Q2 & 1H 2018 PRESENTATION

August 30, 2018

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PCI BIOTECH

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HIGHLIGHTS

▶ First-half 2018

fima CHEM

- Encouraging data from the Phase I study at the dose level selected for the pivotal study
- Initial data suggests that two treatments are well tolerated
- Preparations for pivotal study progressing towards initiation early 2019

fima VACC

- Phase I interim data suggests enhancement of several parameters of importance for vaccination
- Focus on analysis and characterisation of the clinical immune response

fima NAC

- Extension of the top-10 pharma collaboration
- Established research collaborations with the immunotherapy focused companies IMV in Canada and Bavarian Nordic in Denmark (subsequent event)

Corporate

- Oslo Børs listing, as a transfer from Oslo Axess
- Proposed fully underwritten rights issue of NOK 360 million (subsequent event)

PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

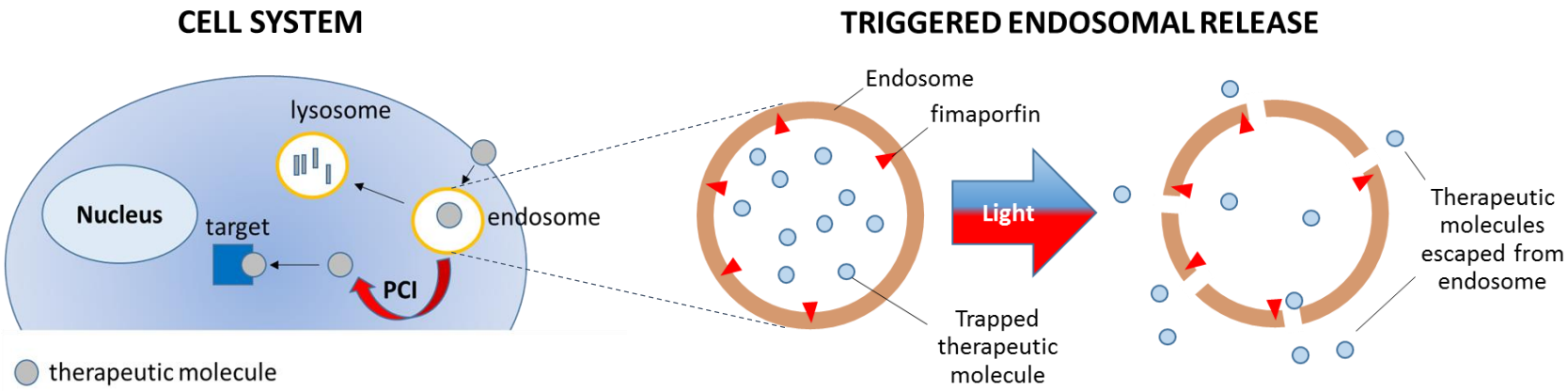
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Oslo University Hospital – the Radium Hospital

Programme	Indications / Therapeutics	Preclinical	Phase I	Phase II	Pivotal	Status
fimaCHEM	*Bile duct cancer / gemcitabine*					- Encouraging Phase I results for treatment in the orphan indication bile duct cancer - Expect to initiate pivotal study early 2019
fimaVACC	*Therapeutic cancer vaccines*					- Phase I study in healthy volunteers - Encouraging initial immune results - One research collaboration
fimaNAC	*Nucleic acid therapeutics*					- Six research collaborations

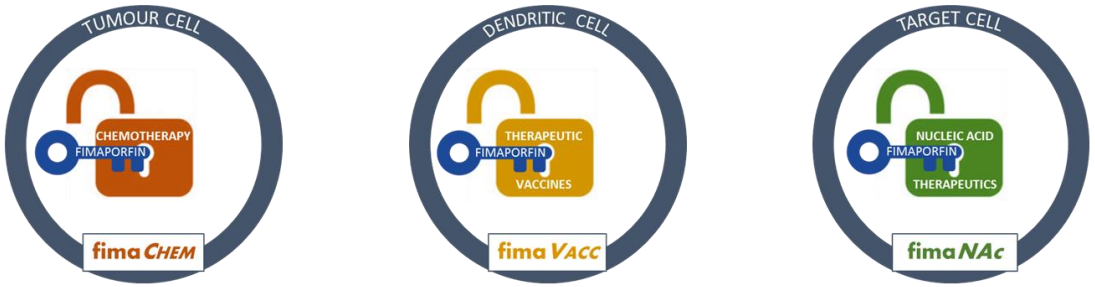
An oncology focused company with three well differentiated assets

