



Localised Cancer Treatment

PCI Biotech

Second Quarter and First Half 2012 Results

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Highlights 1H 2012

- Started inclusion of patients in the ENHANCE study, the Phase II study in head & neck cancer patients
- Bile duct cancer (cholangiocarcinoma) selected as next indication for PCI with Amphinex[®], using the marketed drug gemcitabine. A Proof of Concept study is expected to start by end of 1H 2013
- Promising results from preclinical program to investigate PCI used with vaccines. Decided to continue the preclinical program to optimise a treatment regime, and develop a protocol for a clinical study that can start in 2013
- Completed patient inclusion in the Phase I/II extension study of Amphinex[®]

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– Focused on Localised Cancer Treatment



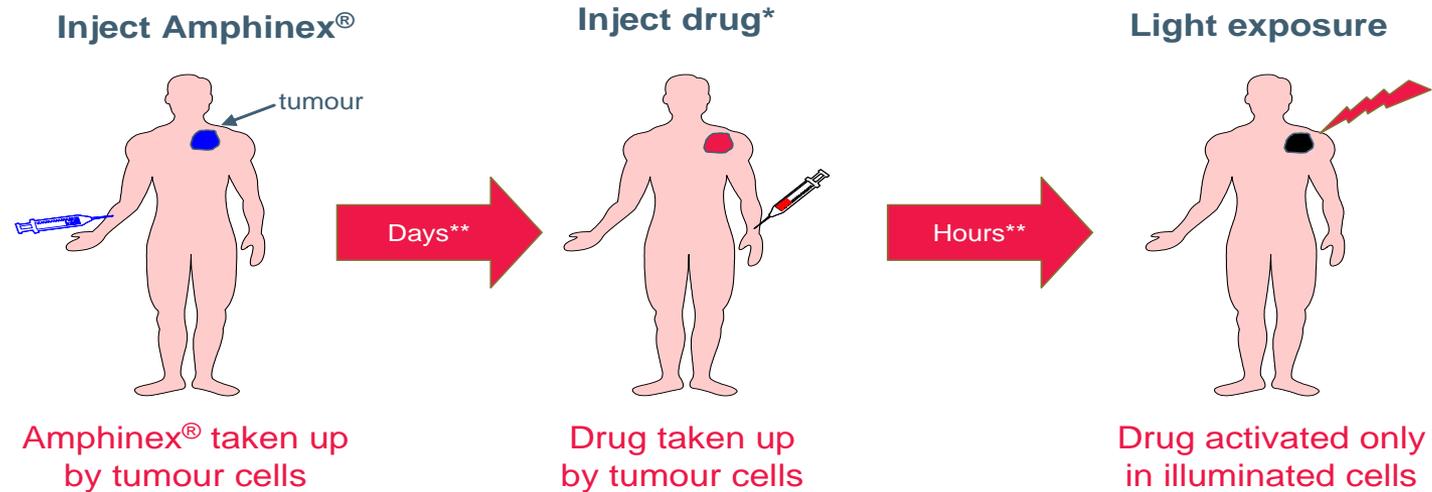
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Photochemical Internalisation – a new technology for localised cancer treatment



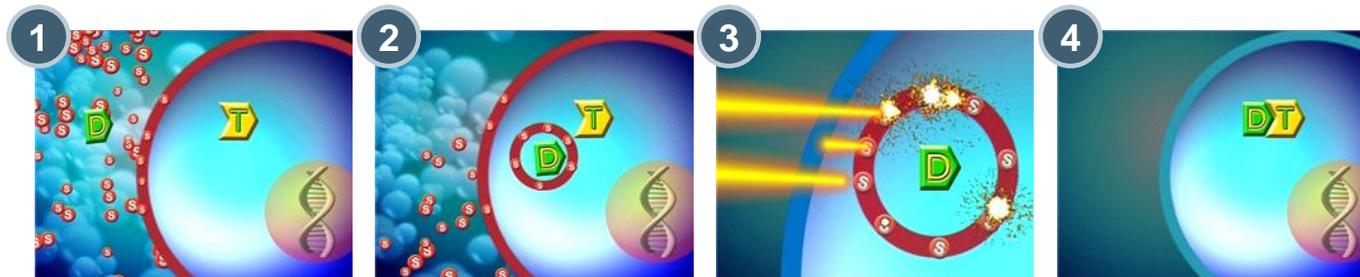
- Light-induced enhancement of various drugs, using a unique and patented photosensitiser, Amphinex[®] to induce the enhancement
- PCI Biotech is developing Amphinex[®] for local enhancement of marketed cancer drugs
- First clinical PCI study with Amphinex[®] for enhancement of the generic cytotoxic bleomycin 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



