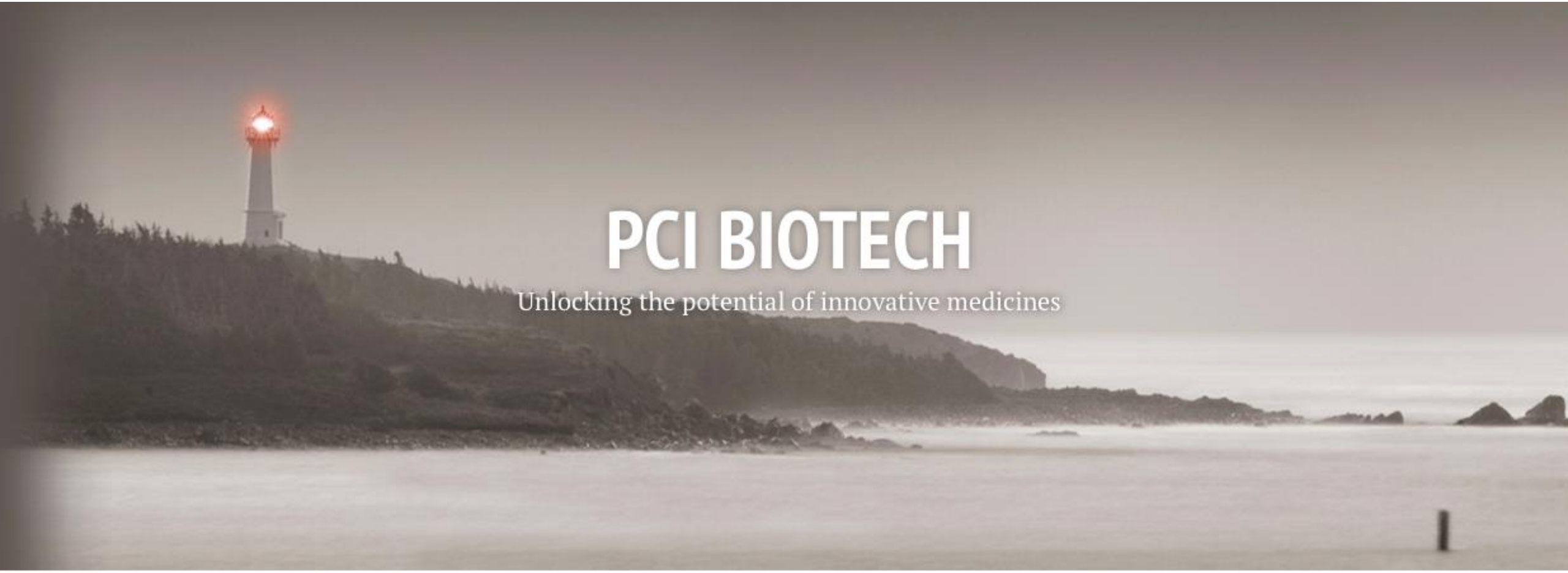

Q1 2019 PRESENTATION

May 8, 2019

Per Walday, CEO
Ronny Skuggedal, CFO

PCI Biotech

PCI BIOTECH

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HIGHLIGHTS

► First quarter 2019

fimaCHEM

- First sites for the pivotal RELEASE study open for enrolment
- Successful safety read-out in the Phase I extension study confirmed (subsequent event)
- Completion of the full Phase I study and formal closure of recruitment (subsequent event)
- Presented Phase I dose-escalation results at the annual conference of the US Cholangiocarcinoma Foundation and at the 3rd Asia-Pacific Cholangiocarcinoma conference in Taiwan

HIGHLIGHTS

► First quarter 2019

fima*VACC*

- Successful clinical translation
  (subsequent event)