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

THREE WELL-DEFINED DEVELOPMENT PROGRAMMES

1 fimaCHEM

PCI may enhance approximately

20%

of relevant approved chemotherapies

- First-in-man study published in Lancet Oncology[1]
- Encouraging tumour responses and survival in Phase I in inoperable extrahepatic bile duct cancer
- Pivotal phase ready, with potential for approval based on interim read
- Orphan disease with high price potential

2 fimaVACC

Total sales of cancer vaccines estimated to reach

$7.5bn

in 2022[2]

- Expected market growth largely driven by therapeutic vaccine combinations with checkpoint inhibitors
- Strong preclinical data – ongoing clinical study with encouraging initial results
- Aim is to out-license the technology on non-/semi-exclusive basis – opportunity to develop own vaccination products

3 fimaNAc

Main

HURDLE IS DELIVERY

into cells

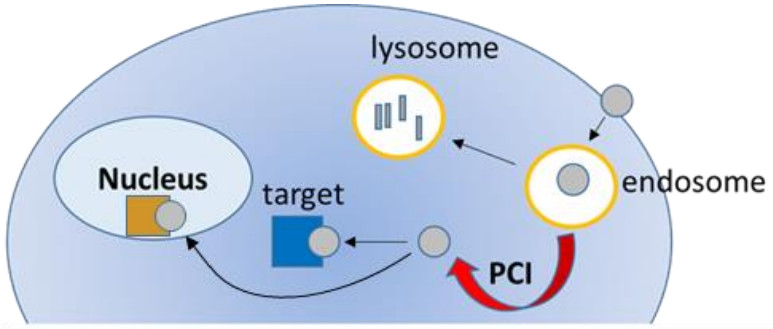
- Estimated sales of $18bn in 2030[3] (RNAi alone)
- Strong preclinical data with several RNAi's
- Collaborative approach
- Aim is to out-license the technology on non-/semi-exclusive basis

1) Lancet Oncology (2016) **17**(9): p1217–1229
2) GBI Research (2016) Global Cancer Vaccines Market to 2022
3) Research and Markets (2015) RNAi therapeutics market

PCI TECHNOLOGY

► fimaCHEM – mode of action

Cancer cell



chemotherapeutic

Chemotherapeutics

Endocytosis

fima CHEM

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

▶ Excellent fit between medical need and fimaCHEM

- ▶ Orphan indication, yearly incidence rate of 1-2 per 100,000 in the western world – higher in Asia
- ▶ Five-year survival rate of less than 5% and almost 0% when inoperable
- ▶ Average survival inoperable: ≈12 months
- ▶ 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

- Combination therapy with gemcitabine and cisplatin is recommended
- Gemcitabine is significantly enhanced by fimaCHEM
- Enhancing systemic therapy locally

Easy illumination through standard endoscopic methods

- Patients are treated with endoscopic methods (ERCP) for diagnosis and stenting
- Optic fibre and illumination easily included in the ERCP procedure

Boosting chemotherapy effect where it is most needed

- Tumours tend to block the bile duct
- Liver function is often affected
- Biliary drainage is key for patient treatment and survival