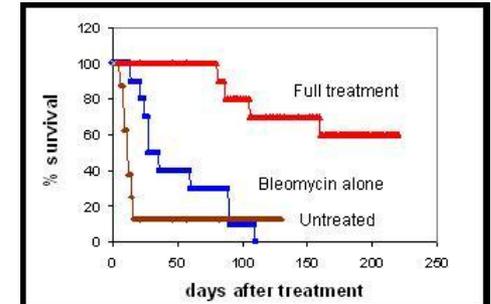
Amphinex may enhance the localised effect of a wide range of different cancer drugs



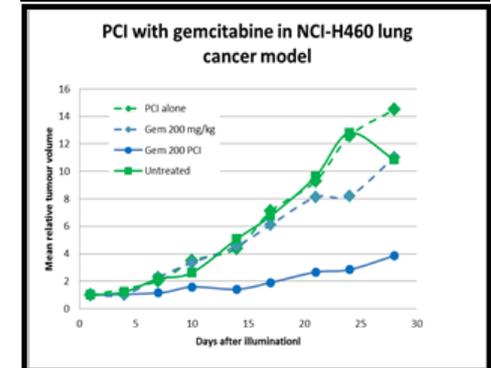
- Positive *in vivo* results with several marketed cancer drugs
 - Enhancement of the local effect of bleomycin in several models

- Significant enhancement of three widely used cancer drugs, including gemcitabine

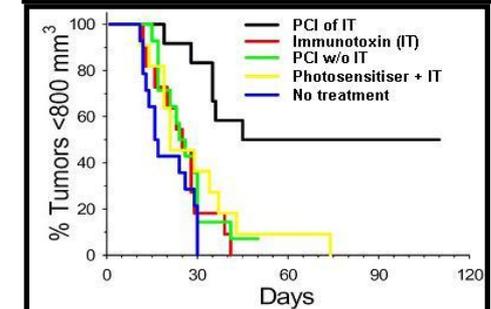
- Effective delivery of macromolecules
 - Proven effective delivery of several types of macromolecules, including targeted immunotoxins



