



*Unlocking the potential of innovative medicines*

# PCI Biotech

*An innovative and versatile platform technology for therapeutic enhancement and vaccination*

Fourth Quarter 2014 Report and preliminary full year 2014 results

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24 February 2015



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## Highlights

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- The modified ENHANCE study with Amphinex in recurrent head & neck cancer was progressed by completion of the two first cohorts and initiation of the third cohort in the intra-tumour light dose-escalation part
- The clinical study in inoperable bile duct cancer was initiated and progressed in 2014, with the first dose cohort completed and the second cohort initiated in the Phase I dose escalation part of the Phase I/II study with Amphinex in combination with gemcitabine
- Results showing that the PCI technology can significantly improve vaccination treatment in a melanoma model, was published December 2014 in Journal of Controlled Release, a well-renowned international pharmaceutical journal
- New supporting pre-clinical data with PCI Biotech's novel CTL-induction technology, for use within therapeutic vaccines, has been filed during 2014 to further strengthen the PCI vaccination patent estate
- PCI Biotech was awarded NOK 12.5 million over three years in a BIA grant from The Research Council of Norway for the project "Development of photochemical internalisation to enhance the effect of therapeutic and prophylactic vaccines"

## Highlights

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### *Post-closing events:*

- Completion of the third light dose cohort in the ENHANCE study – patients for the next cohort are currently being screened
- Successful completion of the second dose cohort in the study for patients with inoperable bile duct cancer – enrolment for the next dose cohort has been initiated
- A fully underwritten rights issue of NOK 70 million was completed 12 February 2015
- In January 2015 PCI Biotech announced a successful Investigational New Drug application (IND) review for Amphinex, The IND is a clearance by the United States Food and Drug Administration (FDA) to include patients in the USA in PCI Biotech's phase II clinical programmes for Amphinex

PCI Biotech

*Unlocking the potential of innovative medicines*



*PCI Technology*

# PCI technology – enabling drugs to reach intracellular therapeutic targets



## STEP 1:

- TPCS<sub>2a</sub> (S) and the active molecule (D) are injected into the body and carried by the blood stream to the cell

## STEP 2:

- TPCS<sub>2a</sub> (S) and the active molecule (D) are taken up by the cell, but D is unable to reach the target (T), as it is encapsulated in an endosome
- S is washed away from the cell membrane, but trapped in endosomes

## STEP 3:

- Light activates TPCS<sub>2a</sub> (S) in the membrane of the endosome
- The membrane integrity is affected and the active molecule released

## STEP 4:

- The active molecule (D) can now bind to its target (T) and initiate the therapeutic response



### The active molecule

- Anticancer agent, e.g. bleomycin, gemcitabine
- Oligonucleotide, e.g. siRNA
- Protein, e.g. antibody-drug conjugate
- Peptide: e.g. antigen



### The PCI component

- Light sensitive component
- Amphinex® - TPCS<sub>2a</sub>



### The target

- Target for the active molecule
- E.g. DNA, mRNA, enzyme, microtubuli

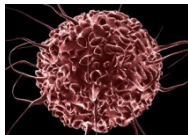
*PCI mechanism of action – triggered endosomal escape through illumination*

# PCI technology – enabling drugs to cover additional areas of unmet medical need



## Existing & innovative treatments

### Cells



Cancerous cell



Dendritic cell

### Active ingredient (trapped in endosome)

- Small molecules
- siRNA/mRNA
- Antibody targeted drugs
- Peptides
- Antigens



### Photosensitizer (Amphinex™)



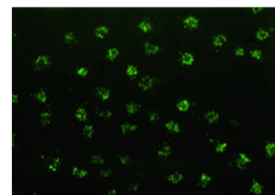
### Light source



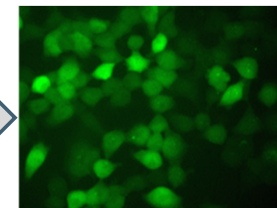
Red light



Blue light



Endosomal escape  
Release of drug in cells

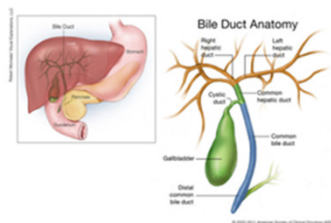


# PCI Biotech is leveraging PCI (TPCS<sub>2a</sub>) in three distinct areas



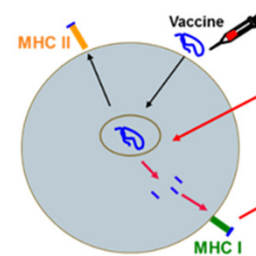
## Local cancer treatment

- bleomycin in head and neck cancer
- gemcitabine in bile duct cancer



## PCI vaccination technology

- therapeutic vaccination

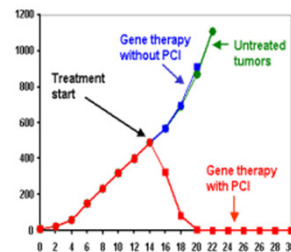


PCI – induce presentation on MHC class I

- Make it possible to achieve cytotoxic T-cell response with protein/ peptide vaccines
- Can solve a key challenge for many vaccine approaches

## PCI macromolecule delivery

- immunotoxins
- siRNA & other oligo
- gene therapy





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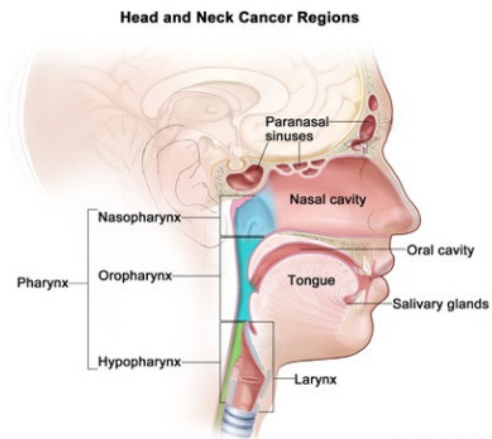
*Amphinex<sup>®</sup> – A New Paradigm for Localized Cancer Treatment*

- PCI of Bleomycin for H&N Cancer*
- PCI of Gemcitabine for Bile duct cancer*

# Head & neck cancer – introduction and motivation

## Introduction to head & neck cancer

- Cancer affecting the cell lining of mouth and throat
- The sixth most common cancer with a worldwide incidence of ~650,000
- Five-year survival rate of 40-50%
- HPV induced cancer is increasing, affecting younger people



## Why target head & neck cancer?

- **Large patient population with high unmet medical need**
  - Local recurrence without distant metastases is common
  - Adverse effects of existing local treatments affect quality of life
  - A field with historic lack of innovations
  - Need of new functional and cosmetic benign treatments
- **Recurrent disease mainly given palliative treatment**
  - Quality of life and locoregional control considered most important
  - Treatment options often limited to palliative systemic therapy

