



PCI BIOTECH

Unlocking the potential of innovative medicines

Q4 & Interim Full Year 2018 PRESENTATION

February 13, 2019

Per Walday, CEO

Ronny Skuggedal, CFO



PCI BIOTECH

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HIGHLIGHTS

► Fourth quarter 2018

fima *CHEM*

- Preparations for the RELEASE study progressing towards initiation in 1H 2019
- Continued positive early signs of efficacy from Phase I dose-escalation
- Preliminary confirmation of safety read-out from the Phase I extension study
- Presented Phase I dose-escalation results at 2018 ESMO congress and at the annual conference of the US CCA Foundation in Jan 2019 (subsequent event)

HIGHLIGHTS

► Fourth quarter 2018

fima VACC

- Phase I interim data suggest enhancement of several parameters of importance for vaccination
- US patent granted for “band-aid-like” device for skin illumination/injection

HIGHLIGHTS

► Fourth quarter 2018

fima*NAC*

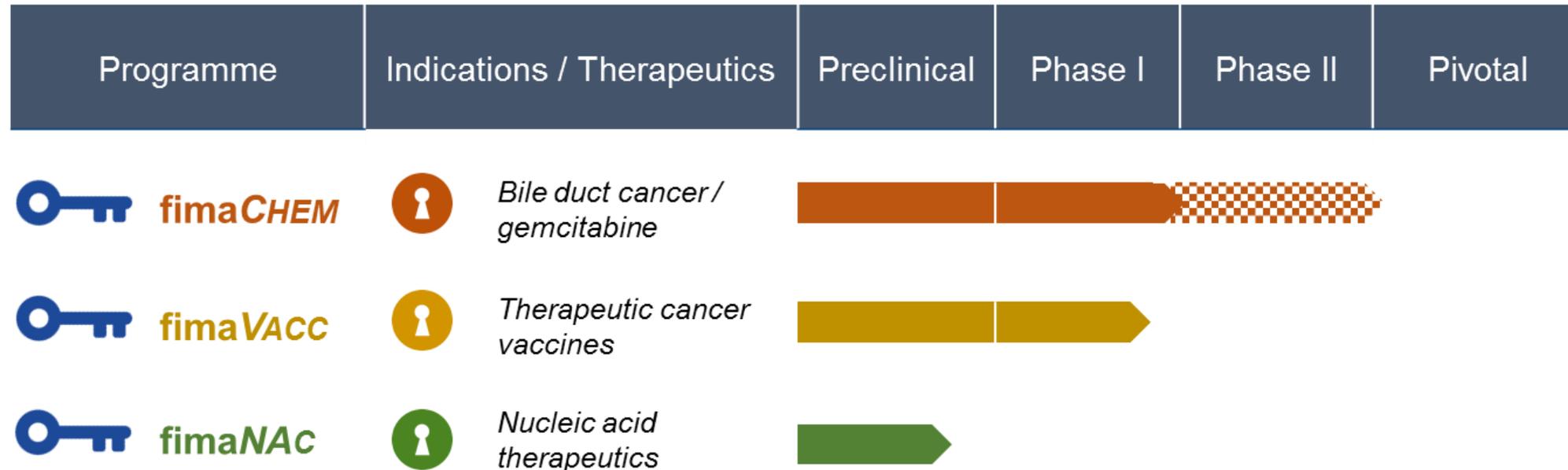
- Extension of preclinical research collaboration agreement with a top-10 large pharma company

Corporate

- Completed fully underwritten rights issue of NOK 360 million
- Further strengthened the clinical organisation and the Scientific Advisory Committee