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

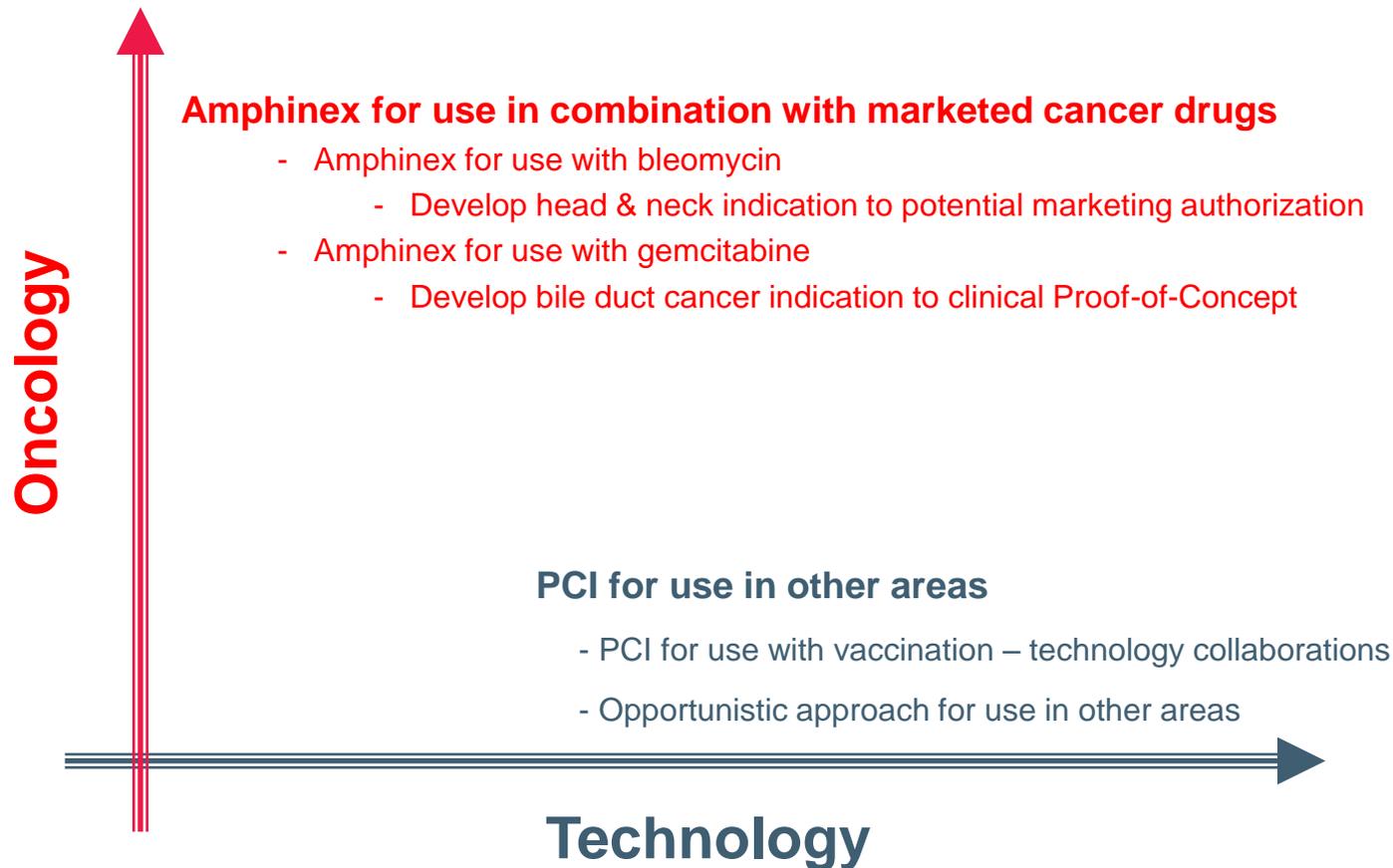
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Strategy

Growth of PCI Biotech via 2 axes

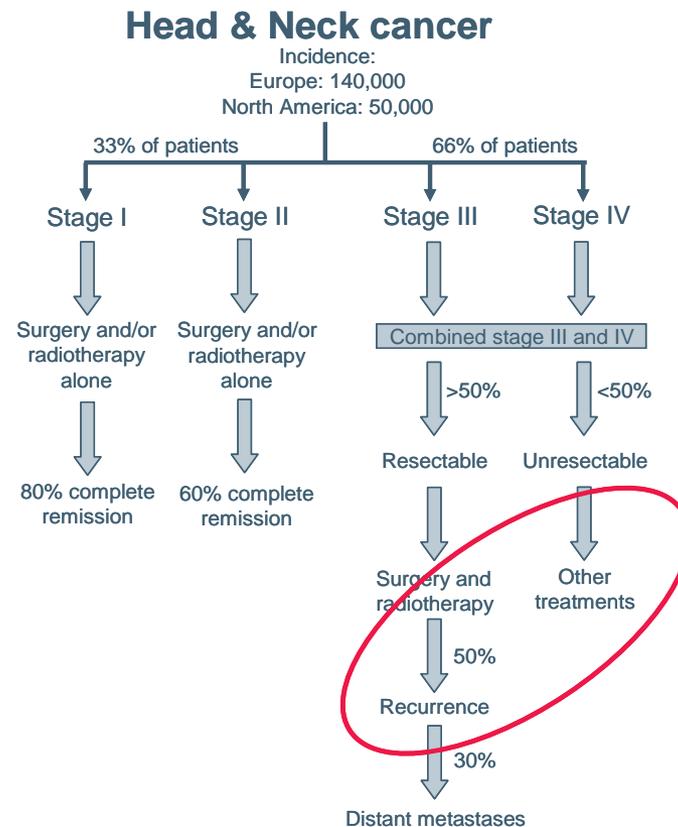


Head & neck cancer

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



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 – 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 Europe (exploring the possibility to open additional sites in India)

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
- 5 University hospitals currently involved in the study. One hospital (Aintree University Hospital in Liverpool, UK) is about to be activated
- Further European hospitals currently in process
- Exploring the possibility to open additional sites in India
 - India has a very high incidence of head & neck cancer and a number of hospitals offering high quality treatment options for these patients

