Q2 2016 PRESENTATION

August 30, 2016

Per Walday, CEO
Ronny Skuggedal, CFO

PCI BIOTECH

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HIGHLIGHTS

- First half 2016 and beyond

fimaCHEM

- Completed Phase I study in bile duct cancer
- Orphan designation of fimaporfin in bile duct cancer granted in EU
- Commissioned independent expert evaluation of promising early response results
- First-in-man study published in Lancet Oncology, with independent commentary

fimaVACC

- Ready for clinical validation in healthy volunteers
- Read-out 1H 2017 of a major milestone towards potential commercialisation
- Research agreement signed with Ultimovacs

Strategy

- Launched three well-defined strategic development areas:
- **fimaCHEM**, **fimaVACC** and **fimaNAC**

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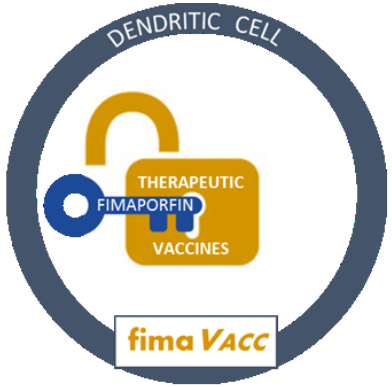
PCI BIOTECH AT A GLANCE

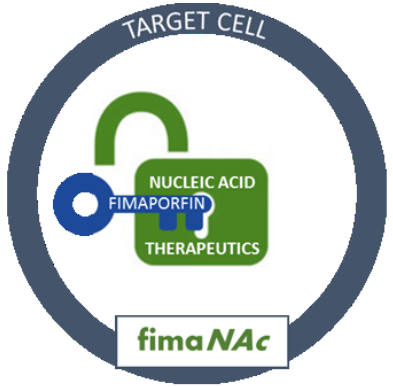
► Unlocking the potential of innovative medicines

- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Norwegian Radium Hospital
- Clinical programme
  - **fima CHEM** – Phase I/II with fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer
- Pre-clinical programmes
  - **fima VACC** – Vaccination technology that provides strongly enhanced T-cell responses, ready for clinical validation
  - **fima NAc** – Efficient intracellular delivery of nucleic acid therapeutics, with two active research collaborations

Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

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PHOTOCHEMICAL INTERNALISATION

► Triggered endosomal release through illumination

STEP 1:

- Fimaporfin (S) and the active molecule (D) are injected into the body and reaches the target cells

STEP 2:

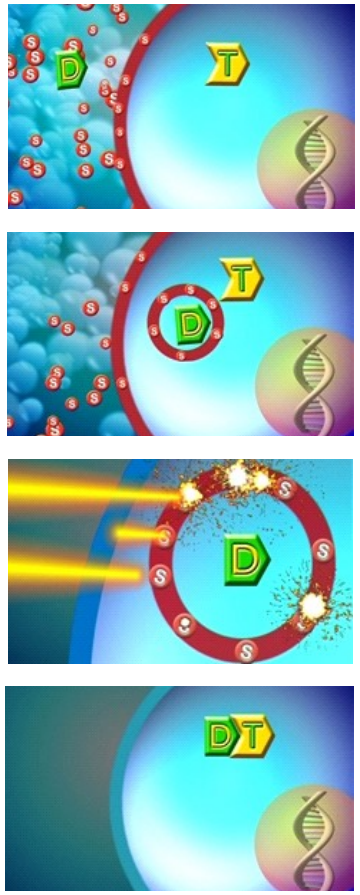
- Fimaporfin (S) and the active molecule (D) are taken up by the cell, but D is unable to reach the target (T), as it is encapsulated in an endosome
- S is washed away from the cell membrane, but trapped in endosomes

STEP 3:

- Light activates fimaporfin (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