*High unmet medical need for better localised treatment*

# Substantial head & neck cancer market potential

## Sizeable immediate target market

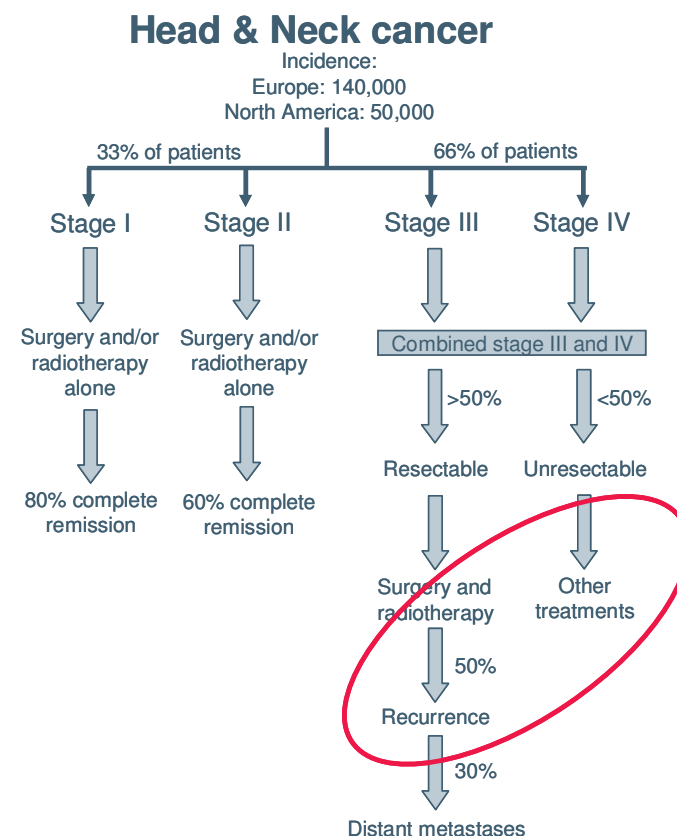
- Incidence is stable, close to 200,000 across Europe and the US
- Immediate target is inoperable recurrent patients
- Almost 40,000 assumed to be eligible for PCI treatment\*
- Substantial upside potential earlier in the treatment algorithm

## Attractive price potential

- Cetuximab (Erbix) is the most relevant price comparator
  - Sales >\$1.8 billion in 2012 (~40% estimated to be in H&N)
  - Average total price / patient close to \$70k in US and \$40k in EU

## High potential market penetration

- Anticipated benefits of PCI with Amphinex
  - Greater efficacy
  - Less systemic side effects
  - Better cosmetic and functional outcome, with improved quality of life



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

# Amphinex<sup>®</sup> head & neck cancer – Phase II study

Summary of study design	
<b>Cancer type</b>	Squamous cell carcinoma of the head and neck
<b>Phase</b>	II
<b>Photosensitizer</b>	Amphinex <sup>®</sup> (PCIB)
<b>Drug</b>	Bleomycin (single dose)
<b>Light source</b>	Red laser 652 nm (PCIB)
<b>Fixed variables</b>	Bleomycin dose
<b>Variables</b>	Amphinex <sup>®</sup> dose and light dose
<b>Purpose of study</b>	Assess safety and efficacy of a single treatment of Amphinex <sup>®</sup> induced PCI of Bleomycin
<b>Patient description</b>	Recurrent head and neck squamous cell carcinoma, with or without metastasis, unsuitable for radiotherapy and surgery.
<b>Treatment modalities</b>	Surface and/or intra-tumour illumination
<b>Patient sample size</b>	Up to 80 patients
<b>Primary endpoint:</b>	Progression Free Survival at 6 months

## Current status and plans

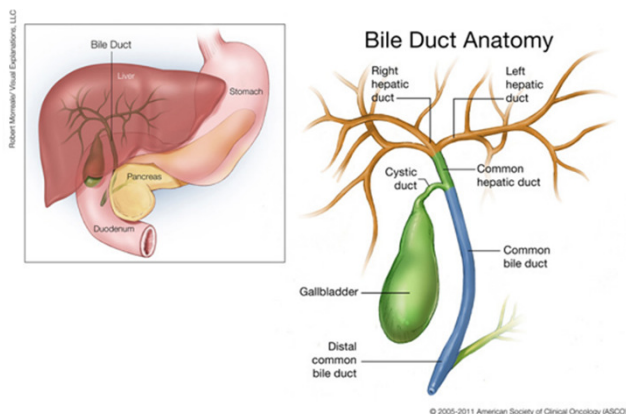
- Intra-tumour illumination is optimized in a separate light-dose escalation part of the study.
- Number of clinical sites has been increased during 2014.
- Third light-dose cohort concluded Feb 2015 – no safety concerns and clear tumour response with clinical benefits. However, re-growth of tumour in the rim of the treatment area in some patients suggest a need to increase the treatment margins to achieve a durable disease response.
- Interim/PoC analysis after 12 patients treated with the intra-tumour illumination light dose selected.



# Bile duct cancer – introduction and motivation

## Introduction to bile duct cancer

- Cancer affecting the cell lining of the bile duct (Medical term: Cholangiocarcinoma)
- Rare disease – incidence rate of 1-2 per 100,000 in the western world
- Five-year survival rate of less than 5%, and 0% when inoperable
- Incidence and mortality rates are increasing worldwide



## Why target bile duct cancer?

- **Patient population with high unmet medical need**
  - Most patients die of unrelieved biliary obstruction
  - Resection only potential cure, but only possible in ~30%
  - Remarkable resistance to chemotherapy – none approved
  - Medical need for better local treatment methods
- **Orphan indication represents a distinct market opportunity**
  - A range of development and market incentives
  - Orphan market totaled \$50b in 2011 (~6% of pharma sales)
- **Easy access with light through routine endoscopic methods**

*Attractive due to orphan benefits and absence of satisfying treatments*

# Bile duct cancer – an orphan indication with a sizeable market potential

## Immediate target market is as first line treatment

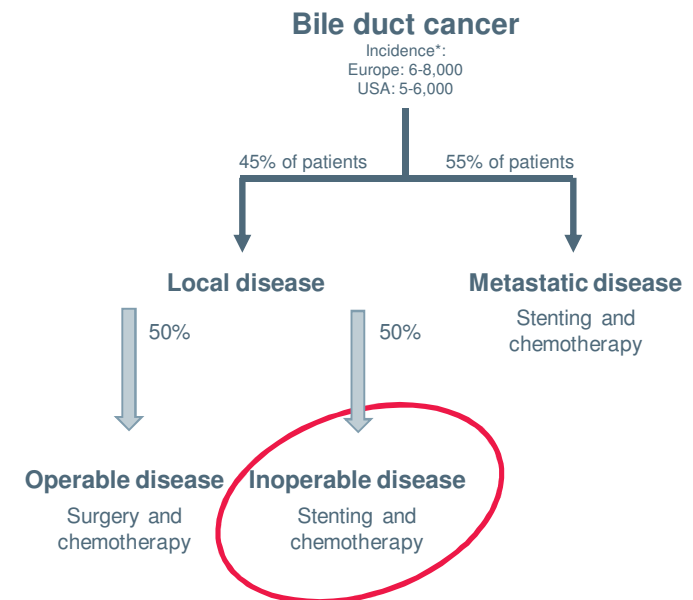
- Immediate target is inoperable patients with local disease
- Approximately 3,000 assumed to be eligible for PCI treatment
- Possible upside potential in metastatic disease