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

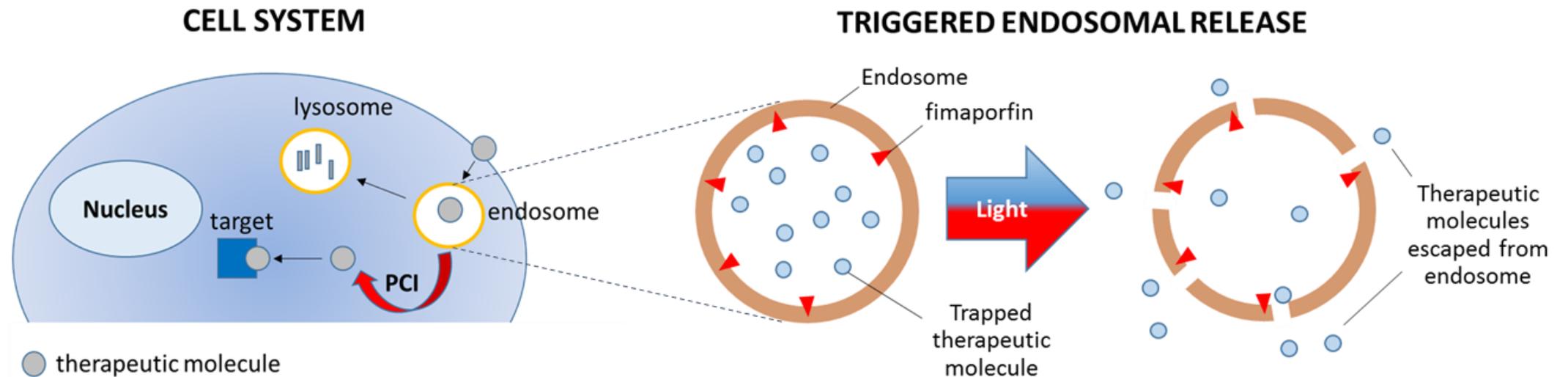


An oncology focused company with three well differentiated assets

PCI TECHNOLOGY

- ▶ Enabling drugs to reach intracellular therapeutic targets

Mode of action



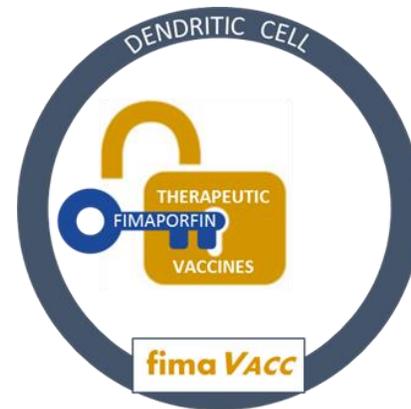
PCI TECHNOLOGY

- ▶ Enabling drugs to reach intracellular therapeutic targets

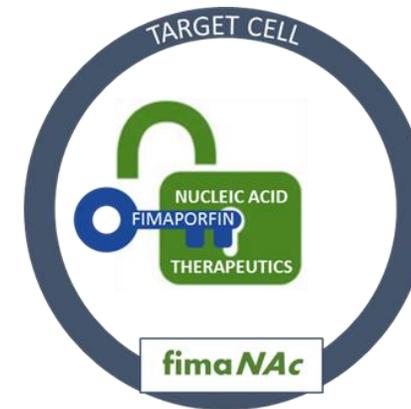
PCI – the solution to a key challenge for several modalities