D

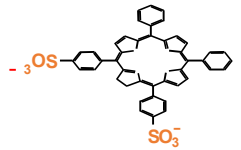
The active molecule

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

S

The PCI component

- Light sensitive component
- Fimaporfin - Amphinex®



T

The target

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

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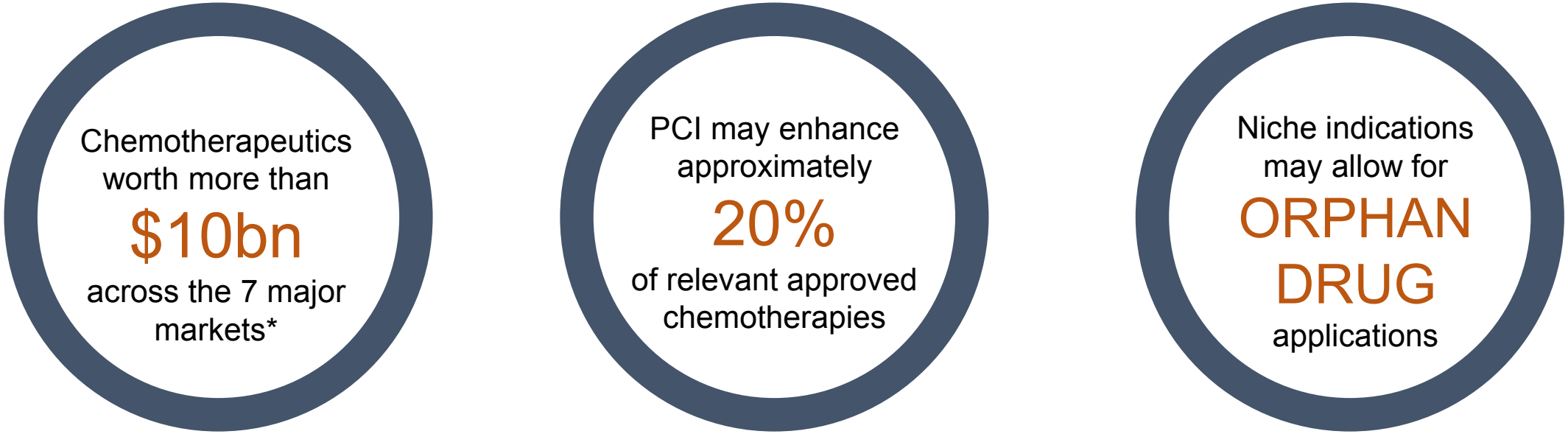
CHEMOTHERAPEUTICS

- A cornerstone in current cancer therapy

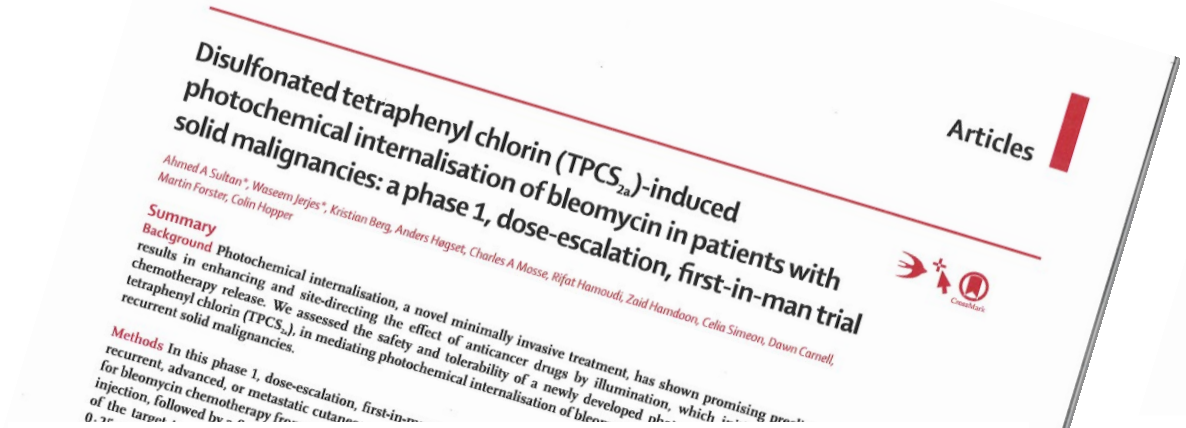


- fimaCHEM may enable approved drugs to fulfil unmet local treatment needs
- First-in-man study published in Lancet Oncology**, with independent expert commentary
- Ready for Phase II in bile duct cancer with promising early signs of efficacy
- Opportunity for development in further niche indications

