Q1 2017 PRESENTATION

May 16, 2017

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PCI BIOTECH

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HIGHLIGHTS

► Q1 2017

fimaCHEM

- Presentation of updated Phase I data at the International Liver Congress and at the Cholangiocarcinoma Foundation Annual meeting
- Interaction with regulatory authorities to determine fastest way to market
- Preparing for repeated treatments in Phase II through an extension of Phase I

fimaVACC

- Phase I in healthy volunteers ongoing – results from the first phase of the study expected 2Q
- Awarded up to NOK 14.3 million for further development of the vaccination platform

fimaNAc

- Four active research collaborations ongoing

Corporate

- Completion of a fully underwritten rights issue of NOK 70 million

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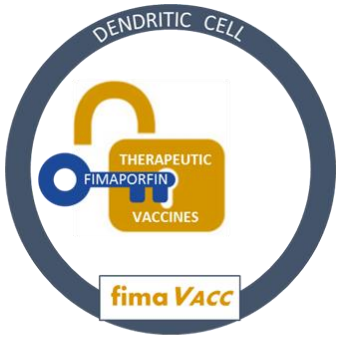
PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

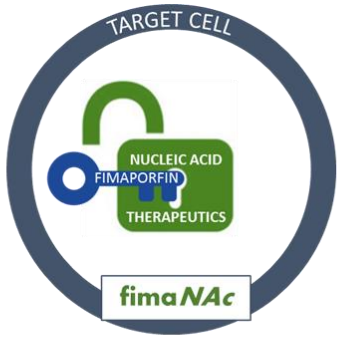
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation ("PCI") technology, originating from the Norwegian Radium Hospital
- Clinical programmes
  - **fimaCHEM** – Fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer, Phase I completed
  - **fimaVACC** – Vaccination technology that provides strongly enhanced cellular immune responses, Phase I ongoing
- Pre-clinical programme
  - **fimaNAc** – Efficient intracellular delivery of nucleic acid therapeutics, with four active research collaborations

PCI – the solution to a key challenge for several modalities

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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CHEMOTHERAPEUTICS

- A cornerstone in current cancer therapy

Chemotherapeutics will remain a **CORNERSTONE** in cancer treatment for the foreseeable future

PCI may enhance approximately **20%** of relevant approved chemotherapies

Niche indications may allow for **ORPHAN DRUG** applications

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

* **Lancet Oncology** (2016) **17**(9): p1217–1229

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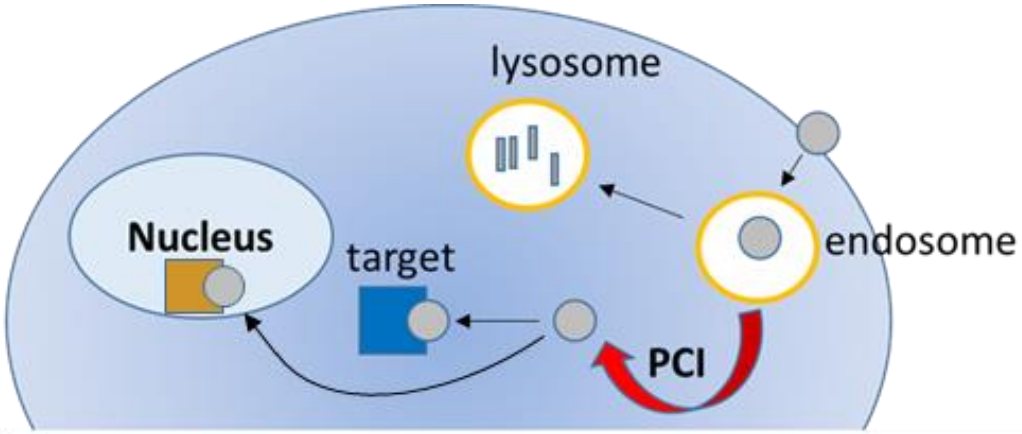
PCI TECHNOLOGY