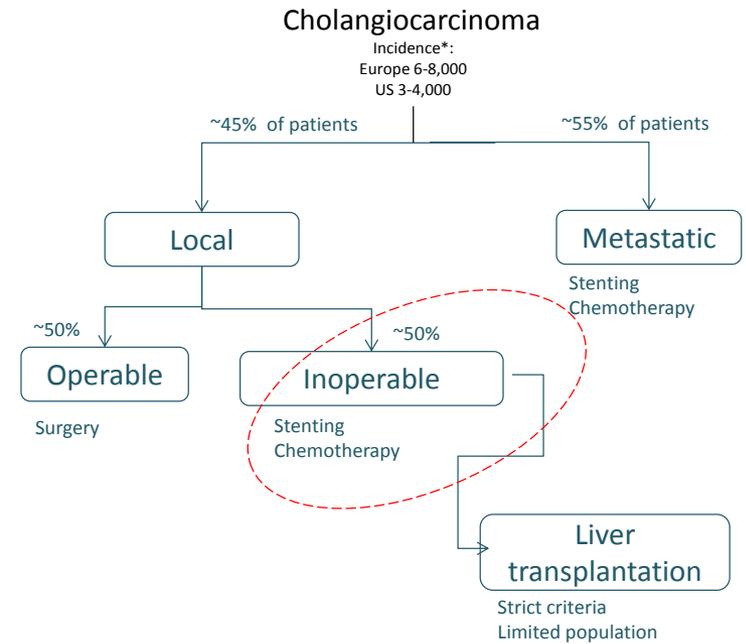


Bile duct cancer

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 improve quality of life and prolong life
- 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 it is one of the most studied and used chemotherapies in bile duct cancer



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

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 cancer
- 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/cisplatin chemo
 - Control arm: stenting alone followed by gemcitabine/cisplatin 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



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- 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 I: Approx. NOK 7 million
 Phase II: Approx. NOK 12 million

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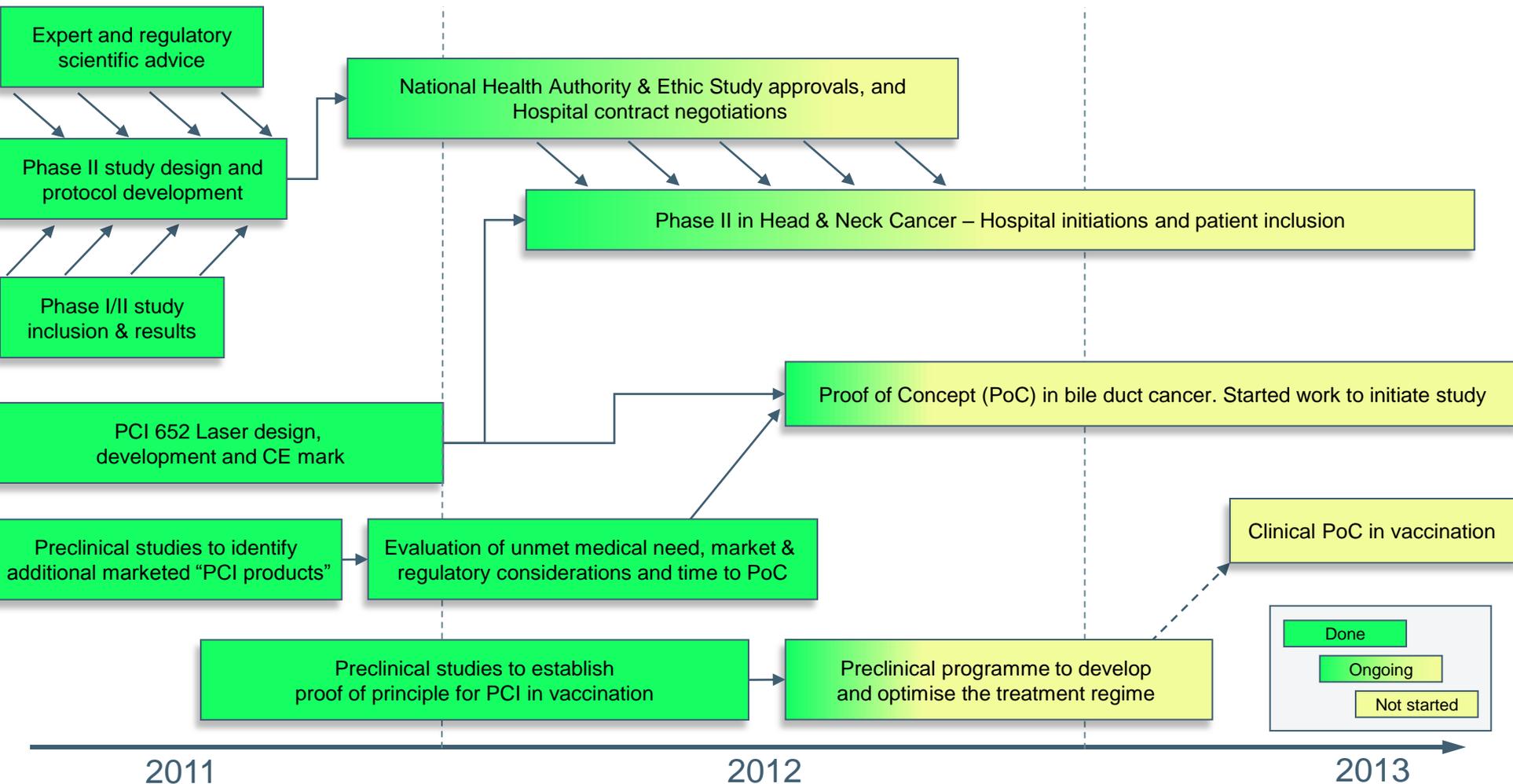