## High price potential

- Lack of approved medicinal treatment options
- Orphan indication implies a high price

## Potential significant majority share of the market

- Anticipated benefits
  - No competing marketable treatment alternatives
  - Greater efficacy due to local chemotherapy boost
  - Easy light access through established standard procedures



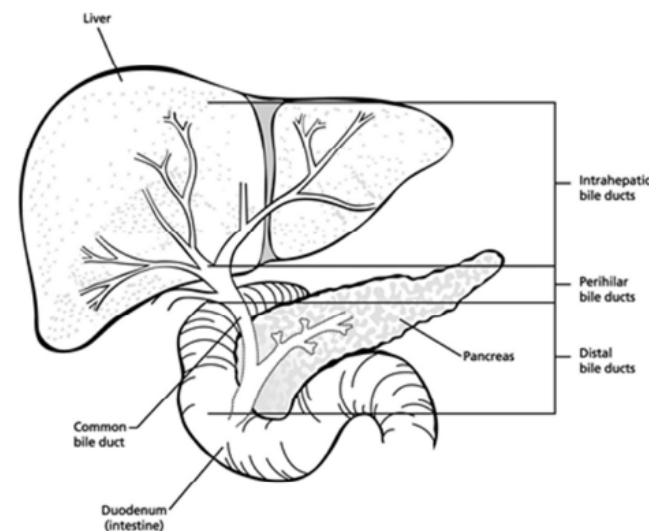
\*Source; Khan et al, Lancet 2005; 366:1303  
Gatta et al, Eur J Cancer 2011; 47:2493  
Bragazzi et al, Transl Gastrointest Cancer 2012; 1:21

# Amphinex<sup>®</sup> bile duct cancer – Phase I/II study

Summary of Study Design	
<b>Cancer type</b>	Bile duct (Cholangiocarcinoma)
<b>Phase</b>	I/II
<b>Photosensitizer</b>	Amphinex <sup>®</sup> (PCIB)
<b>Drug</b>	Gemcitabine (Cisplatin)
<b>Light source</b>	Red laser 652 nm (PCIB)
<b>Fixed variables</b>	Gemcitabine and Cisplatin
<b>Variables</b>	Amphinex <sup>®</sup> and/or light dose
<b>Purpose of study</b>	Open-label, multi-centre study to assess the safety and efficacy of a single treatment of Amphinex <sup>®</sup> induced PCI of gemcitabine, followed by systemic cisplatin/ gemcitabine. All patients are stented. Phase I to find light and Amphinex <sup>®</sup> dose. Phase II randomized to compare PCI vs. stenting alone
<b>Patient description</b>	Locally advanced inoperable bile duct cancer
<b>Treatment modality</b>	Intraluminal illumination
<b>Patient sample size</b>	Up to 45 patients
<b>Primary endpoint:</b>	Progression free survival

## Current status and plans

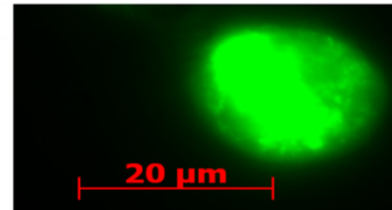
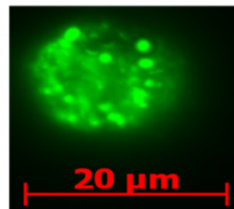
- Safety driven Phase I
- Number of clinical sites has been increased during 2014
- Second dose cohort (3 pts) concluded Feb 2015 – no safety concerns
- Enrolment for the next dose cohort has been initiated
- 5:2 randomisation in Phase II, 35 pts in total