▶ fimaCHEM – mode of action

Cancer cell

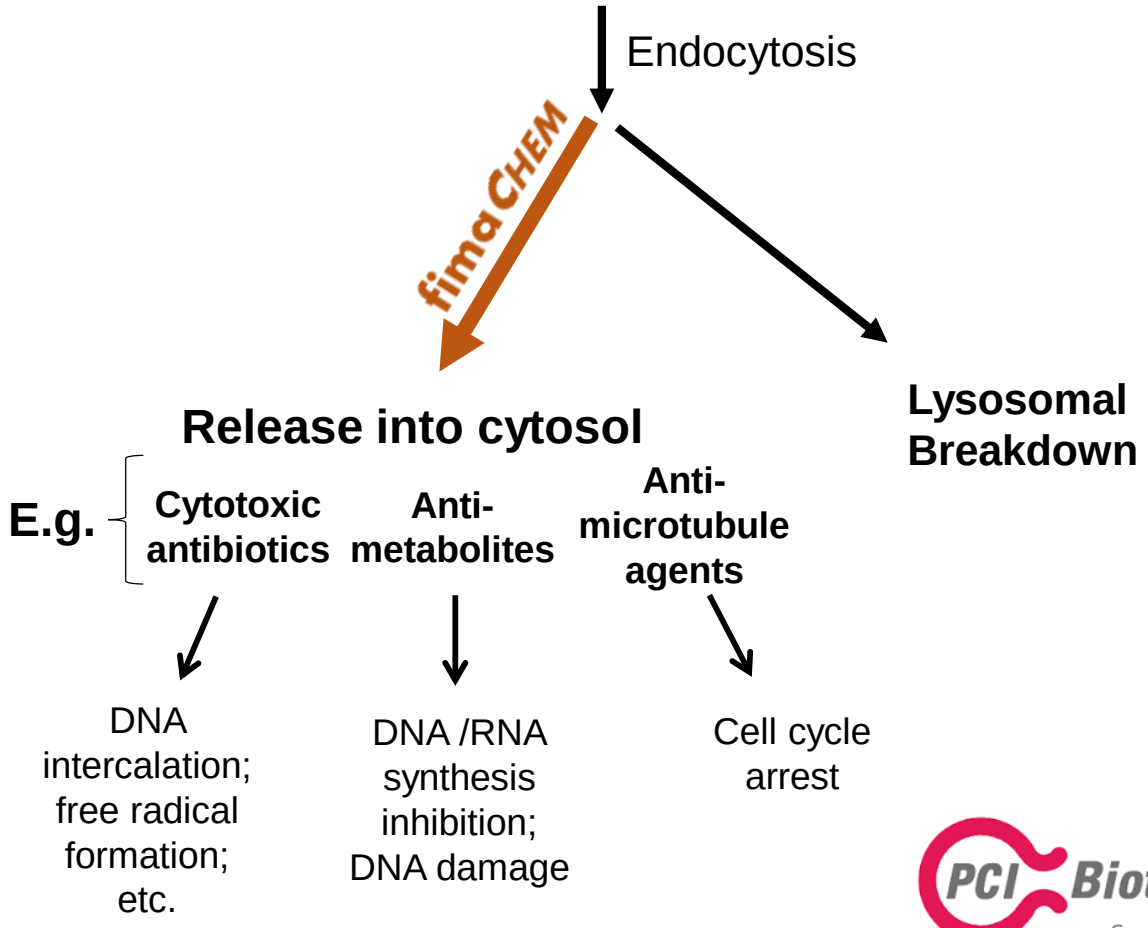


chemotherapeutic

The intracellular trafficking of chemotherapeutics is not well characterised for many products, but it is known that endocytotic uptake and/or sequestering into endosomes can lead to high endosomal content.

fimaCHEM can release biologically active chemo-therapeutics that are trapped in endosomes, thereby enabling them to reach their target before being inactivated in lysosomes.