* Business Insights "The cancer market outlook to 2016". Jun 2011
** Lancet Oncology http://dx.doi.org/10.1016/S1470-2045(16)30224-8, July 2016

First-In-Man Study Published in Lancet Oncology

- With independent expert commentary

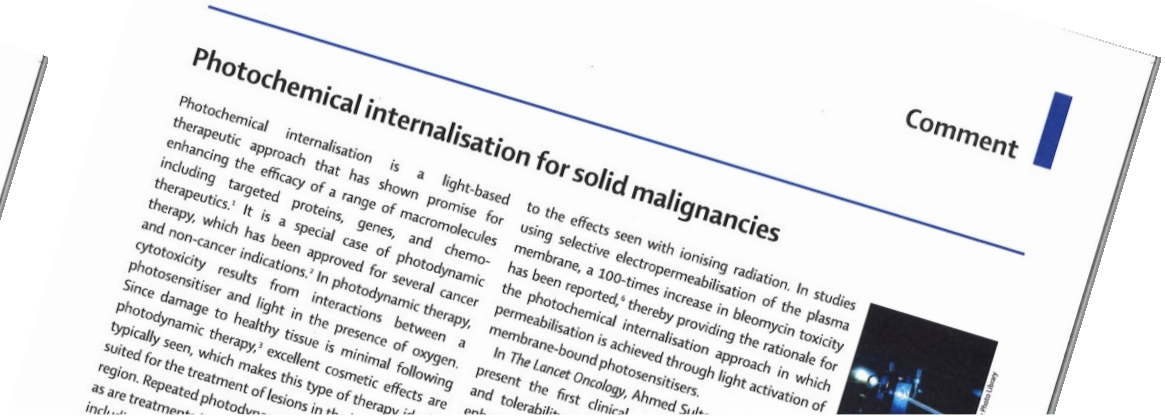

Articles

Disulfonated tetraphenyl chlorin ($TPCS_{2a}$)-induced photochemical internalisation of bleomycin in patients with solid malignancies: a phase 1, dose-escalation, first-in-man trial

Ahmed A Sultan*, Waseem Jerjes*, Kristian Berg, Anders Høgset, Charles A Mosse, Rifat Hamoudi, Zaid Hamdoon, Celia Simeon, Dawn Carnell, Martin Forster, Colin Hopper

Summary

Background Photochemical internalisation, a novel minimally invasive treatment, has shown promising


Comment

Photochemical internalisation for solid malignancies

Photochemical internalisation is a light-based therapeutic approach that has shown promise for enhancing the efficacy of a range of macromolecules including targeted proteins, genes, and chemotherapeutics.[1] It is a special case of photodynamic therapy, which has been approved for several cancer and non-cancer indications.[2] In photodynamic therapy, cytotoxicity results from interactions between a photosensitiser and light in the presence of oxygen. Since damage to healthy tissue is minimal following photodynamic therapy,[3] excellent cosmetic effects are typically seen, which makes this type of therapy ideal for the treatment of lesions in the region. Repeated photodyn... as are treatment... including