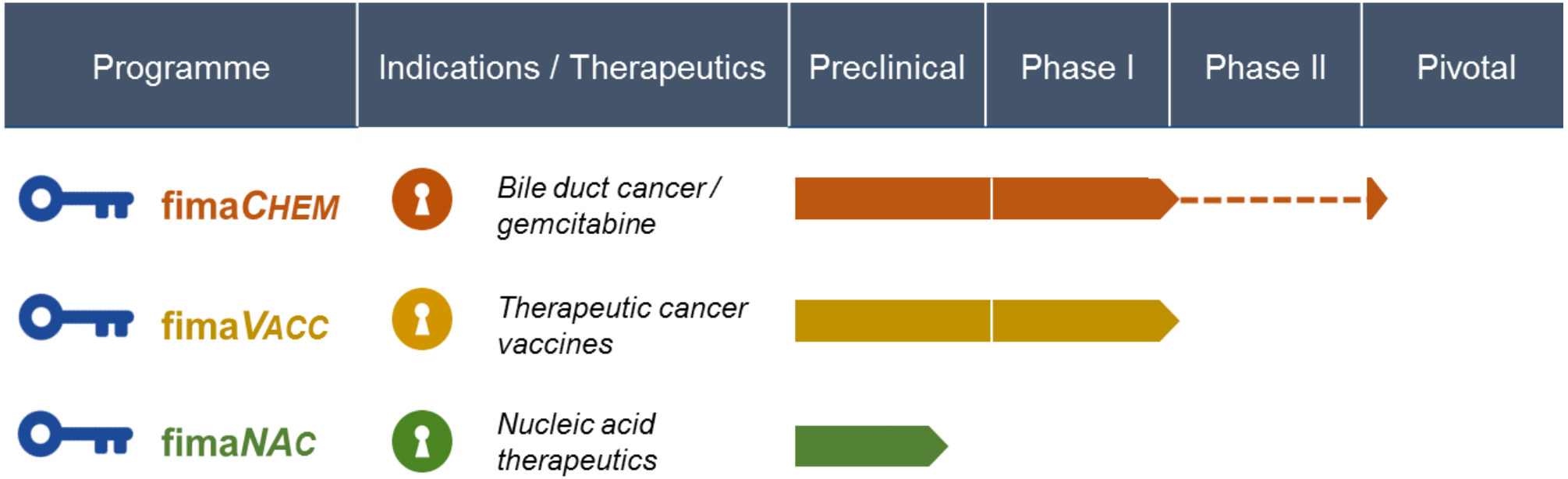
Corporate

- Further strengthened the Scientific Advisory Committee with Professor Sjoerd van der Burg, to ensure adequate scientific support to the fima*VACC* programme

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 Oslo University Hospital

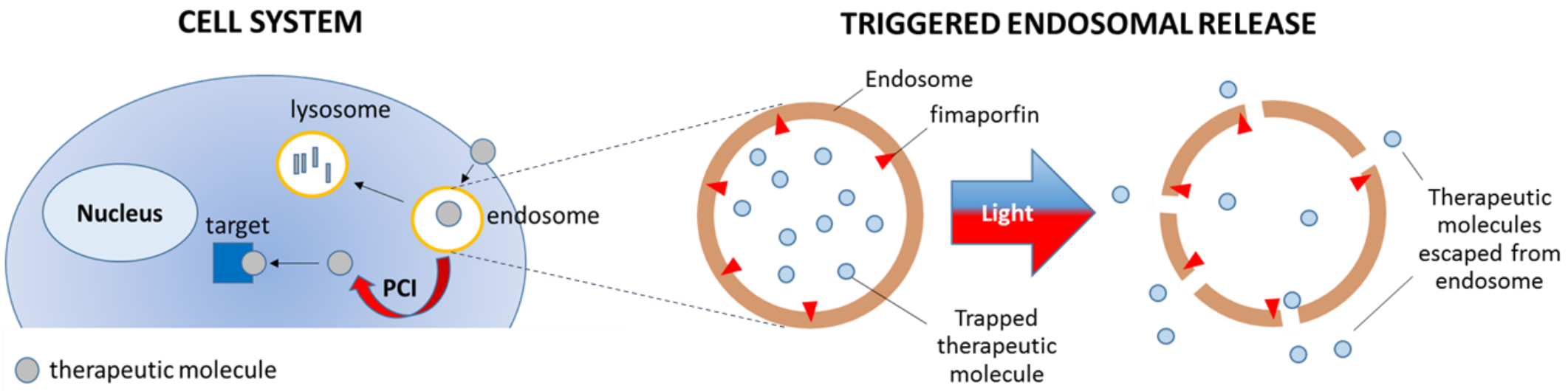


An oncology focused company with three well differentiated assets

PCI TECHNOLOGY

- Enabling drugs to reach intracellular therapeutic targets

Mode of action

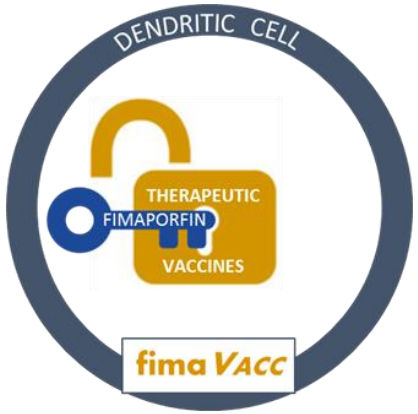


PCI TECHNOLOGY

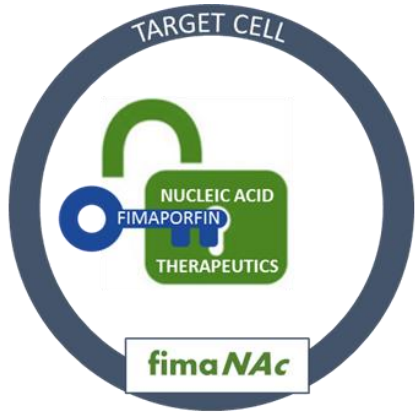
- Enabling drugs to reach intracellular therapeutic targets