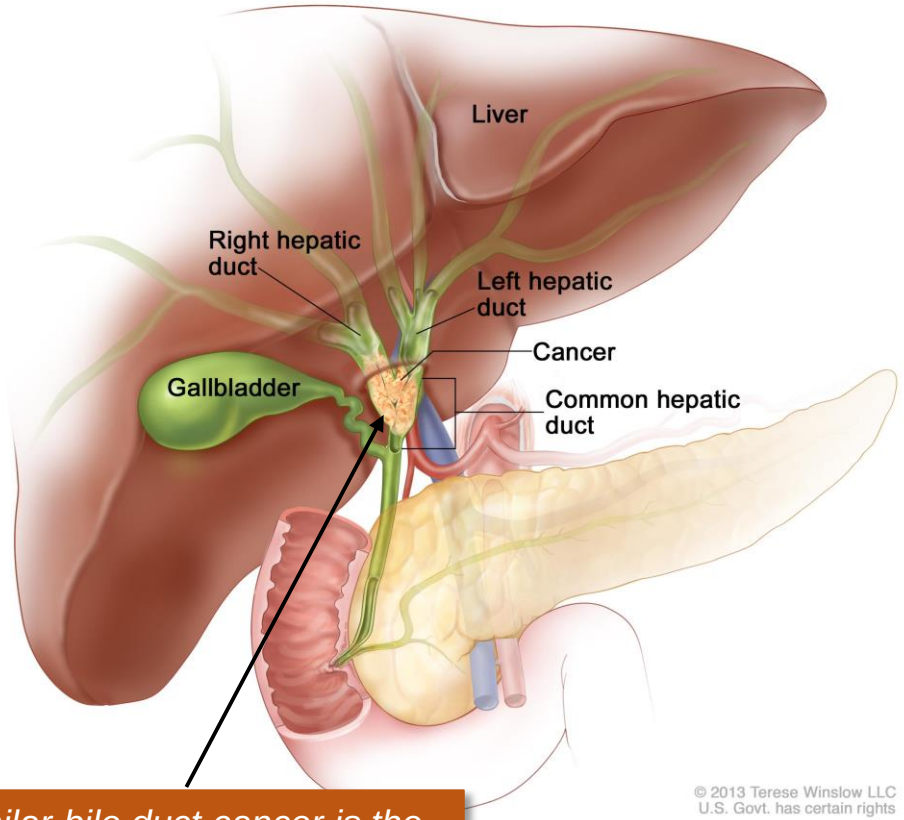
Chemotherapeutics



BILE DUCT CANCER

► Location and classification

- Often referred to as cholangiocarcinoma
- The cancer cells originates from the cells inside the bile duct (called cholangiocytes)
- Cholangiocarcinoma includes:
  - Intrahepatic tumours (10%*)
  - Perihilar tumours (60-70%*)
  - Distal tumours (20-30%*)
  - Different incidence, pathobiology and management



Perihilar bile duct cancer is the initial target for PCI treatment

* Bile duct cancer, Am Cancer Soc, 10/30/2013

BILE DUCT CANCER

▶ Why target bile duct cancer

- Orphan indication, yearly incidence rate of 1-2 per 100,000 in the western world – higher incidences in Asia
- Five-year survival rate of less than 5%, and almost 0% when inoperable – average approx. 12 months survival
- Current management
  - Surgery
    - Only potentially curative treatment
    - Less than ⅓ are resectable at presentation
  - Stenting
    - **Endoscopic** stenting for palliative biliary drainage
  - Chemotherapy
    - No approved chemotherapy
    - Recommended chemotherapy: **gemcitabine** and cisplatin