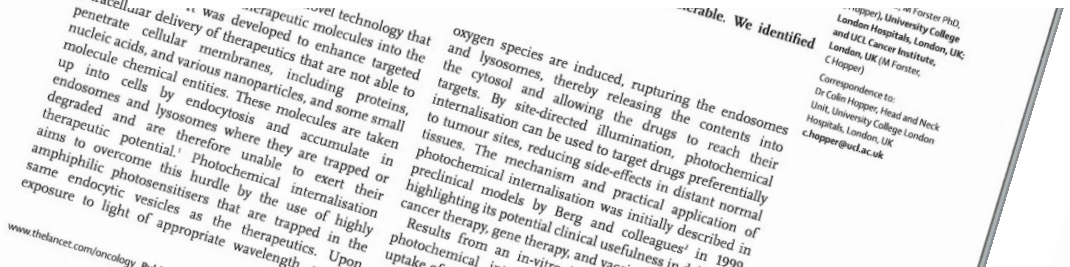
to the effects seen with ionising radiation. In studies using selective electropermeabilisation of the plasma membrane, a 100-times increase in bleomycin toxicity has been reported,[6] thereby providing the rationale for the photochemical internalisation approach in which permeabilisation is achieved through light activation of membrane-bound photosensitisers.

In The Lancet Oncology, Ahmed Sul... present the first clinical ... and tolerabilit...

THE LANCET Oncology

the premier publication worldwide for original clinical trials research in oncology

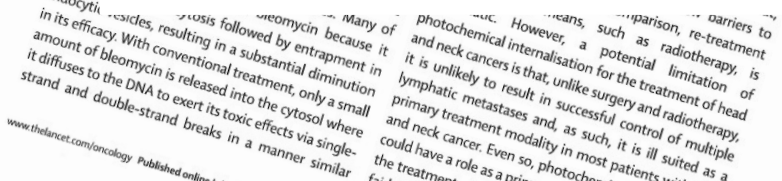
"The results of this phase 1, first-in-man, dose-escalation trial… …are encouraging. Overall, the results… …suggest that photochemical internalisation might have a role in the treatment of early lesions and palliation of advanced disease… These findings provide the basis for further studies."


...was developed to enhance targeted ... penetrate cellular membranes, including proteins, ... nucleic acids, and various nanoparticles, and some small ... molecule chemical entities. These molecules are taken ... up into cells by endocytosis and accumulate in ... endosomes and lysosomes where they are trapped or ... degraded and are therefore unable to exert their ... therapeutic potential.[1] Photochemical internalisation ... aims to overcome this hurdle by the use of highly ... amphiphilic photosensitisers that are trapped in the ... same endocytic vesicles as the therapeutics. Upon ... exposure to light of appropriate wavelength ...

...erable. We identified ... oxygen species are induced, rupturing the endosomes ... and lysosomes, thereby releasing the contents into ... the cytosol and allowing the drugs to reach their ... targets. By site-directed illumination, photochemical ... internalisation can be used to target drugs preferentially ... to tumour sites, reducing side-effects in distant normal ... tissues. The mechanism and practical application of ... photochemical internalisation was initially described in ... preclinical models by Berg and colleagues[2] in 1999, ... highlighting its potential clinical usefulness in ... cancer therapy, gene therapy, and ... Results from an in-vitro ... photochemical ...

...Hopper), University College London Hospitals, London, UK; and UCL Cancer Institute, London, UK (M Forster, C Hopper)

Correspondence to: Dr Colin Hopper, Head and Neck Unit, University College London Hospitals, London, UK c.hopper@ucl.ac.uk


...Many of ... photochemical internalisation for the treatment of head ... and neck cancers is that, unlike surgery and radiotherapy, ... it is unlikely to result in successful control of multiple ... lymphatic metastases and, as such, it is ill suited as a ... primary treatment modality in most patients ... and neck cancer. Even so, photoch... could have a role as a pri... the treatmen...

...bleomycin because it ... in its efficacy. With conventional treatment, only a small ... amount of bleomycin is released into the cytosol where ... it diffuses to the DNA to exert its toxic effects via single- ... strand and double-strand breaks in a manner similar ...

...vesicles, resulting in a substantial diminution ... ...tosis followed by entrapment in ...