Enabling approved drugs to fulfil unmet local treatment need



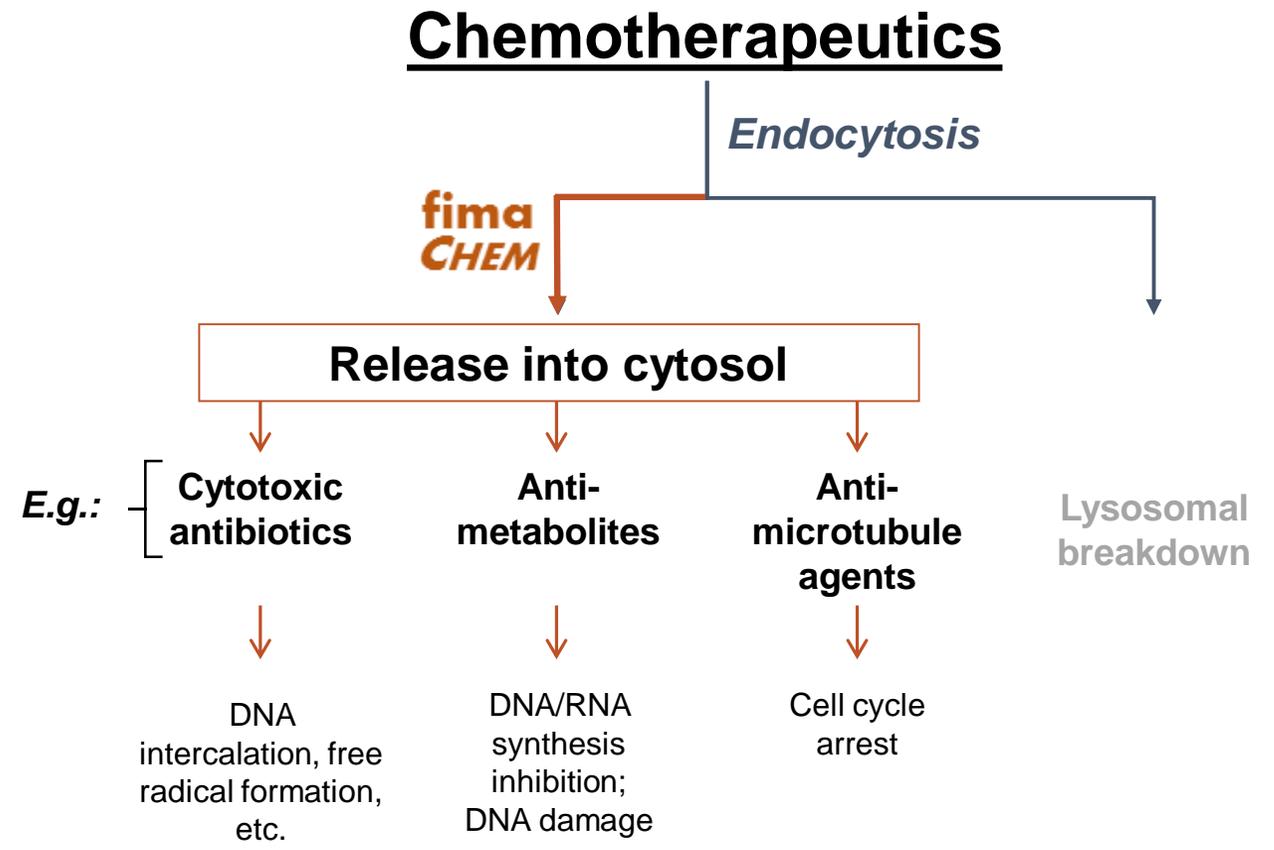
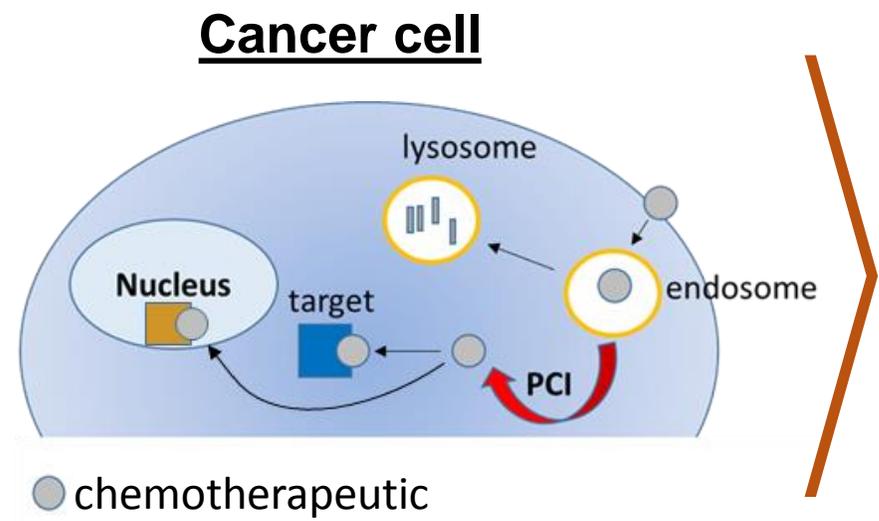
Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