Excellent technology fit with PCI

Targeted illumination is done using standard endoscopic procedure

The active chemotherapy gemcitabine is significantly enhanced by fima CHEM

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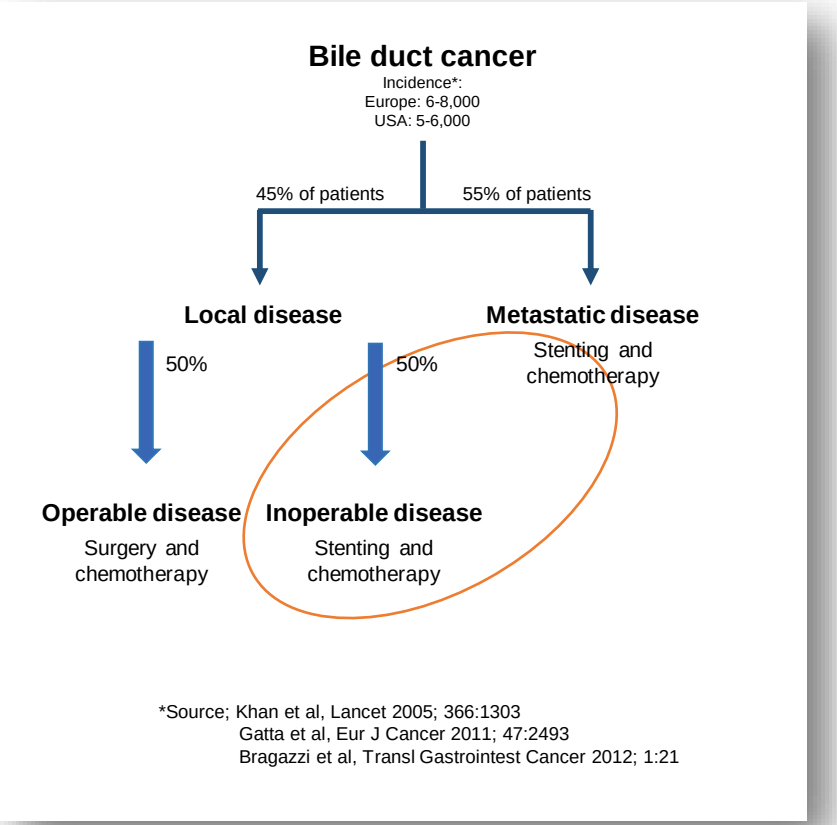
Bile Duct Cancer

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 in distal and more advanced metastatic disease
  - Higher incidences in Asia
- **Attractive price potential for orphan drugs**
  - Lack of approved medicinal treatment options
  - Diseases with <10,000 in US support annual pricing >$100,000[1]
- **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



[1] LifeSciCapital, OD Market Sector Analysis 2016

BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Six month radiology data – promising tumour response in the two highest dose cohorts

Cohort III & IV – response at single lesion level

Measurable lesions	Lesion shrinkage		Stable lesion	Lesion growth
19 (total number of targets selected across the two independent readers)	**17**	**12** (lesion not detectable)	**1** (<20% reduction & <10% increase)	**1** (>10% mass increase)
		5 (>20% mass reduction)		

Cohort III & IV – RECIST classification of patients

RECIST	PD	SD	PR	CR	NA*
Central read	2**	1	2	2	2

* Not measurable / Not radiologically evaluable
** Progressive disease due to appearance of new lesions

PD: Progressive disease (>20% growth)
SD: Stable Disease
PR: Partial Response (>30% shrinkage)
CR: Complete Response (no visible tumour)

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BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Phase I results including survival presented at the International Liver Congress

- Average OS in this Phase I study with a single **fimaCHEM** with gemcitabine treatment followed by standard cisplatin + gemcitabine treatment was by end of March 14.5 months, with 25% of the patients still being alive

- The median overall survival (OS) in the studies that established gemcitabine and cisplatin as standard treatment in bile duct cancer was 11.7 and 11.2 months respectively (Valle et al. NEJM (2010) 362:1273-81 and Okusaka et al. BJC (2010) 103:469-74); gallbladder cancer patients had a poorer outcome in the latter study and OS was 13 months when these patients were excluded

- Important to note that these studies include a wide range of different inoperable bile duct cancer patients, while the **fimaCHEM** Phase I study focused on inoperable perihilar bile duct cancer patients – these results are therefore not directly comparable to the data in the **fimaCHEM** Phase I study

- A recent retrospective study of long-term survival of 572 patients with inoperable perihilar bile duct cancer showed a one-year survival of 41.8% (Gaspersz et al. (2017) J Hepatol 66(Suppl.1):S446-7)

Encouraging emerging survival data, although on few patients

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BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Phase I study extension to provide safety data for repeated treatment

- PCI Biotech is about to start an extension to the Phase I study, with the objective to determine safety and tolerability of repeated treatment with **fimaCHEM**
- The purpose of the Phase I extension study is to explore feasibility of further optimisation of the **fimaCHEM** treatment by opening up for retreatment 3-4 months after the initial treatment
- The extension study will include a minimum of 6 evaluable patients, i.e. patients that are on the study for at least approx. 5 months, receiving 2 **fimaCHEM** treatments and completing at least 4 cycles of gem-cis
- The study will be run in Europe and safety read-out is expected to take approx. 3 quarters, with external costs estimated to be NOK 10-14 million, depending on patient recruitment rate and number of patients needed to reach 6 evaluable patients