...means, such as radiotherapy, is ... ...parison, re-treatment ... ...barriers to ...

www.thelancet.com/oncology Published online ...

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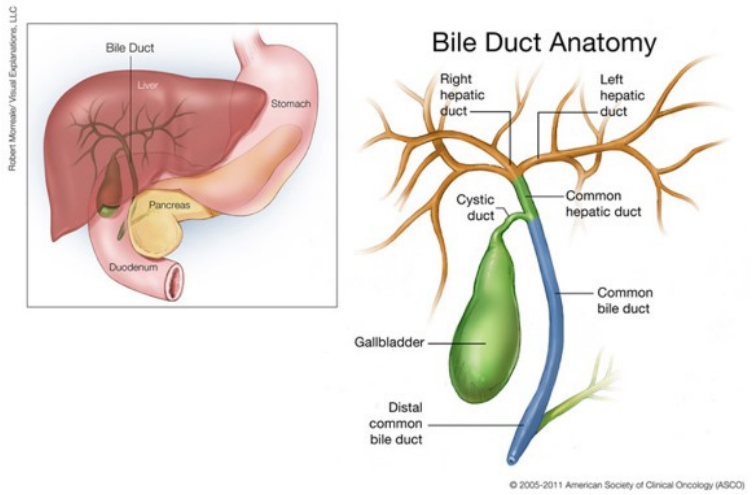
Bile Duct Cancer

- A rare but fatal disease

- Rare disease, with an incidence rate of 1-2 per 100,000 in the western world
- Five-year survival rate of less than 5%, and 0% when inoperable
- Phase I/II trial ongoing with fimaporfin in combination with gemcitabine



Why target bile duct cancer?

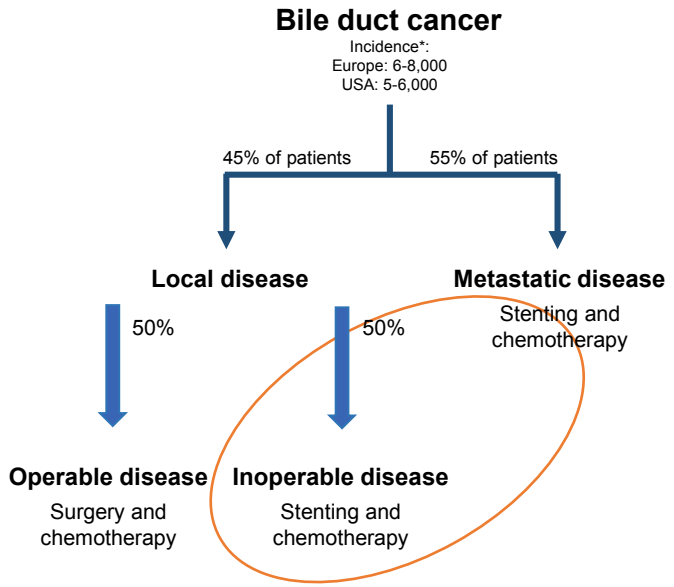
- Significant inoperable patient population with high unmet local treatment need
- Orphan indication without approved medical treatments
- Limited development pipeline
- Active chemotherapy enhanced by PCI
- Easy access with light through routine endoscopic methods

Attractive due to orphan benefits and absence of satisfying treatments

Bile Duct Cancer

▶ A sizeable orphan market potential

- **Immediate target market is as first line treatment**
  - Incidence is close to 15,000 across Europe and the US
  - Immediate target is inoperable patients with local disease
  - Approximately 3,000 assumed to be eligible for fimaCHEM
  - Possible upside potential in more advanced 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