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

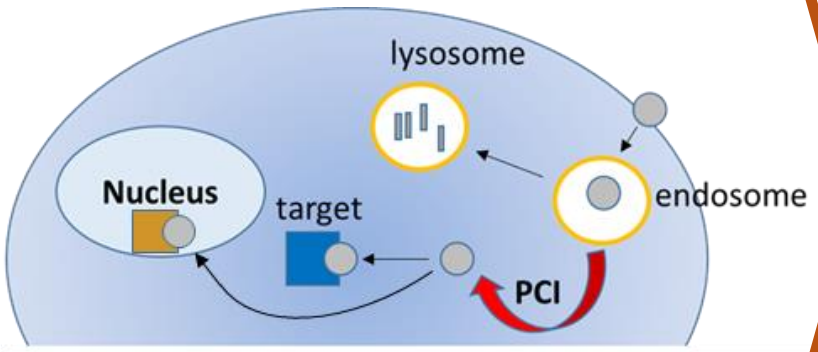


Providing a delivery solution for nucleic acid therapeutics

PCI TECHNOLOGY

► fimaCHEM – mode of action

Cancer cell



chemotherapeutic

Chemotherapeutics

Endocytosis

fimaCHEM

Release into cytosol

E.g.:

- **Cytotoxic antibiotics** → DNA intercalation, free radical formation, etc.
- **Anti-metabolites** → DNA/RNA synthesis inhibition; DNA damage
- **Anti-microtubule agents** → Cell cycle arrest

Lysosomal breakdown

BILE DUCT CANCER – EXTRAHEPATIC INOPERABLE

- Excellent fit between medical need and **fimaCHEM**

- Orphan indication
- Average survival inoperable: 11-12 months[1]
- 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: **gemcitabine** and cisplatin

Enhancing the active and recommended chemotherapy

Easy illumination through standard endoscopic methods

Boosting chemotherapy effect where it is most needed

[1] N Engl J Med 2010;362:1273-81

BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

► Cohort IV is selected dose for pivotal study – limited but encouraging data

Positive early signs of efficacy – mOS of 21.7 months at selected dose in Cohort IV

Parameters	Cohort IV (N=6) (0.25mg/kg)	Phase I – full study (N=16) (0.06-0.25mg/kg)
Objective Response Rate (ORR)	**3/5 patients** (2 PR; 1 CR)	**4/12 patients** (2 PR; 2 CR)
Median Overall Survival (mOS)	**21.7 months**	**14.4 months**

BILE DUCT CANCER – PHASE I Extension STUDY

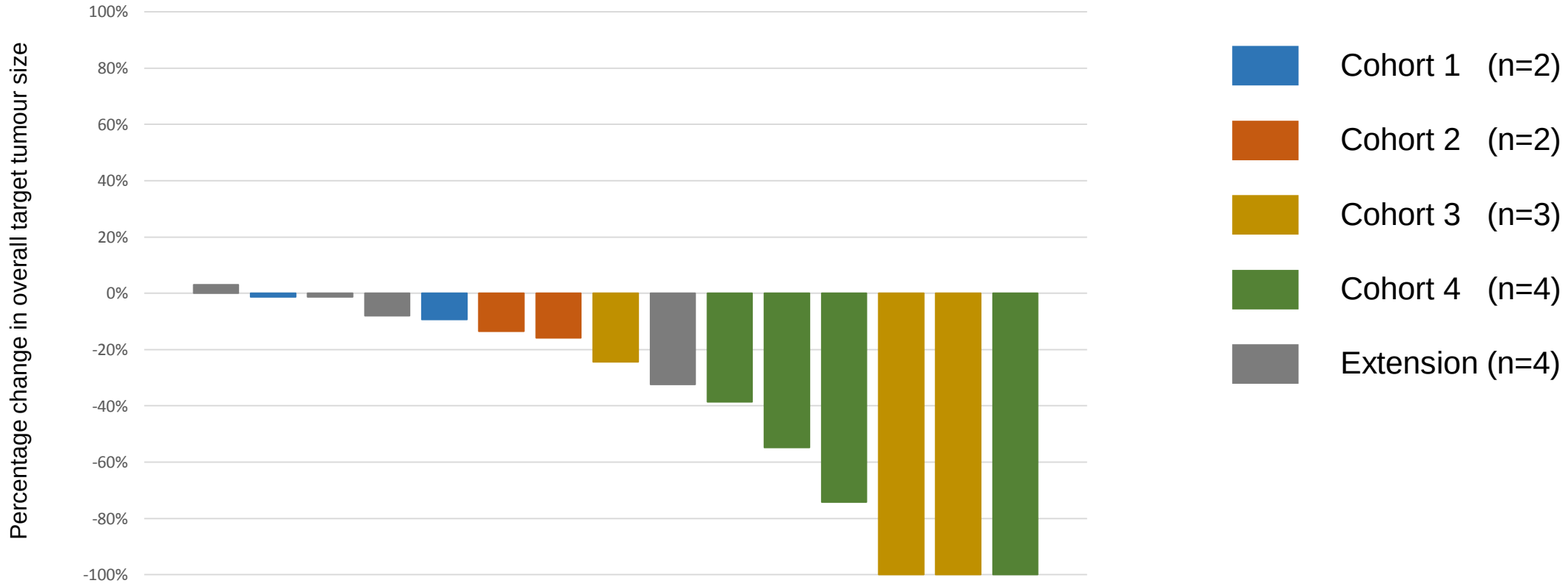
- Extension cohort to explore safety of repeated treatment

