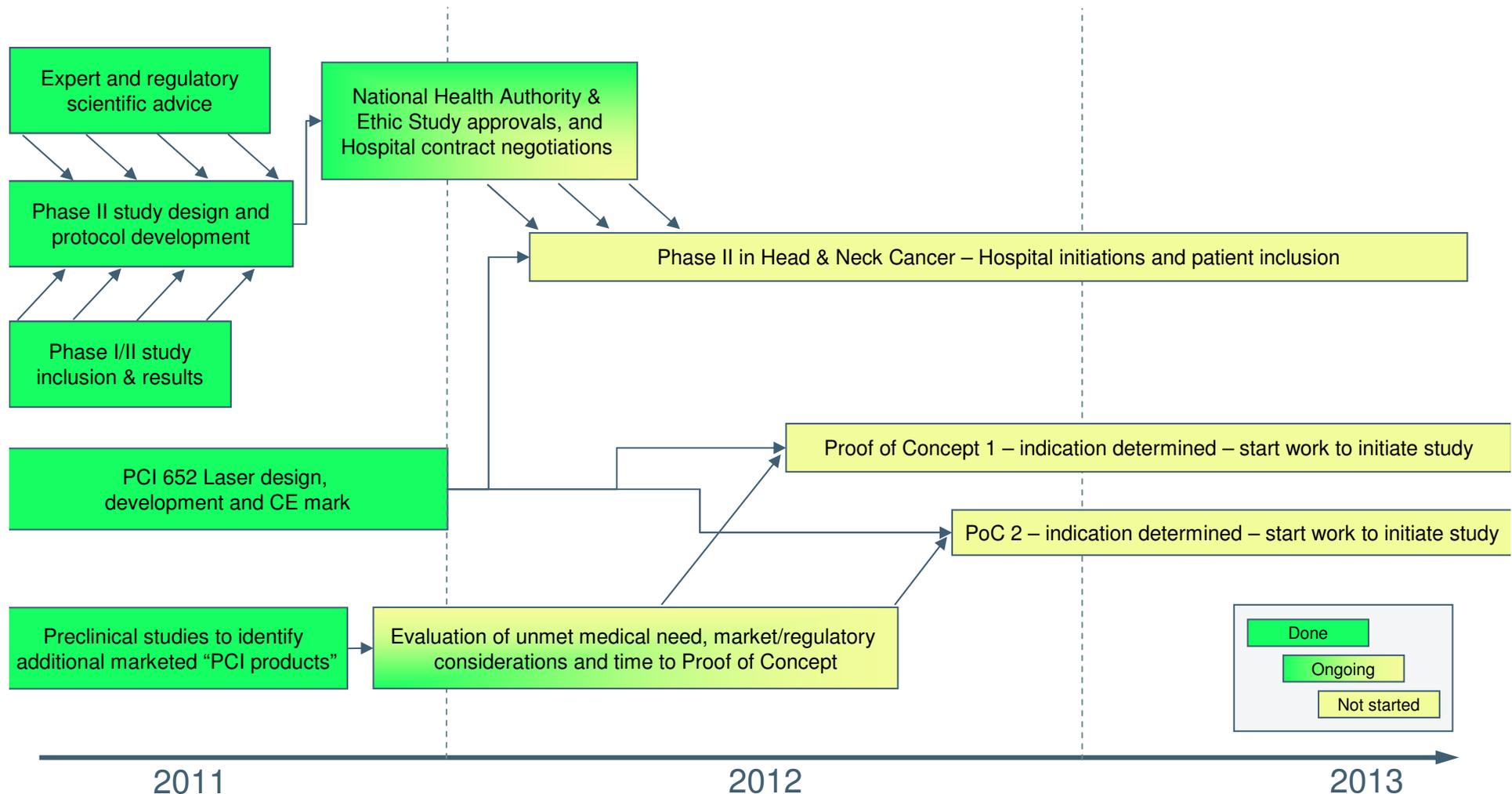
- Aim to start Proof of Concept studies with Amphinex used in combination with docetaxel, gemcitabine and/or erlotinib in 2012 and 2013
- Three widely used cancer drugs with positive results with PCI
- These drugs have the following approved indications:

| Cancer | Docetaxel (Gx) | Gemcitabine (Gx) | Erlotinib |
|-------------|----------------|------------------|-----------|
| Lung | ✓ | ✓ | ✓ |
| Pancreas | | ✓ | ✓ |
| Prostate | ✓ | | |
| Ovarian | | ✓ | |
| Gastric | ✓ | | |
| Breast | ✓ | ✓ | |
| Head & neck | ✓ | | |