## Unlocking the true potential of new treatment paradigms

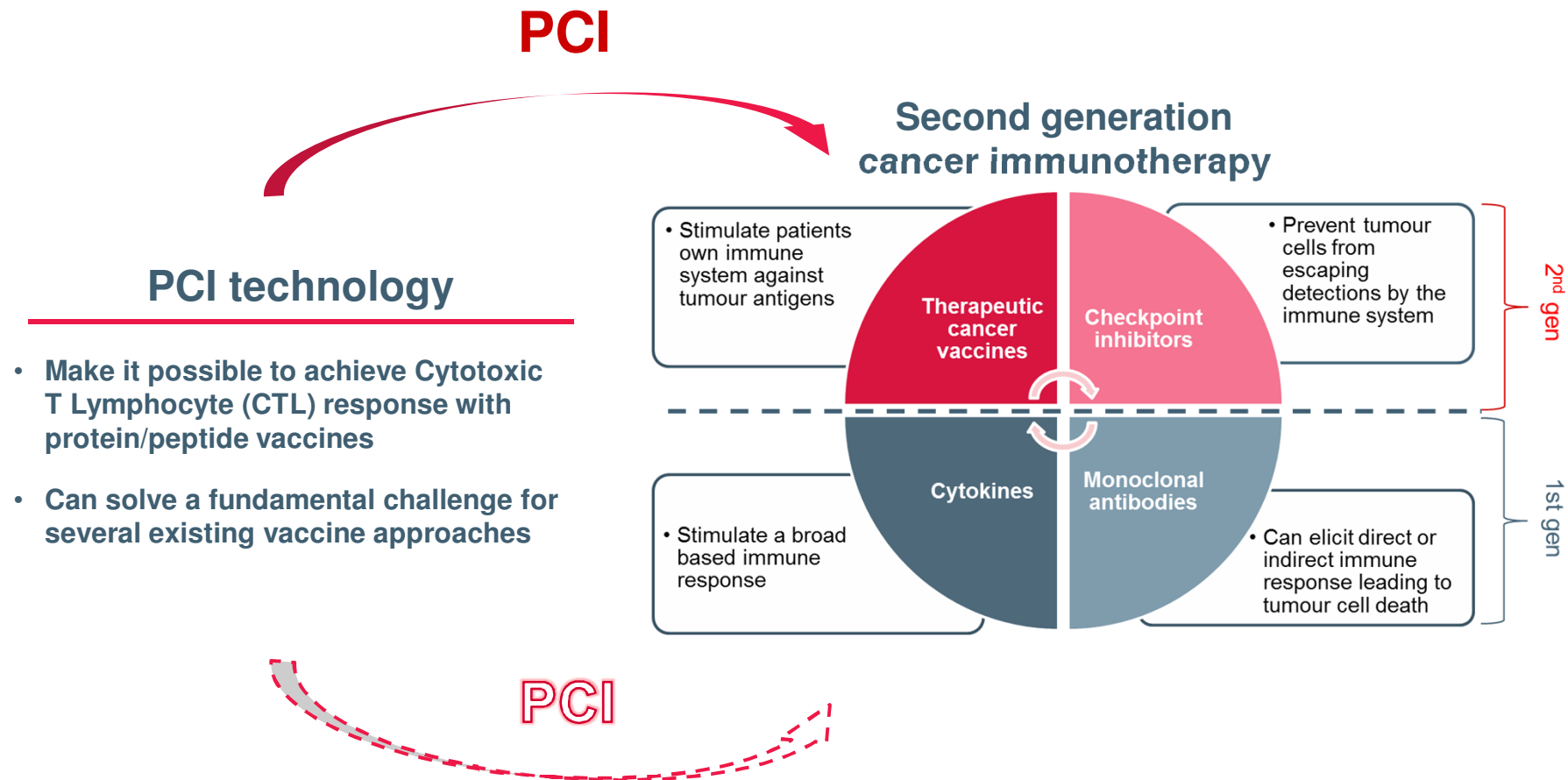
Immunotherapy

Macromolecules





# An opportunity to play a key role in the second generation cancer immunotherapy paradigm

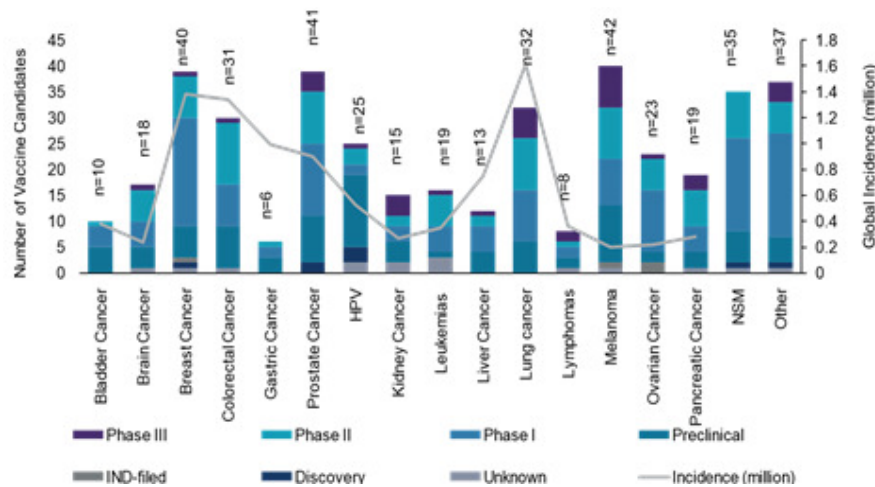


# Cancer therapeutic vaccines – substantial development pipeline and expected market growth

## Development pipeline

Therapeutic Cancer Vaccines Market, Global, Development Pipeline, Candidates by Indication, 2012-2019

Source: GBI Research's Proprietary Pipeline Products database; GLOBOCAN 2008

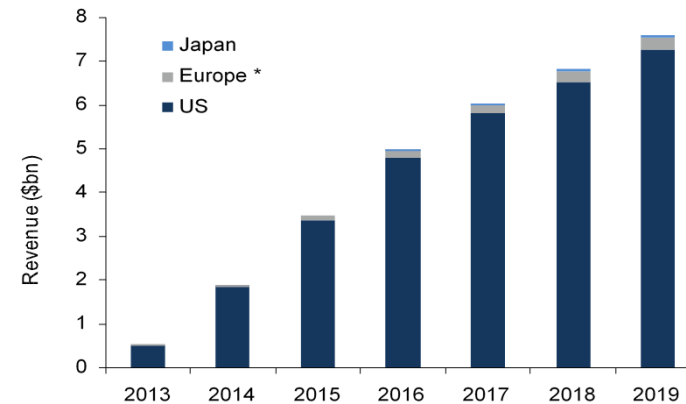


- “233 companies plus partners are today developing 275 cancer vaccine drugs in 600 developmental projects in cancer across 161 different targets”<sup>1</sup>
- Top 5 indications: Breast, Colorectal, Lung, Prostate, Melanoma

## Market size forecast

Therapeutic Cancer Vaccines Market, Global, Revenue Forecast (\$bn), 2013-2019

Source: GBI Research's Proprietary Pipeline Products Epidemiology and Market Size Databases



- “Provenge” currently the only marketed therapeutic cancer vaccine (annual global sales of approx. \$200 million)
- Therapeutic cancer vaccine market could grow to a value of \$7.6 billion by 2019<sup>2</sup>
- All therapeutic cancer vaccines will need immune-potentiating technologies to be effective

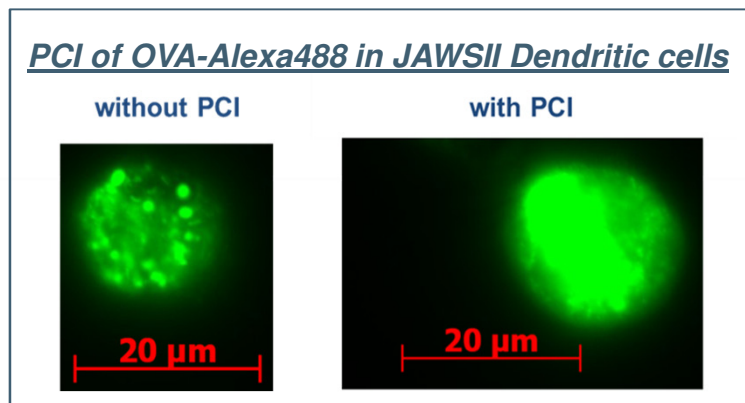
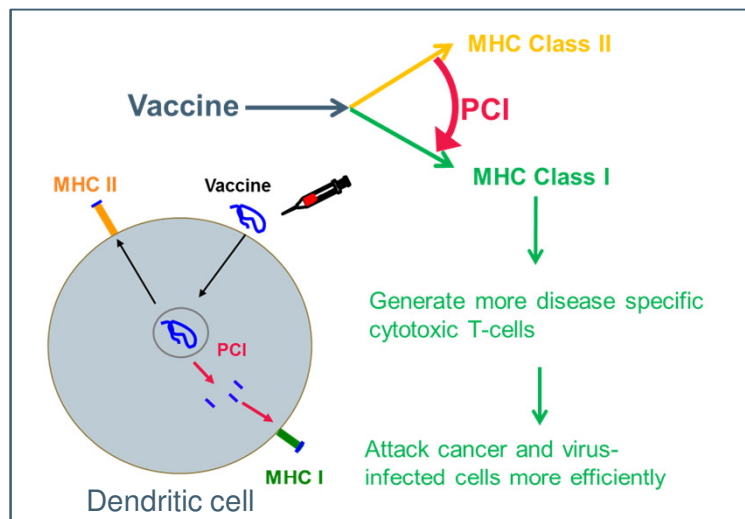
<sup>1</sup> Bioseeker Group; Cancer Vaccines Drug Pipeline Update 2014