- **Summary of characteristics and interim results**
  - A total of seven patients were included – five of these received two fima*CHEM* treatments
  - Safety endpoint reached – the pivotal study will be initiated with up to two treatments
  - Four of the seven included patients had radiologically measurable disease
  - The average tumour burden (overall target tumour diameter) in patients with measurable disease in the extension was about twice the average tumour burden in the dose escalation
  - None of the measurable local treated tumours showed progression during the six months follow-up period, but two patients had progression due to appearance of new lesions
  - Three of the seven patients were alive at last censoring (March – May), all having received two treatments – the emerging median overall survival is approximately 14 months

BILE DUCT CANCER – CLINICAL PHASE I STUDY

- Dominated by significant target tumour reduction in the first 6 months

- **Best Overall Response – all patients with measurable disease in all cohorts including extension (n=15)**



BILE DUCT CANCER – RELEASE STUDY

- Progress towards initiation of the pivotal study

- **Achieved safety endpoint in the extension study confirmed after formal review by the appointed Cohort Review Committee**
- **Ongoing regulatory and ethics approvals progressing well – all approvals achieved in Norway, Germany, Sweden, Denmark, France and Spain**
- **Ongoing site initiations progressing well – two sites open for enrolment**
- **Presentation of Phase I data at the US CCA Foundation annual conference in USA (Jan'19) and at the 3rd Asia-Pacific CCA conference in Taiwan (Mar'19)**

BILE DUCT CANCER – RELEASE STUDY

- Randomised study with interim analysis for potential accelerated/conditional approval

- **Orphan designation granted in both the US and EU**
- **Fastest way to market determined through regulatory interactions with authorities**

- First line treatment of patients with inoperable extrahepatic bile duct cancer
- Approx. 40 key hospitals (Europe & USA)
- Approx. 36 months to interim and 50 to final analysis

- Randomisation (1:1) of 186 patients
- Primary endpoint: PFS[a], with OS[b] as key secondary
- Interim analysis primary endpoints: PFS followed by ORR[c]

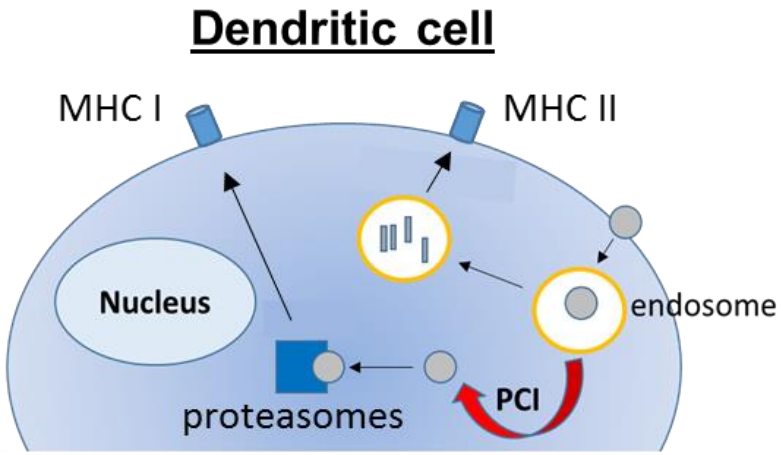
RELEASE trial progress reporting:

- Key milestones will be communicated in press releases
  - Start of study (first patient enrolled); IDMC[d] recommendations; clinical results presentations, filing, etc.
- Progress will be updated in quarterly reports
  - Number of country approvals
  - Number of sites open for enrolment

[a]PFS: Progression Free Survival; [b]OS: Overall Survival; [c]ORR: Objective Response Rate; [d]IDMC: Independent Data Monitoring Committee