Bile Duct Cancer

▶ Current status

- **Phase I finished with good tolerability and promising early signs of efficacy**
  - No serious unexpected safety findings and no apparent increase in adverse reactions with increasing doses
  - Commissioned independent expert evaluation of early promising response data – expected Q3 2016
- **Fimaporfin granted orphan designation in EU for use in bile duct cancer**
  - Supports further development in this indication
  - Provides important development and commercialisation benefits
- **Phase II strategy to be determined when independent evaluation of response is available**
  - Considering whether the study can be designed as a pivotal study with possible market approval potential
  - A successful pivotal study could significantly shorten the time to market for this orphan indication

fima VACC

IMMUNOTHERAPY

- A new hope for millions of patients

- fima VACC enhances cellular immune responses important for therapeutic effects
- Ready for clinical validation in healthy volunteers
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

* Citi Research "Immunotherapy – the beginning of the end for cancer". Baum, May 2013
** Clinicaltrials.gov. PCIB analysis, August 2016

[1]CPI: Checkpoint inhibitors

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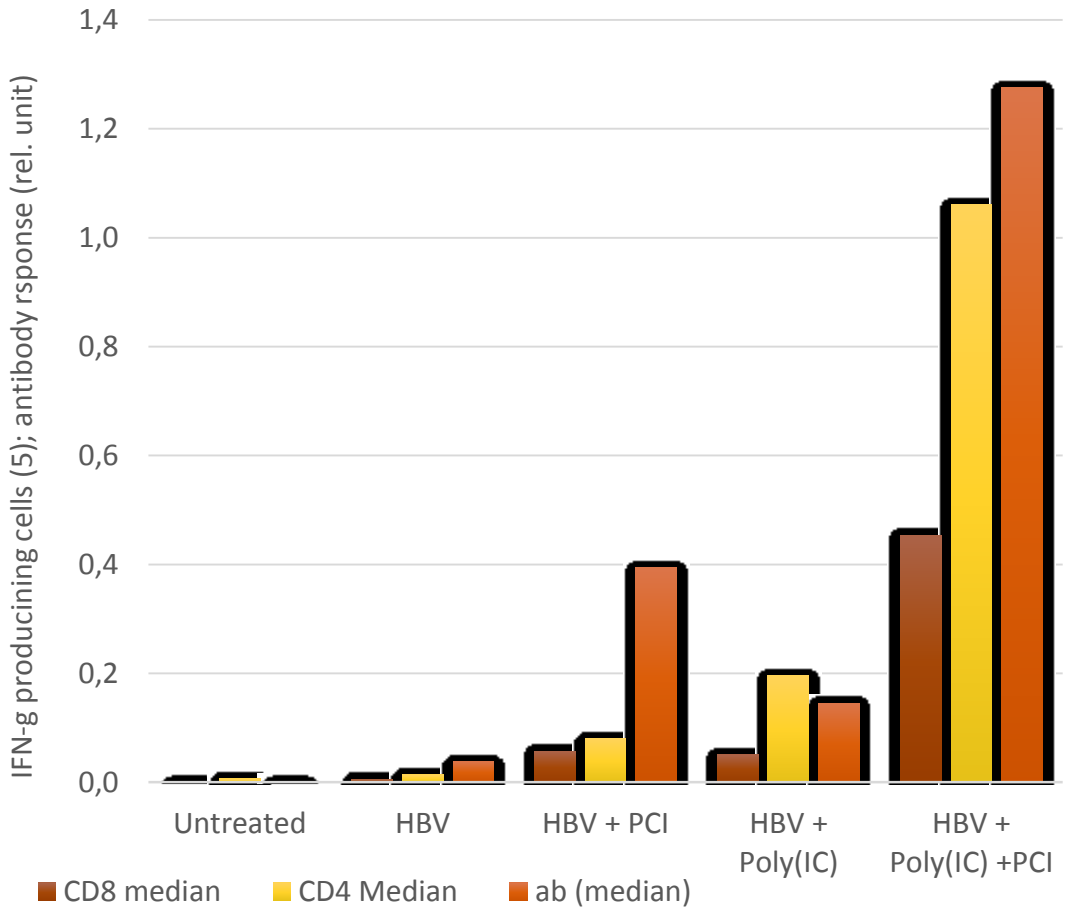
PCI VACCINATION