PCI TECHNOLOGY

► **fimaCHEM** – mode of action



BILE DUCT CANCER – EXTRAHEPATIC INOPERABLE

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

- ▶ Orphan indication
- ▶ Incidence: 1-2/100,000 in western world – higher in Asia
- ▶ Average survival inoperable: 11-12 months
- ▶ Current management
 - Surgery
 - Only potentially curative treatment
 - Less than 1/3 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

BILE DUCT CANCER – CLINICAL PHASE I STUDY

► Cohort IV is selected dose for pivotal study – limited but encouraging data (Jan 2019)

Continued positive early signs of efficacy – mOS determined to 21.7 months at selected dose

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 – RELEASE STUDY

▶ Progress towards initiation of the pivotal study

▶ Preparations progressing towards initiation of RELEASE in first half 2019

- Preliminary confirmation of achieved safety endpoint in the extension study – final confirmation pending completion of site monitoring and formal review by the appointed Cohort Review Committee
- Ongoing regulatory, ethics and contract negotiations progressing well – all country approvals in Norway
- Strengthened the clinical organisation by appointing Karin Staudacher, M.Sc. as Clinical Project Director
- Presentation of Phase I data at the 2018 ESMO and the US CCA Foundation conference (Jan'19)

▶ Orphan designation

- Granted in both the US and EU, recognising the medical need and potential therapeutic benefits

▶ Fastest way to market determined through regulatory interactions with authorities

- Single randomised pivotal study with potential for accelerated / conditional approval based on interim analysis