Exploring safety of repeated treatment as a Phase I extension permits parallel performance of activities, streamlining the work towards a Phase II study with repeated treatment

BILE DUCT CANCER

► Status and strategy going forward

- **Phase I completed with good tolerability and very promising early signs of efficacy**
  - No serious unexpected safety findings and no apparent increase in adverse reactions with increasing doses
  - Very promising early signs of efficacy – significant tumour shrinkage observed radiologically
  - Results verified at central evaluation by study-independent external radiological experts in RECIST
  - Encouraging emerging survival data
- **Orphan designation**
  - Granted Orphan Drug Designation in EU; US application submitted
- **Regulatory interactions with EU and US authorities, to determine fastest way to market**
  - Promising signs of efficacy in a life threatening orphan indication without approved treatment alternatives
  - The ongoing regulatory interactions are now likely to continue into 2H 2017
- **Initiated activities to engage US stakeholders**
  - Co-sponsored and presented Phase I at the annual US Cholangiocarcinoma Foundation meeting in Salt Lake City
- **Streamlining the work towards initiation of a Phase II study with repeated treatment**
  - Exploring safety of repeated treatment as a Phase I extension permits parallel performance of activities

IMMUNOTHERAPY

- A new hope for millions of patients

Total estimated immunotherapy sales of **$35bn** in 2023*

More than **100** projects in development**

Combinations with **THERAPEUTIC VACCINES** may enhance CPI[1] response rates

- **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

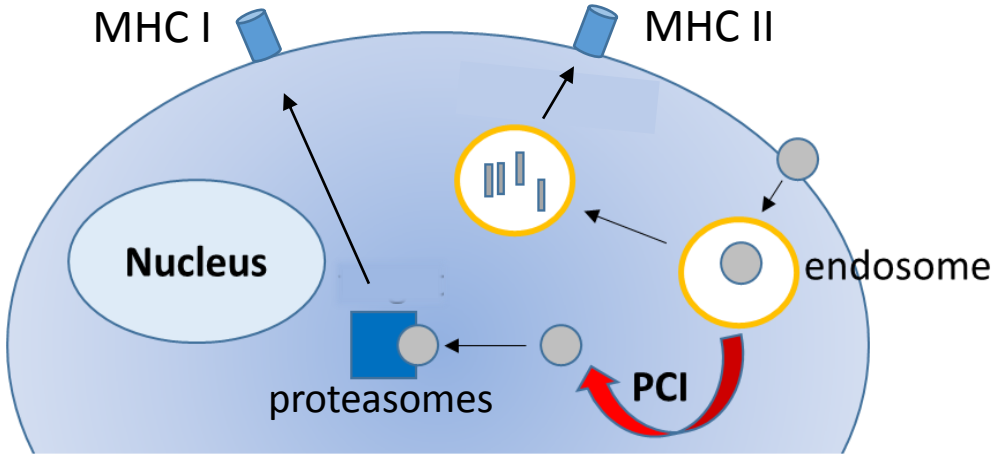
* Citi Research "Immunotherapy – the beginning of the end for cancer". Baum, May 2013
** Clinicaltrials.gov. PCIB analysis, August 2016

[1]CPI: Checkpoint inhibitors

PCI TECHNOLOGY

▶ fima VACC – mode of action

Dendritic cell



vaccine antigen

Vaccine antigens taken up by dendritic immune cells are released into the cytosol by fima VACC treatment. Proteasomes in the cytosol process these to short peptides. The peptides bind to MHC class I proteins that are transported to the cell surface, leading to an enhanced MHC class I presentation of the administered vaccine antigen.

Vaccine

Endocytosis

fima VACC

MHC Class I

Generate more disease specific cytotoxic T-cells

Attack cancer and virus-infected cells more efficiently

MHC Class II

Antibodies and helper T-cells

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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 in solution and can be autoclaved)
- Cost effective synthesis
- Important recent IP generation

PROGRESSING CLINICAL TRANSLATION

▶ Phase I study in healthy volunteers

- 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:
  - First subject dosed: September 2016; Read-out of results from first phase: 1H 2017