<sup>2</sup> GBI Research, March 2013

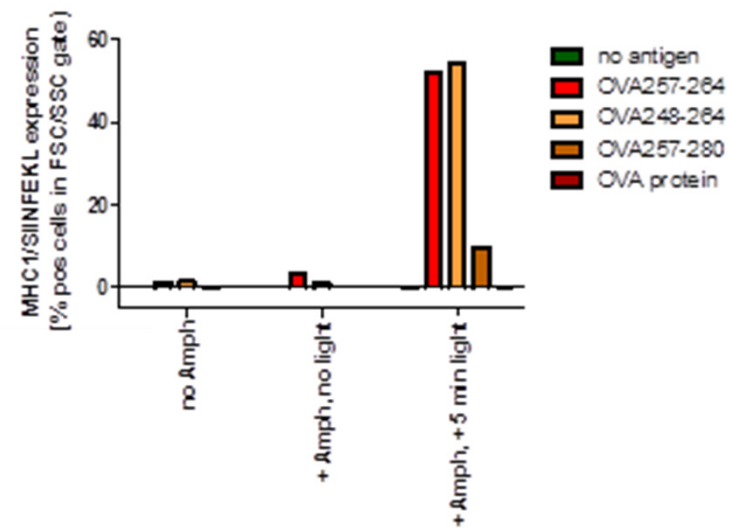
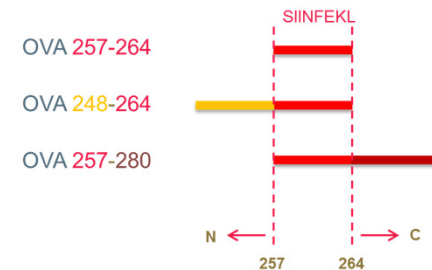
\*France, Germany, Italy, Spain, UK

# PCI for vaccination – enhancing cytotoxic T-cell response by light-induced cross presentation

*PCI-induced endosomal antigen escape re-routes presentation to MHC Class I*



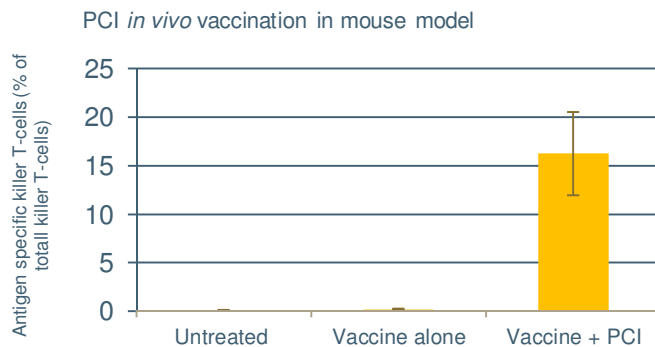
## MHC1/SIINFEKL expression in B6 macrophage



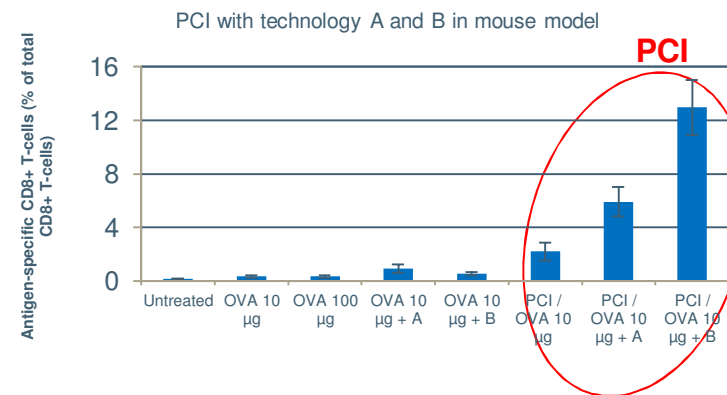
# Cancer therapeutic vaccines – PCI as a powerful CTL-induction technology



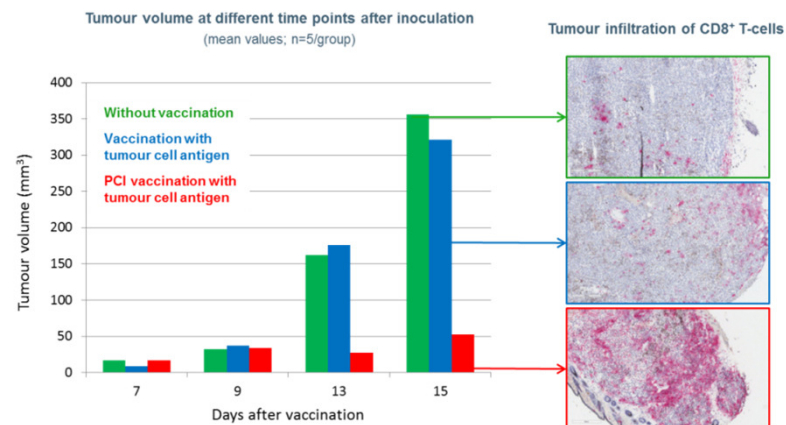
## 1 An effective immune-potentiator,



## 2 that works in synergy with state-of-the-art vaccine technologies



## 3 and translates into therapeutic effect in disease models.



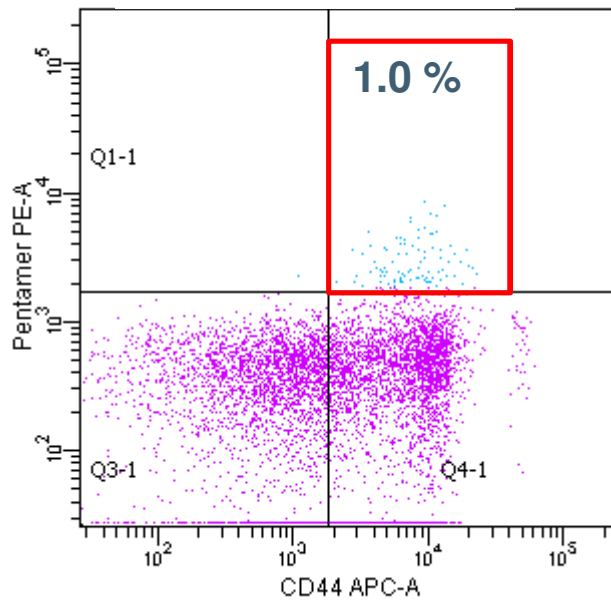
# PCI with HPV peptide antigen – antigen specific CD8 T-cells in blood