BILE DUCT CANCER – RELEASE STUDY

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

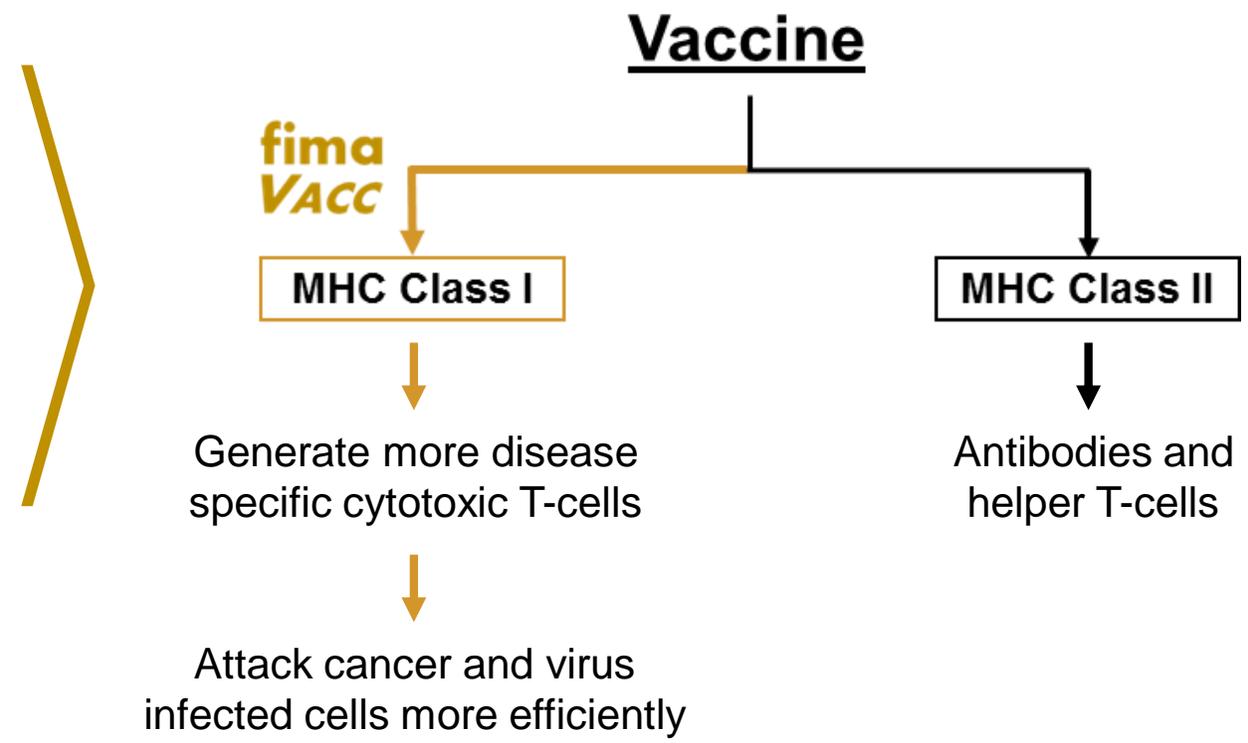
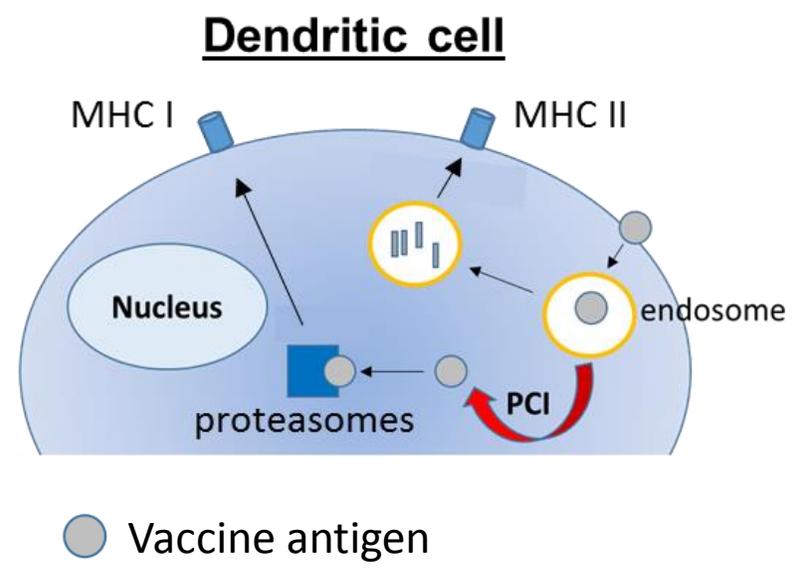
- First line treatment of patients with inoperable extrahepatic bile duct cancer
- Approx. 40 key hospitals (Europe & USA)
- Approx. 36 months to interim and 50 to final analysis
- Randomisation (1:1) of 186 patients
- Primary endpoint: PFS^a, with OS^b as key secondary
- Interim analysis primary endpoints: PFS followed by ORR^c

RELEASE trial progress reporting:

- Key milestones will be communicated in press releases
 - Start of study (first patient dosed); 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

PCI TECHNOLOGY

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



PROGRESSING CLINICAL TRANSLATION

▶ Phase I study in healthy volunteers

▶ Overall objective:

- Determine the safety, tolerability and immune response of **fima VACC**

▶ Study consists of three parts:

1. Tolerability – *completed*
2. **fima VACC** vaccination – *completed*
3. Optimisation of the **fima VACC** regimen – *tbd*

PROGRESSING CLINICAL TRANSLATION

▶ Phase I study in healthy volunteers

▶ Status:

- More than 90 subjects treated
- Data generated so far suggest enhancement of antigen specific T-cell response at tolerable doses:
 - ✓ earlier responses
 - ✓ higher response rates