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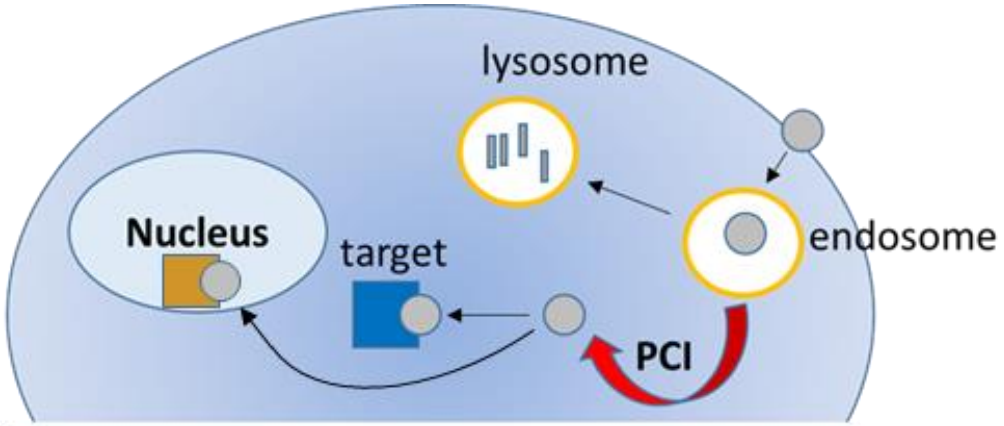
* Research and Markets “RNAi therapeutics market”. Dec 2015