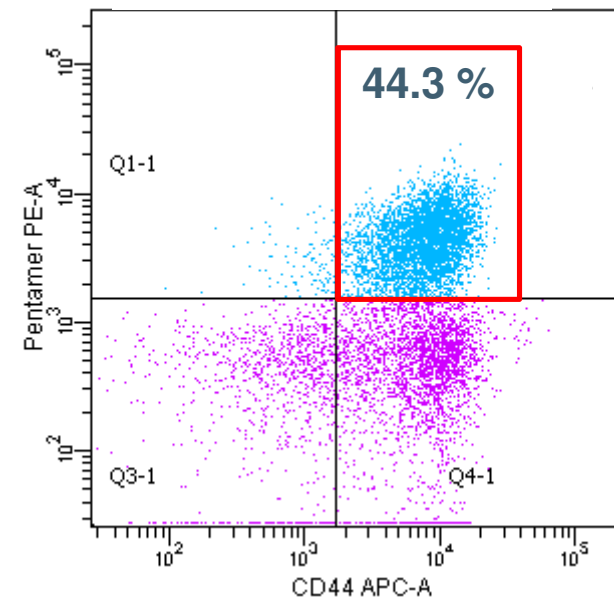
## HPV peptide vaccination with state-of-the-art vaccination technology

(3<sup>rd</sup> immunisation)

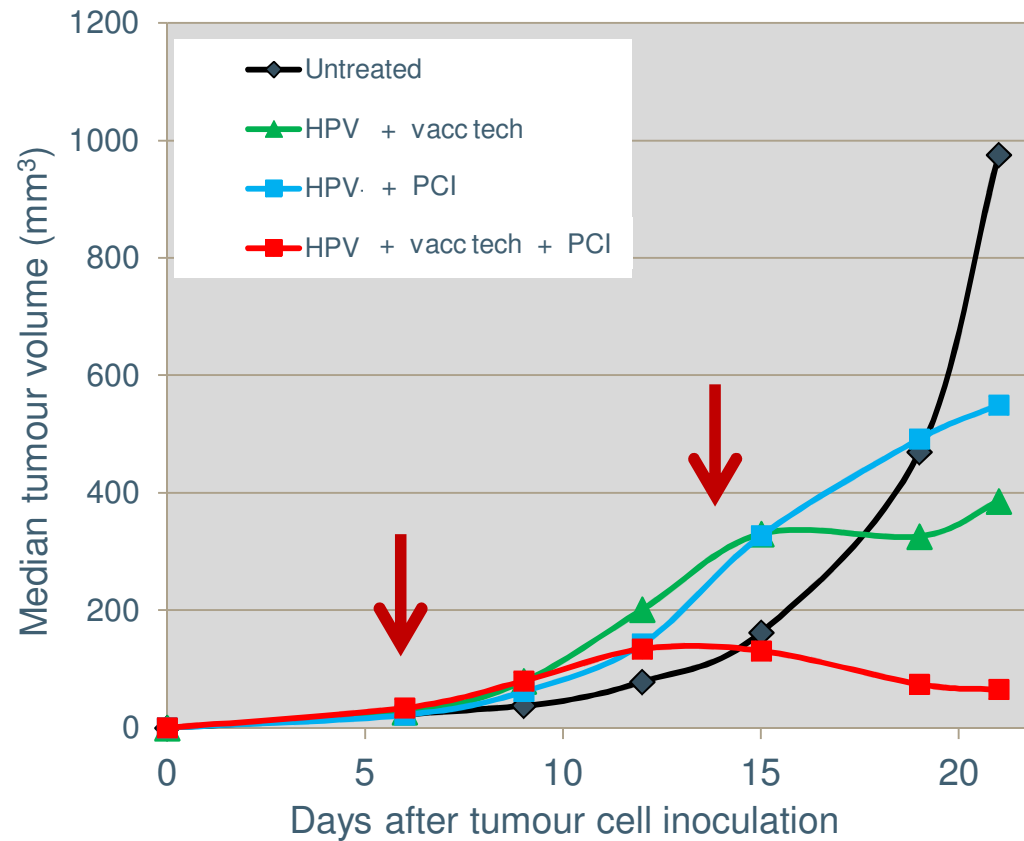
Without PCI



With PCI



# Therapeutic vaccination with HPV long peptide antigen in TC-1 mouse tumour model – PCI induces strong anti-tumour response



- Intradermal vaccination at days 6 and 13 after tumour cell inoculation
- 5 animals per group

# Cancer therapeutic vaccines – competitive advantages and user-friendly PCI solutions



**Safety** – TPCS<sub>2a</sub> tested in Phase I study (i.v. inj.) at much higher doses than what will be used for vaccination

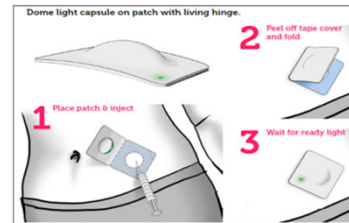
**Stability** – TPCS<sub>2a</sub> can be autoclaved and is stable at room temperature, also in solution

**Innovation** – Unique mode of action; indication that TPCS<sub>2a</sub> provides CTL-induction by MHC class I antigen presentation in dendritic cells and macrophages

**Cost effectiveness** – Simple and cost effective synthesis of TPCS<sub>2a</sub>

**Broad applicability** – Peptide and protein antigens as well as particulate antigen formulations; Prophylactic & therapeutic vaccination, *in vivo* & *ex vivo*

## CONCEPTS



## DESIGNS



*Clinical safety and preclinical efficacy evidence, combined with a comprehensive patent estate on PCI-mediated CTL-induction (products, uses and devices)*

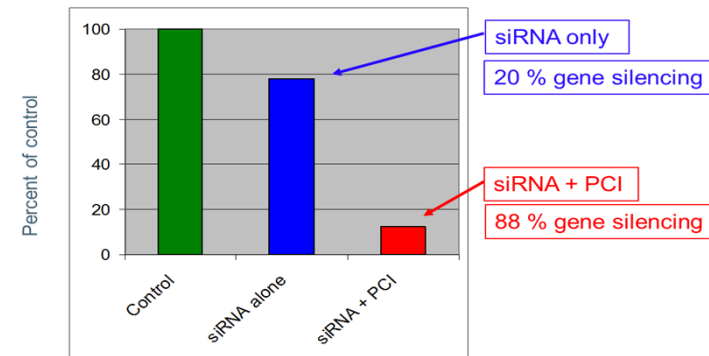
# Macromolecules – endosomal escape of a range of products, pre-clinical data