PROGRESSING CLINICAL TRANSLATION

▶ Phase I study in healthy volunteers

▶ Status:

- In-depth analyses of T-cell responses by Prof. van der Burg's group
 - High bar set for induction of CD8 T-cells – notoriously difficult to induce responses in man with selected vaccine antigen
 - Data from the first two **fima VACC** cohorts analysed suggest that the vaccination regimen provides a higher number of responders (5 of 6) compared to control (2 of 6)
 - Analyses of further cohorts will be completed with the aim of confirming these preliminary positive findings prior to publication

SAC REINFORCEMENT AND PATENT GRANTED

- ▶ SAC reinforced with immunological expertise and device patent granted
- ▶ Immunological expertise in the Scientific Advisory Committee (SAC) further strengthened by the addition of Professor Sjoerd van der Burg
- ▶ Device patent granted in the US in Oct 2018

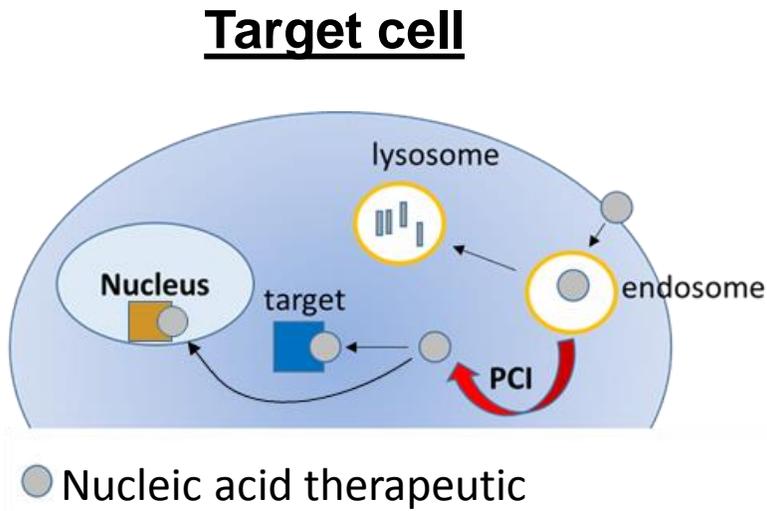


Disposable “band-aid-like” device for user-friendly illumination/injection of the vaccination site