PCI TECHNOLOGY

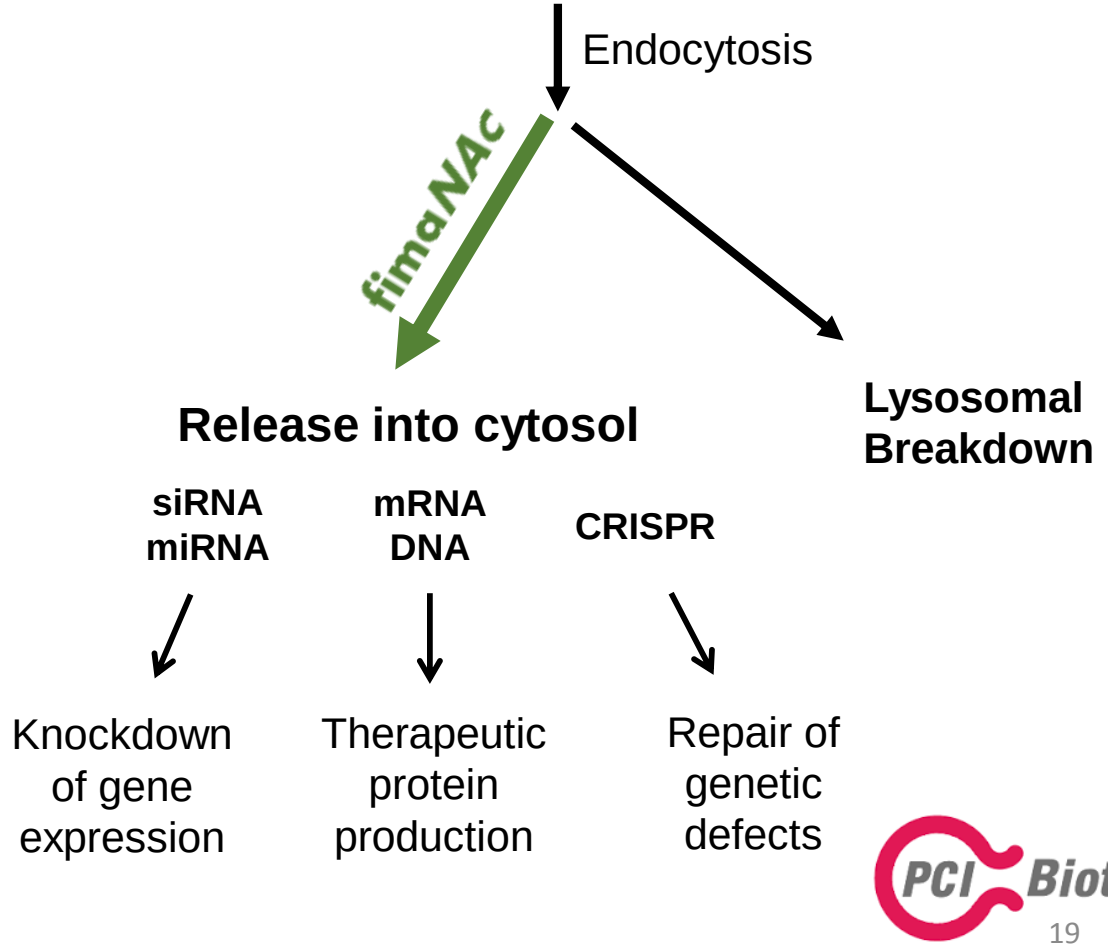
▶ fimaNAc – mode of action

Target cell



Nucleic acid therapeutics need to enter into the cell cytosol to exert their therapeutic effect. Being quite large molecules, they cannot readily pass the cell membrane, but are taken up by endocytosis. Treatment of target cells with **fimaNAc** enable release of nucleic acid therapeutics that are trapped in endosomes, allowing them to exert their effect.

Nucleic Acid Therapeutics



RESEARCH COLLABORATIONS

- Five active collaborations within nucleic acid therapeutics and vaccination

fimaNAc

BioNTech

- Initiated 3Q 2016
- German biotechnology company developing individualised cancer immunotherapies
- Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer

RXi Pharmaceuticals

- Initiated 2Q 2015
- Listed on Nasdaq
- Innovative therapeutic siRNA
- Clinical programs in dermatology and ophthalmology

EtheRNA

- Initiated 4Q 2016
- A global leader in mRNA-based immunotherapies
- Evaluate synergistic effects between companies' technologies

Top-10 large pharma

- Initiated 3Q 2015
- A global leader in nucleic acid therapeutics
- Collaborative research funded by partner
- Evaluate synergistic effects between companies' technologies

fimaVACC

Ultimovacs

- Initiated 1Q 2016
- Norwegian immunotherapy company
- Therapeutic cancer vaccine against human telomerase
- Clinical programs in prostate and lung cancer

Research collaborations aim to evaluate synergies between the fima platform and partner technologies, with the potential for further partnerships

FINANCE

- Fully underwritten rights issue completed in January 2017

- Net proceeds of NOK 65 million
- More than 100% oversubscription
- Shareholder base doubled since year-end 2015 to approximately 3.000 shareholders

Top 10 shareholders per 15 May 2017

Name	Number	%
FONDSAVANSE AS	2 540 840	10,20
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 761 273	7,07
MP PENSJON PK	1 447 504	5,81
NORDNET LIVSFORSIKRING	833 516	3,35
Myrlid AS	550 630	2,21
GRESSLIEN ODD ROAR	550 000	2,21
BERG-LARSEN ALEXANDER	545 433	2,19
VICAMA AS	500 000	2,01
NORDNET BANK AB	463 039	1,86
SYVERTSEN SVEIN ERIK	437 107	1,76
Total 10 largest shareholders	9 629 342	38,67
Total other shareholders	15 271 048	61,33
Total number of shares	24 900 390	100,00

FINANCE

- Key financial figures Q1 2017

(In NOK 1,000)	**2017 Q1**	**2016 Q1**	**2016 FY**
Other income	2 428	2 584	10 475
Operating costs	12 281	9 893	43 502
Operating results	-9 854	-7 309	-33 027
Financial items	221	173	843
Comprehensive income	**-9 632**	**-7 136**	**-32 184**
Cash & cash equivalents	**69 929**	**39 635**	**14 002**
Net cash flow from operating activities	**-9 105**	**-9 614**	**-35 247**

- NOK 10 million in annual non-dilutive funding last two years
- A Phase I extension study will impact the financial runway and with current plans PCI Biotech is financed into 2H 2018

PCI BIOTECH

- Well positioned for attractive development opportunities

Main focus going forward:

- Progressing development of **fima*CHEM*** in bile duct cancer
  - Regulatory interactions to determine fastest way to market
  - Extension to Phase I to explore safety of repeated treatment
  - Prepare for Phase II study
- Clinical validation of **fima*VACC*** immunotherapy results
  - Expected to provide read-out of results from first phase in 1H 2017
- Partnering and alliance progress for all programmes

PCI BIOTECH HOLDING ASA

- Enquiries

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