## 1 Intracellular delivery of immunotoxin – *in vivo*



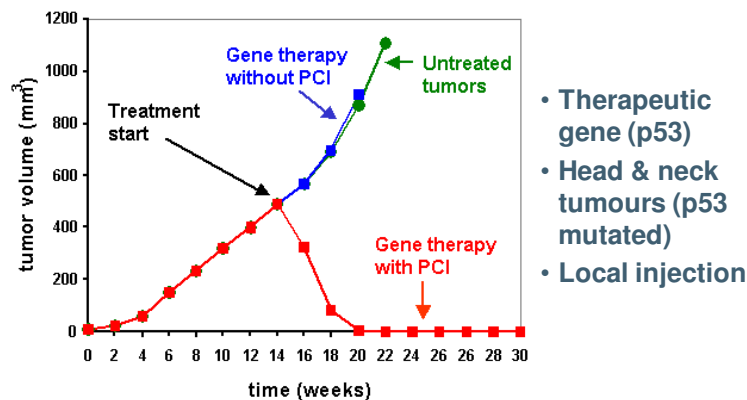
Selbo, et al. (2009). *PLoS ONE*, 4, e6691

## 2 Intracellular delivery of siRNA



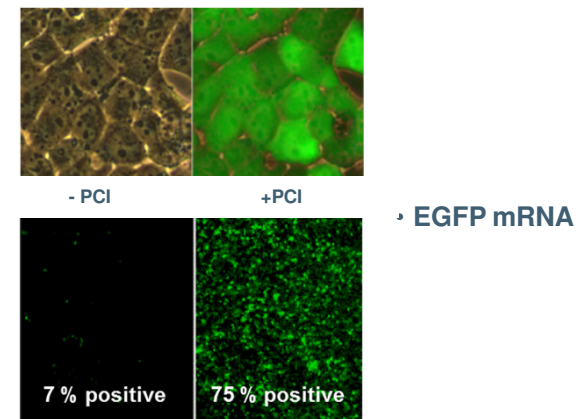
Bøe, S., Longva, A.S. and Hovig, E. (2007). *Oligonucleotides* 17, 166-73

## 3 Intracellular delivery of gene therapy – *in vivo*



Ndoye et al. (2006) *Mol. Ther.* 13:1154-1162

## 4 Intracellular delivery of mRNA



Bøe, S et al. (2010) *Oligonucleotides* 20:1-6



PCI Biotech

*Unlocking the potential of innovative medicines*



*Financial key figures*

# PCI Biotech

## Financial key figures 2014 and 2013



<i>(In NOK 1,000)</i>	Note	Q4 2014	Q4 2013	01.01 - 31.12 2014	01.01 - 31.12 2013
<b>Other Income</b>	5	1 542	1 986	7 297	6 681
Research and development	8	9 719	10 102	39 341	32 789
General and administrative		2 088	1 207	4 428	3 217
<b>Operating costs</b>		<b>11 807</b>	<b>11 309</b>	<b>43 769</b>	<b>36 006</b>
<b>Operating results</b>		<b>-10 265</b>	<b>-9 323</b>	<b>-36 472</b>	<b>-29 325</b>
<b>Financial income and costs</b>					
Financial income		143	474	812	1 717
Financial expenses		84	0	180	0
<b>Net financial result</b>		<b>59</b>	<b>474</b>	<b>632</b>	<b>1 717</b>
<b>Ordinary profit before taxes</b>		<b>-10 206</b>	<b>-8 849</b>	<b>-35 840</b>	<b>-27 608</b>

# PCI Biotech

## Financial key figures 2014 and 2013



<i>(In NOK 1,000)</i>	Note	31.12 2014	31.12 2013
<b>Fixed and intangible assets</b>			
Operating assets		14	18
<b>Total fixed and intangible assets</b>		<b>14</b>	<b>18</b>
<b>Current assets</b>			
Short term receivables	7	4 614	6 123
Cash & cash equivalents	7	15 754	46 595
<b>Total current assets</b>		<b>20 368</b>	<b>52 718</b>
<b>Total assets</b>		<b>20 382</b>	<b>52 736</b>
<b>Shareholders equity and liabilities</b>			
<b>Shareholders equity</b>			
Paid in capital		99 911	99 911
Other reserves		-90 797	-56 515
<b>Total equity</b>	10	<b>9 114</b>	<b>43 396</b>
Trade debtors		2 586	4 061
Other short term debt		8 682	5 279
<b>Total debt</b>		<b>11 269</b>	<b>9 340</b>
<b>Total shareholders equity and liabilities</b>		<b>20 382</b>	<b>52 736</b>

# PCI Biotech

## Financial key figures 2014 and 2013



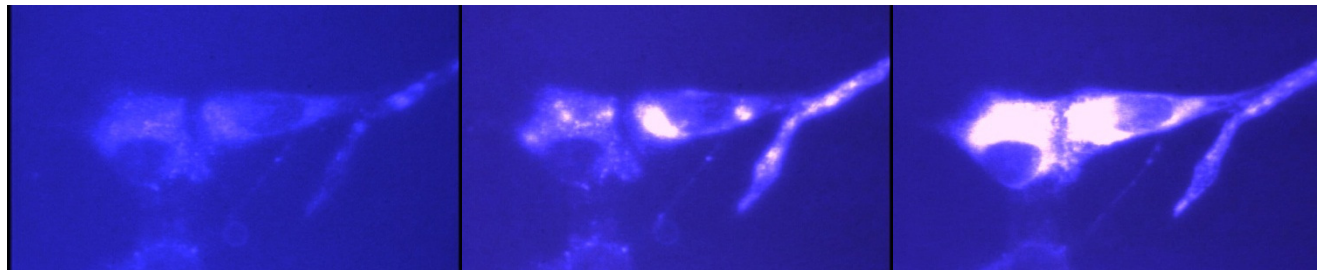
<i>CASH FLOW (in NOK '000)</i>	<b>Q4 2014</b>	<b>Q4 2013</b>	<b>FY 2014</b>	<b>FY 2013</b>
Net cash flow from operations	-3 891	-5 932	-30 841	-26 876
Net cash flow from investments	-	-	-	-
Net cash flow from financial activities	-	-	-	388
<b>Net change in cash during the period</b>	<b>-3 891</b>	<b>-5 932</b>	<b>-30 841</b>	<b>-26 488</b>

- A fully underwritten rights issue of NOK 70 million was completed 12 Feb '15
  - Extraordinary general meeting held 6 Jan '15, resolved to increase the share capital with NOK 21,000,000 through the issue of 7,000,000 new shares
  - The new total share capital is NOK 44,179,170 divided by 14,726,390 shares
  - Net proceeds are estimated to approximately NOK 65 million – expected to give a financial runway of approximately two years, with the current cost base
  - The new shares were admitted to trading on the Oslo Axess from 13 Feb '15