- Indication selection criteria
 - Market and regulatory considerations
 - Approved product indications
 - Unmet medical need
 - Time to Proof of Concept

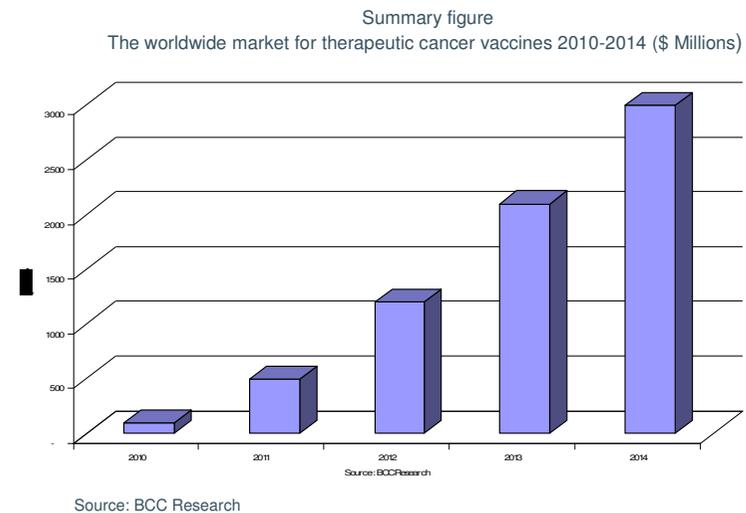


Amphinex development – current activities



PCI for vaccination – research program initiated

- Therapeutic vaccines – first product on the market in 2010
- Rapid market growth expected - market 2014 estimated to be USD ~3 billion
- Aim to establish proof-of-principle for both *in vivo* and *ex vivo* vaccination
- First set of PCI results from NTNU, Norway, indicates a good technical fit for PCI
- Further experiments will be performed at University Hospital Zurich, Switzerland.
- Results on proof-of-principle expected in 2012
- Program is part of a BIA-project funded by the Norwegian Research Council



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Financial results

Financial key figures 2011 and 2010

| <i>P&L (TNOK)</i> | Q4 2011 | Q4 2010 | 2011 | 2010 |
|----------------------------------|---------------|---------------|----------------|----------------|
| Grants | 2 765 | 1 741 | 7 423 | 10 444 |
| Research and development costs | 6 913 | 4 344 | 22 226 | 20 185 |
| General and administrative costs | 667 | 2 488 | 2 273 | 6 502 |
| Total operating costs | 7 580 | 6 832 | 24 499 | 26 687 |
| Operating results | -4 815 | -5 091 | -17 076 | -16 243 |
| Profit before tax | -3 939 | -4 130 | -13 749 | -13 940 |
| | | | | |
| Cash flow (TNOK) | | | | |
| Net cash flow from operations | -3 683 | -571 | -15 699 | -8 283 |
| Net cash flow from investments | | | | |
| Net cash flow from financials | | | | 83 274 |
| Net cash flow | -3 683 | -571 | -15 699 | 74 991 |

Financial key figures 2011 and 2010

| <i>Balance (TNOK)</i> | 31.12.2011 | 31.12.2010 |
|------------------------------------|---------------|----------------|
| Fixed assets | 17 | 78 |
| Short term receivables | 5 033 | 3 649 |
| Cash & cash equivalents | 95 115 | 110 814 |
| | | |
| Equity | 92 533 | 105 423 |
| Long term debt | 0 | 0 |
| Short term debt | 7 632 | 9 118 |

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Summary

PCI Biotech – well positioned for attractive development opportunities



- Amphinex with bleomycin**
 - Phase I/II study completed
 - Positive initial clinical results – well tolerated and strong tumour response
 - Phase II study in head & neck cancer being initiated
 - Strong patent position
 - 2,000 vials of the new formulation of GMP produced Amphinex available
- Line extensions**
 - Identified further marketed cancer drugs and indications
 - Aim to start further clinical proof of concept studies in 2012 and 2013
- Other**
 - Initiated program to investigate PCI for vaccination
 - Received CE marking for the PCI 652 medical laser designed for PCI treatment
- Finance**
 - Good financial position for further development of Amphinex and the PCI platform

2012

- Amphinex Phase I/II extension study completed
- Amphinex head & neck cancer Phase II study initiated
- Start Proof of Concept line extension study in second indication
- PCI vaccination – proof of principle studies completed

2013 - 2014

- Finalize Amphinex Phase II head & neck cancer study
- Start Proof of Concept line extension study in third indication
- Amphinex MAA filing and/or licensing deal

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