PCI TECHNOLOGY

▶ **fima VACC** – aiming to enhance immunogenicity of vaccines for immunotherapy field



Vaccine antigen

Vaccine

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

SOLID PROGRESS OF THE fimaVACC PROGRAMME

- Successful clinical translation and SAC reinforced with immunological expertise

- The Phase I study provides successful clinical translation for **fimaVACC**
  - Proof of concept and efficacy in terms of intradermal dosing in humans
  - A positive overall characterisation of tolerability, with efficacy seen at well tolerated dose levels

- *"These encouraging results obtained by including fimaporfin during vaccination merit further exploration in a relevant clinical disease to assess if the enhanced immune responses translates into clinical benefit"*

  said Professor Sjoerd van der Burg – new member of the Scientific Advisory Committee (SAC)

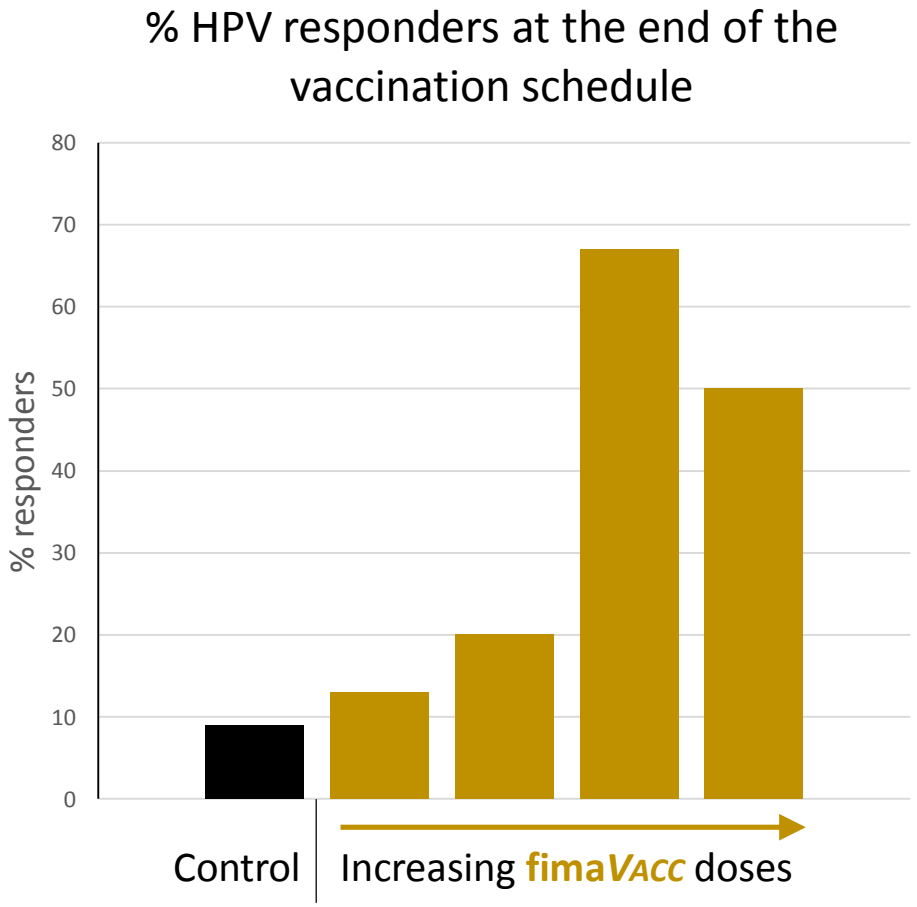
CLINICAL TRANSLATION OF VACCINATION TECHNOLOGY

- Phase I study in healthy volunteers

- Overall objective:
  - Determine the safety, tolerability and immune response of **fimaVACC**
- More than 90 subjects enrolled
- Results – compared to control **fimaVACC** induces:
  - Substantial increase in number of T-cell responders to HPV E7 peptides
  - Clearly enhanced overall T-cell responses
  - More robust CD8 T-cell responses (notoriously difficult to induce with E7)
  - Increased functionality of the induced CD8 T-cells
  - ➢ Highly sought-after features – especially for therapeutic vaccination