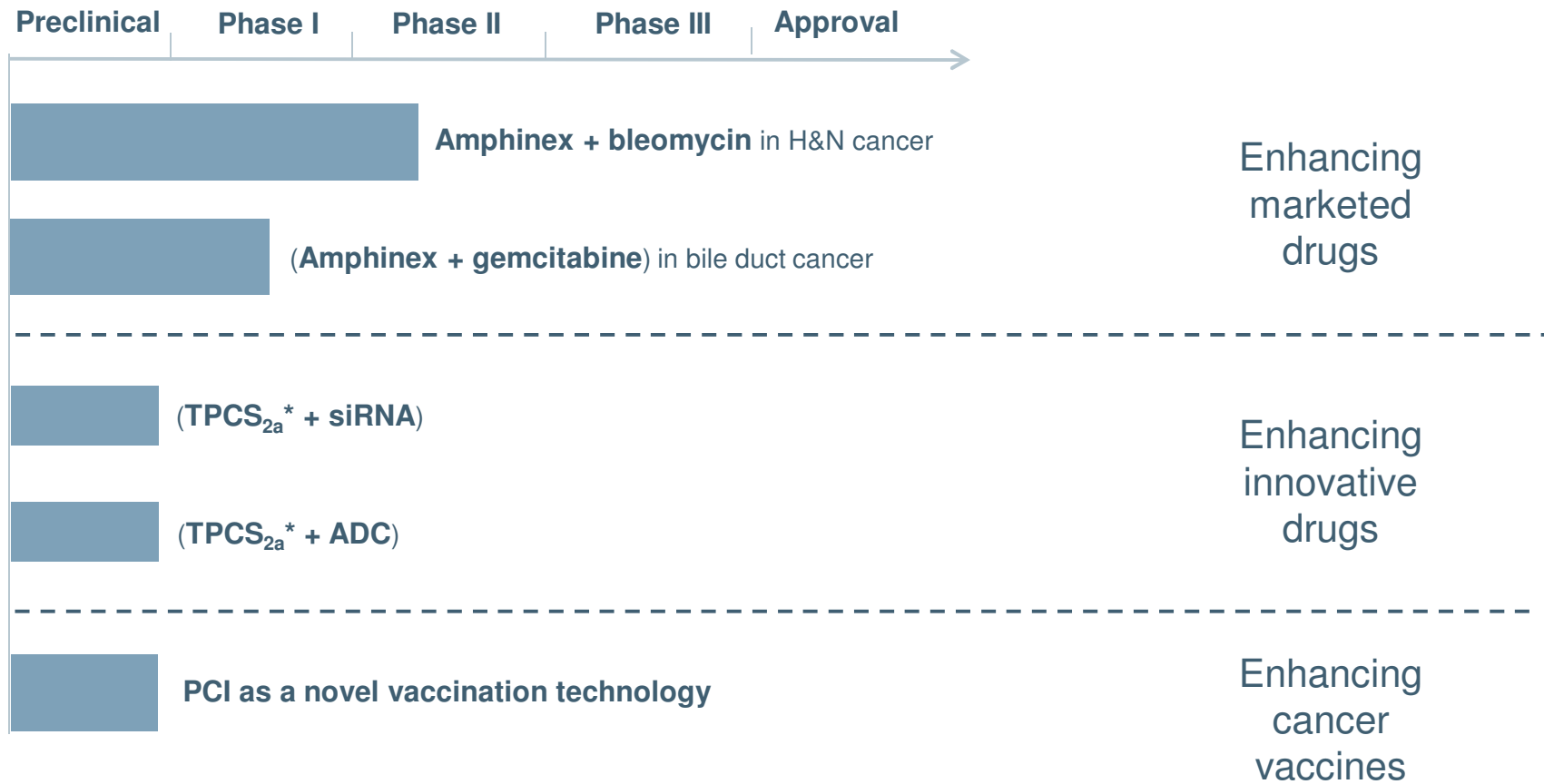
### Top 10 shareholders per 13 Feb '15:

Name	No of shares	(%)
FONDSAVANSE AS	2 049 138	13,9
PHOTOCURE ASA	1 483 339	10,1
RADIUMHOSPITALET FO	1 359 853	9,2
STOREBRAND VEKST	1 198 791	8,1
MP PENSJON PK	899 408	6,1
VICAMA AS	743 288	5,1
KLP AKSJE NORGE VPF	670 095	4,6
KOMMUNAL LANDSPENSJONSKASSE	628 858	4,3
BERGEN KOMMUNALE	350 000	2,4
HOLBERG NORGE VERDIPAPIRFONDET	283 696	1,9
	<b>9 666 466</b>	<b>65,6</b>

*Looking ahead*



# PCI – a versatile technology with a pipeline of partnering opportunities



\* Active pharmaceutical ingredient in Amphinex

## Development and commercial strategy; A flexible partnering strategy

### H&N and bile duct cancer

- Successful Phase II studies are important value-enhancing milestones
- PCI Biotech will maintain a flexible licensing strategy, but licensing agreements based on Phase II data is assumed to maximise the ROI for shareholders
- Contacts with major oncology companies made – expect these to move into more meaningful interactions as we get closer to Phase II read-out milestones

### Therapeutic vaccination

- High development failure rate linked to efficacy makes PCI an attractive licensing asset
- High deal activity – a large number of pre-clinical stage
- Aim is to license to several partners for use in different disease areas and/or with different technologies
- Our partnering efforts is allowing us to build more robust data based on initial feedback from key vaccine players, and has increased our understanding of vaccine developer requirements

### Macromolecules

- Many potential partners, as the technology works with most macromolecules
- Opportunistic approach; use existing pre-clinical data to attract partners
- Aim is to license to several partners for use with different macromolecular technologies in different disease areas
- All major siRNA companies have been approached and discussions are on-going, particularly in the field of skin disorders

***2014 was a year of heightened partnering activities and learning that should translate into the execution of transactions within the company's financial runway***



# PCI Biotech – well positioned for attractive development opportunities



## Outlook

Focus on the clinical development of Amphinex in combination with cancer drugs for localised cancer treatment, based on the company's unique PCI technology. Maintain the high activity level in pre-clinical development and licensing of PCI as a versatile and innovative platform.

Main priorities:

- Effectively progress the light dose optimization and proof of concept of intra-tumour head and neck cancer treatment of Amphinex and bleomycin
- Complete the first part of the proof of concept study of bile duct cancer treatment with Amphinex and gemcitabine
- Solidify a robust vaccination IP estate and further strengthen the promising preclinical results
- Partnering activities across all commercially interesting areas for the PCI platform

## Enquiries

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