- Improving the efficacy of therapeutic cancer vaccines

PCI induces CD8, CD4 and antibody responses



Promising preclinical data:

- Elicit strong responses in all important aspects of immune responses
- Induce antigen-specific killer T-cells
- Long term effects in spleen indicate generation of immunological memory
- Works in synergy with other state-of-the-art vaccine enhancement technologies

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THE fima VACC POTENTIAL

- Opportunity to play a key role in second generation immunotherapy

- Unique mode of action
  - indication of CTL-induction by MHC class I antigen presentation in dendritic cells and macrophages
- Broad applicability
  - peptide and protein antigens
  - particulate antigen formulations
  - prophylactic & therapeutic vaccination

- Excellent stability
  - few logistical challenges (stable at room temperature and solution and can be autoclaved)
- Cost effective synthesis
- Important recent IP generation
- Ready for clinical validation in healthy volunteers

READY TO ENTER CLINICAL VALIDATION

- Well-designed phase I study in healthy volunteers with read-out 1H 2017

- Covance selected as strategic partner for this clinical validation
  - Phase I unit in Leeds, UK
- Objective:
  - Determine the safety, tolerability and immune response of fima VACC in healthy subjects
- Design:
  - Open-label, antigen-adjuvant controlled study (up to total 80 subjects)
- Endpoints:
  - Safety and immunological (induction of vaccine-specific immune responses)
- Timelines:
  - Study start 2H 2016; completion 1H 2017
- Cost:
  - Up to NOK 20 million in external cost

Converting fima VACC to a clinical asset – a major milestone towards commercialisation

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NUCLEIC ACID THERAPEUTICS

- A treatment modality with huge potential

- fimaNAc may provide a delivery solution for many nucleic acid therapy applications
- Opportunistic collaborative approach
- Aim is to out-license the technology on non-/semi-exclusive basis

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* Research and Markets “RNAi therapeutics market”. Dec 2015

RESEARCH COLLABORATIONS

- Three active collaborations within nucleic acid therapeutics and vaccination

Top-10 large pharma company

- Evaluate synergistic effects between companies' technologies
- One of the global leaders in nucleic acid therapeutics
- Collaborative research funded and initiated
- Data generated in research collaboration to be evaluated- potential for a further partnership

RXi Pharmaceuticals

- RXi Pharmaceuticals listed on Nasdaq (NASDAQ: RXII)
- Discovers and develops innovative therapeutics within dermatology and ophthalmology
- Results achieved from this research collaboration to be evaluated- potential for closer collaboration

Ultimovacs

- Ultimovacs AS, Norwegian immunotherapy company
- Developing UV1, a therapeutic cancer vaccine directed against human telomerase
- Results from this research collaboration to be evaluated- potential for closer collaboration

FINANCE

- Key financial figures

(In NOK 1,000)	2016 Q2	2016 1H	2015 FY
Other Income	2 332	4 917	10 467
Operating costs	11 613	21 506	43 096
Operating results	-9 281	-16 589	-32 629
Financial items	111	283	707
Comprehensive income	**-9 170**	**-16 306**	**-31 922**
Cash & cash equivalents	**31 028**	**31 028**	**49 249**
Total liabilities	**-11 360**	**-11 360**	**-12 114**
Net cash flow from operating activities	**-8 607**	**-18 222**	**-31 974**

- Close to NOK 5 million in non-dilutive funding first half of 2016
- Financed into 2017, at current cost base
- Evaluating strategic options, and corresponding capital need and financing alternatives

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- Well positioned for attractive development opportunities

Main focus going forward:

- Progressing development of fimaCHEM in bile duct cancer
  - Independent evaluation of Phase I results expected 3Q 2016
  - Phase II strategy
- Clinical validation of fimaVACC immunotherapy results
  - Expected to provide study read-out already 1H 2017
- Partnering and alliance progress for all programmes

PCI BIOTECH HOLDING ASA

- Enquiries

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