OVERALL T-CELL RESPONSES – HPV E7 PEPTIDES

- Substantial increase in the percentage of subjects responding to vaccination

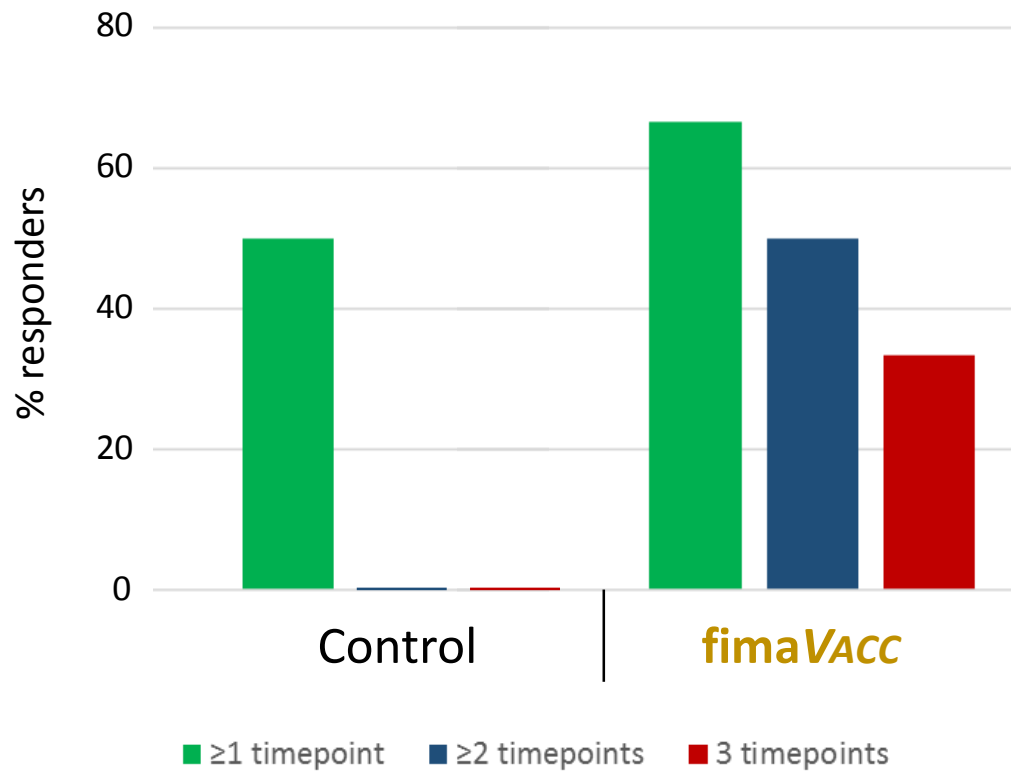


fimaVACC induces more overall T-cell responders than the control with a state of the art adjuvant technology (Hiltonol), after completion of the HPV E7 vaccination schedule

Details on CD8 results at the* fimaVACC *dose with best overall T-cell response is provided on the following two slides