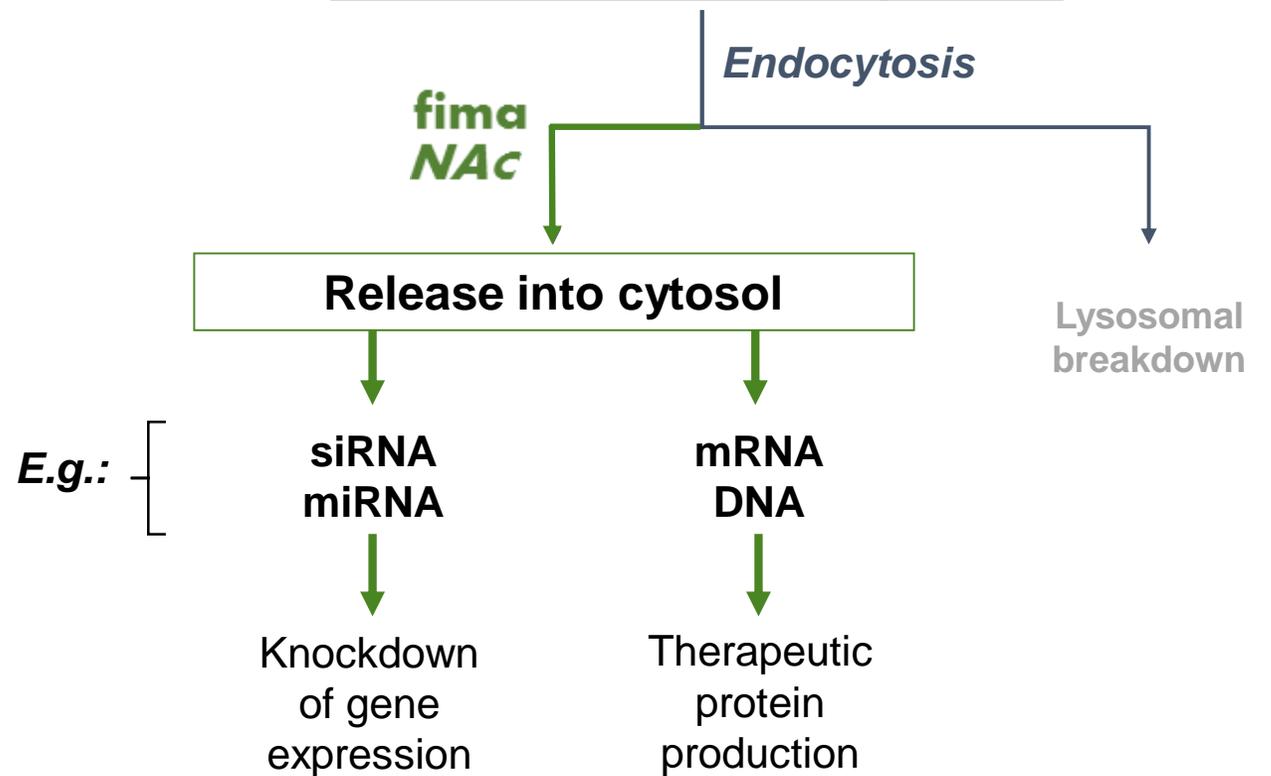
- ▶ Collaboration with Ultimovacs ended based on strategic considerations

PCI TECHNOLOGY

► **fimaNAC** – mode of action



Nucleic acid therapeutic



RESEARCH COLLABORATIONS

▶ Six collaborations established with key players in nucleic acid therapeutics

- ▶ Two new research collaborations established in 2018
- ▶ Top-10 large Pharma collaboration extended to end of 1H'19

fimaNAC

Top-10
large
pharma



* Previously named RXi Pharmaceuticals

FINANCE

▶ Fully underwritten rights issue of NOK 360 million completed in October 2018

- ▶ Important milestone for the **fimaCHEM** development programme
 - expected to fund the RELEASE study beyond interim read-out

▶ The rights issue

- supported by major shareholders and 87% subscription
- net proceeds of NOK 328 million
- part of proceeds placed in Euro to hedge the project currency risk

FINANCE

▶ Key financial figures

- ▶ Other income (public grants) in line with previous year
- ▶ Operating result impacted by R&D activity for **fimaCHEM** and **fimaVacc**

(in NOK 1,000)	Q4 2018	Q4 2017	FY 2018	FY 2017
Other income	2,972	3,067	9,585	10,250
Operating results	-14,278	-15,924	-44,519	-43,431

(in NOK 1,000)	Q4 2018	Q4 2017	FY 2018	FY 2017
Net cash flow operating activities	0*	-2,966	-30,297	-29,943

(in NOK 1,000)	31.12 2018	31.12 2017
Cash	349,326	50,789

* NOK 9 million positive effect from Euro bank deposits for Q4 2018

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 ➤ **fimaCHEM** Initiation of pivotal bile duct cancer study
- 1H 2019 ➤ **fimaVacc** Completion of Phase I immune analyses (timeline adjusted from 2H 2018)

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 a **pivotal phase ready orphan designated** (EU & US) **first-in-class** photochemical internalisation product 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

fima VACC – a clinical stage vaccination technology with **encouraging cellular immune responses**
fima NAc – 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

FOR ENQUIRIES

Per Walday, CEO

Mobile phone: +47 917 93 429

E-mail: pw@pcibiotech.com

Ronny Skuggedal, CFO

Mobile phone: +47 940 05 757

E-mail: rs@pcibiotech.com