Vaccines

PCI for vaccination

- Vaccines identified as an interesting area for PCI
 - Rapid marked growth expected within therapeutic vaccines – first product on the market in 2010 and many products under development
- Need of products that can enhance the therapeutic effect of 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
- Preclinical program at University Hospital Zurich continues to develop and optimise a treatment regime with the aim to establish a protocol for a clinical study that can start in 2013

Development activities



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Financial results

Financial key figures 2012 and 2011

<i>P&L (TNOK)</i>	Q2 2012	Q2 2011	1H 2012	1H 2011	2011
Grants	1 896	885	3 805	2 446	7 423
Research and development costs	5 925	5 482	13 497	10 494	22 226
General and administrative costs	262	531	793	1 118	2 273
Total operating costs	6 187	6 013	14 290	11 612	24 499
Operating results	-4 291	-5 128	-10 485	-9 166	-17 076
Profit before tax	-3 763	-4 297	-9 272	-7 494	-13 749
Cash flow (TNOK)					
Net cash flow from operations	-4 391	-3 766	-9 212	-8 306	-15 699
Net cash flow from investments					
Net cash flow from financials					
Net cash flow	-4 391	-3 766	-9 212	-8 306	-15 699

Financial key figures 2012 and 2011

<i>Balance (TNOK)</i>	31.12.2011	30.06.2011	31.12.2011
Fixed assets	0	44	17
Short term receivables	5 892	3 755	5 033
Cash & cash equivalents	85 903	102 508	95 115
Equity	84 031	98 409	92 533
Long term debt	0	0	0
Short term debt	7 764	7 898	7 632

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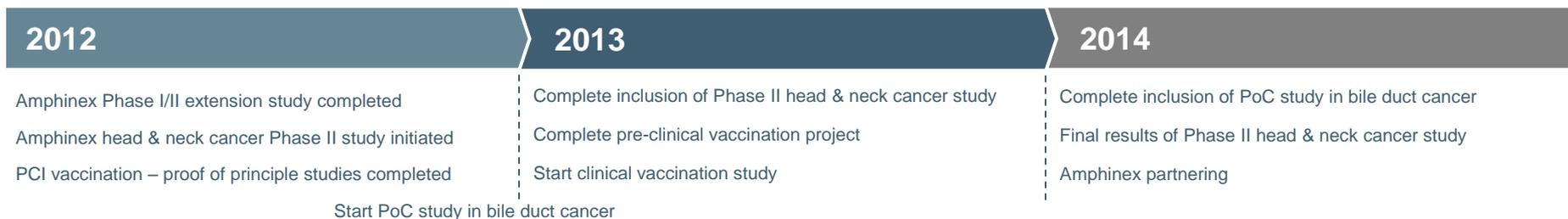


Summary

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
 - Further expansion of sites in Europe
 - Exploring the possibility to open additional sites in India
- 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, with plan to start clinical study in 2013
- Other**
 - PCI 652 medical laser designed and approved for PCI treatment



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