CD8 T-CELL RESPONSES – HPV E7 PEPTIDES

► **fimaVACC** induces more responders and more responses

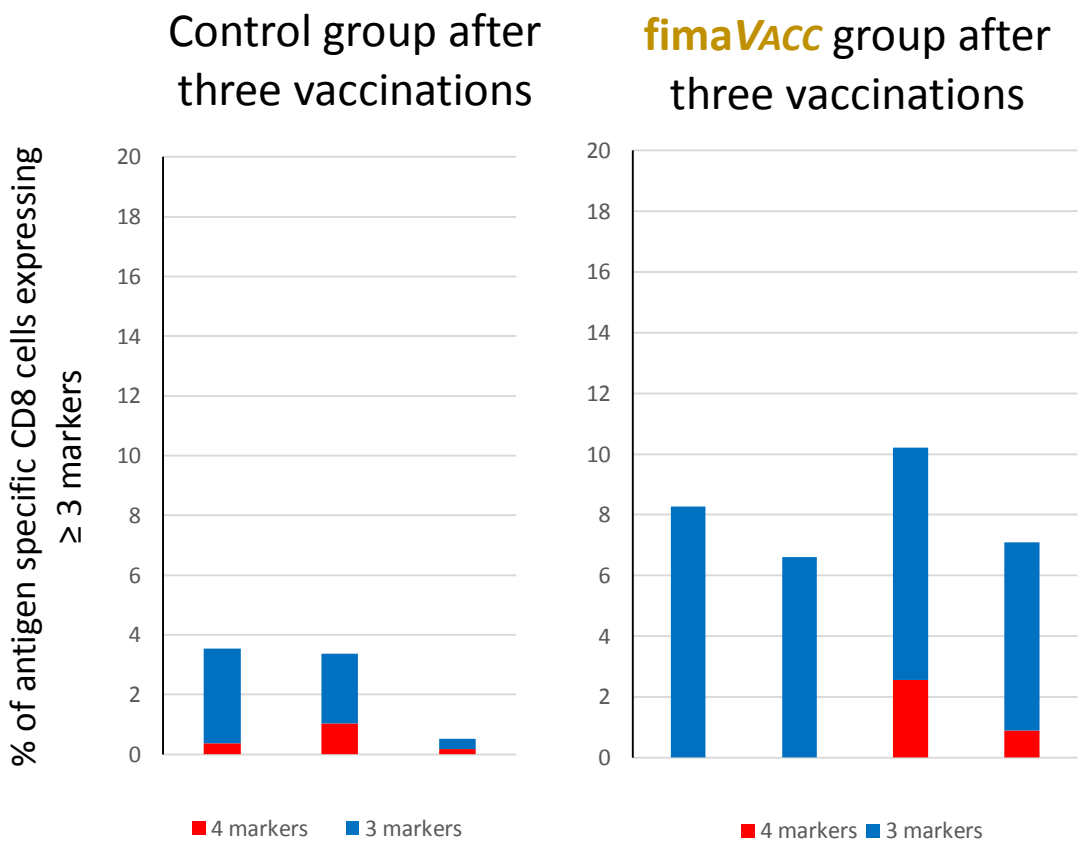


fimaVACC induces more CD8 T-cell responders and responses at more time-points

- CD8 T-cell responses in the control group was less frequent and generally borderline
- 3/6 subjects treated with **fimaVACC** developed CD8 T-cell responses at two or more time-points (0/6 of controls)

CD8 T-CELL RESPONSES – HPV E7 PEPTIDES

► **fimaVACC** substantially increases the frequency of polyfunctional CD8 T-cells

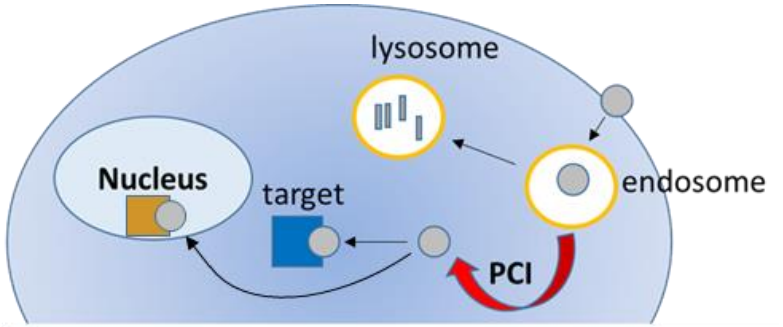


- As compared to the control group, **fimaVACC** substantially increases the frequency of polyfunctional CD8 T-cells (expressing ≥ 3 functional markers)
- CD8 T-cell polyfunctionality is an important parameter indicating the ability of the T-cells to combat cancer cells and to give proper protection against viral infections

PCI TECHNOLOGY

► fimaNAc – mode of action

Target cell



Nucleic acid therapeutic

Nucleic acid therapeutic

Endocytosis

fima NAc

Release into cytosol

Lysosomal breakdown

E.g.:

siRNA
miRNA

Knockdown of gene expression

mRNA
DNA

Therapeutic protein production

RESEARCH COLLABORATIONS

- Six collaborations established with key players in nucleic acid therapeutics

fimaNAc

- Top-10 large Pharma collaboration extended to end of 1H'19

Top-10 large pharma

IMV IMMUNOVACCINE

Phio PHARMACEUTICALS *

BAVARIAN NORDIC

eTheRNA

BIONTECH

* Previously named RXi Pharmaceuticals

FINANCE

- Key financial figures

- Other income (public grants) in line with previous year
- Operating result impacted by preparations for initiation of the pivotal **fimaCHEM** trial

(figures in NOK 1,000)	Q1 2019	Q1 2018	FY 2018
Other income	2,425	2,238	9,585
Operating results	-17,929	-14,663	-44,519

(figures in NOK 1,000)	Q1 2019	Q1 2018	FY 2018
Net change cash and cash equivalents	-20,569*	-12,203	298,537
Cash and cash equivalents	328,757	50,789	349,326

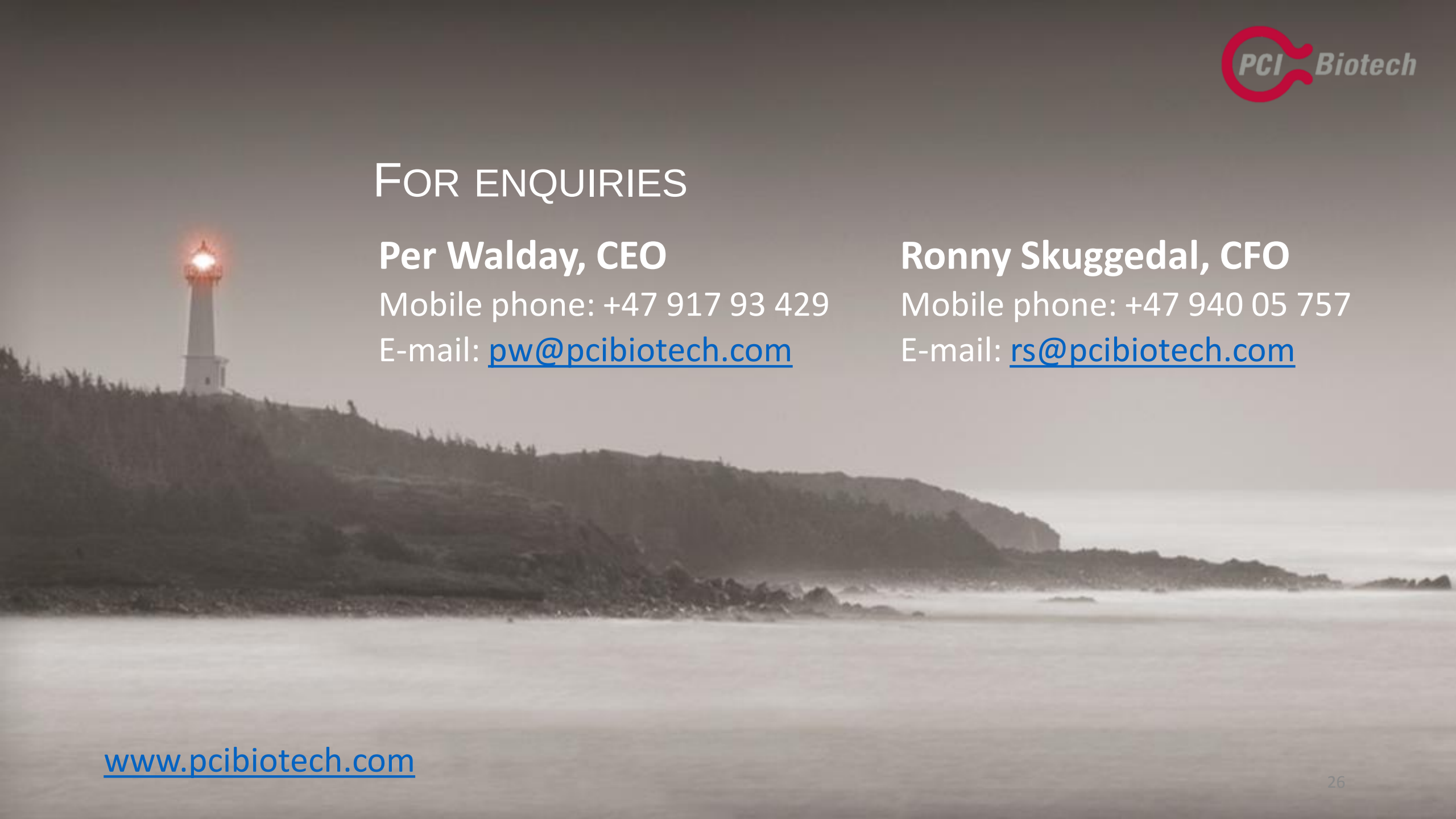
*NOK 5.4 million negative effect for Q1 2019 from currency fluctuation on bank deposits in EURO

KEY ACHIEVEMENTS & NEAR-TERM MILESTONES

2H 2018	✓	**Corporate**	Financing for pivotal **fimaCHEM** study
2H 2018	✓	**fimaNAc**	Established two new research collaborations
2H 2018	✓	**fimaCHEM**	Design of pivotal study finalised
2H 2018	✓	**fimaCHEM**	Safety of repeated treatment
1H 2019	✓	**fimaVACC**	Completion of Phase I immune analyses
1H 2019	➢	**fimaCHEM**	First patient enrolled in pivotal bile duct cancer study
2H 2019	➢	**fimaCHEM**	First US patient enrolled in pivotal bile duct cancer study
2H 2019	➢	**fimaVACC**	Phase I results published and presented at key conference

INVESTMENT HIGHLIGHTS

Market	**Platform technology with three programmes** targeting an **attractive and growing oncology market**, with a clear path to a **high unmet need orphan oncology market** for the lead product candidate
Lead product	**Amphinex®** is an **orphan designated** (EU & US) **first-in-class** photochemical internalisation product entering **pivotal development** for treatment of bile duct cancer – a **disease without approved drugs**
Clinical results	**Positive early signs of tumour response** in a first-in-man study published in Lancet Oncology, and in a Phase I study specifically targeting bile duct cancer – **encouraging survival data**
Pipeline	**fimaVACC – a clinical stage vaccination technology with encouraging cellular immune responses** **fimaNAc – a preclinical gene therapy delivery solution with established key player collaborations**
Strategy	Development strategy for **lead candidate** established based on **thorough regulatory discussions** with FDA and EMA – a single randomised pivotal study with **accelerated/conditional approval** potential
Leadership	Management team, Board of Directors and advisors with **extensive pharmaceutical industry experience** across a range of medical development and commercial areas



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