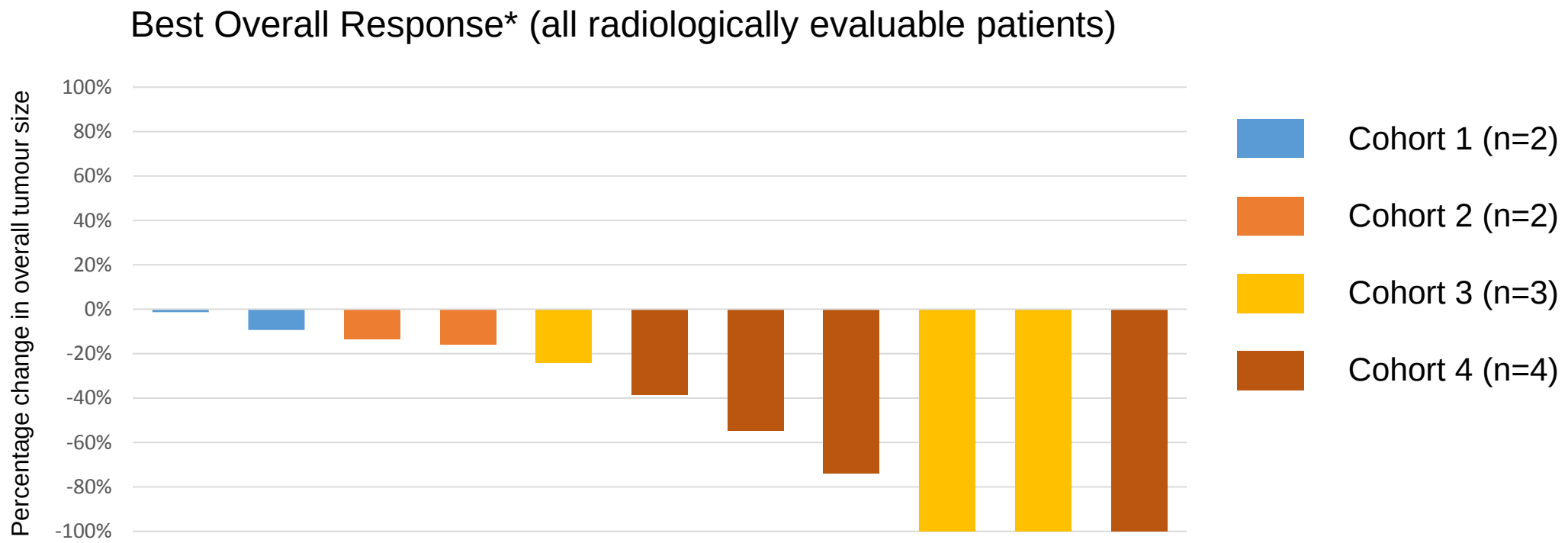
Inducing immunogenic tumour cell death

- Preclinical and clinical data supports the notion of potential abscopal effects with fimaCHEM
- May be ideal for combination with checkpoint inhibitors

BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Encouraging early signs of efficacy in Phase I

- Interim average overall survival (OS) of all 16 patients in Phase I is 18.5 months per August 2018, with 19% of the patients still being alive. Median OS ended at 14.4 months.



*Cohort 1 & 2: local read; Cohort 3 & 4: central read

BILE DUCT CANCER – CLINICAL PHASE I STUDY

- Cohort IV is selected dose for pivotal study – limited but encouraging data (Aug 2018)

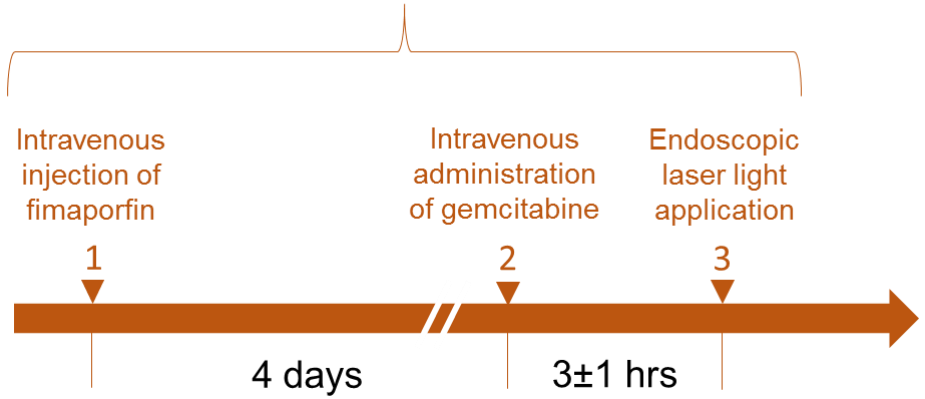
Parameters	Cohort IV (N=6) (0.25mg/kg)	Phase I – full study (N=16) (0.06-0.25mg/kg)
1) Average number gemcitabine/cisplatin cycles	**6.0** (range: 0 - 8)	**6.4** (range: 0 - 8)
2) Patients w/ radiologically measurable lesions	**5/6** (83%)	**11/16** (69%)
3) Average overall tumour size	**5.2 cm** (range: 2.1 - 7.8 cm)	**4.1 cm** (range: 1.5 - 7.8 cm)
4) Objective Response Rate (ORR)	**3/5 patients** (60%) (2 PR; 1 CR)	**4/12 patients** (33%) (2 PR; 2 CR)
5) Interim average Duration of Response (DoR)	**15.4 months** (range: 8.0 – 20.2 months)	**12.4 months** (range: 6.5 – 20.2 months)
6) Overall Survival (OS)	interim median OS: **21.2 months** interim avg OS: 19.0 months (33% alive)	median OS: **14.4 months** interim avg OS: 18,5 months (19% alive)

The table contains key background and measured endpoints for the Phase I dose-escalation study. The background parameters (1-3) were essentially similar for Cohort IV and the full Phase I study. The data is limited, but the measured endpoints (4-6) show a clear trend towards improved outcome in Cohort IV compared to the full study and is also encouraging when seen in relation to the most appropriate published comparator data (see quarterly report for more details).

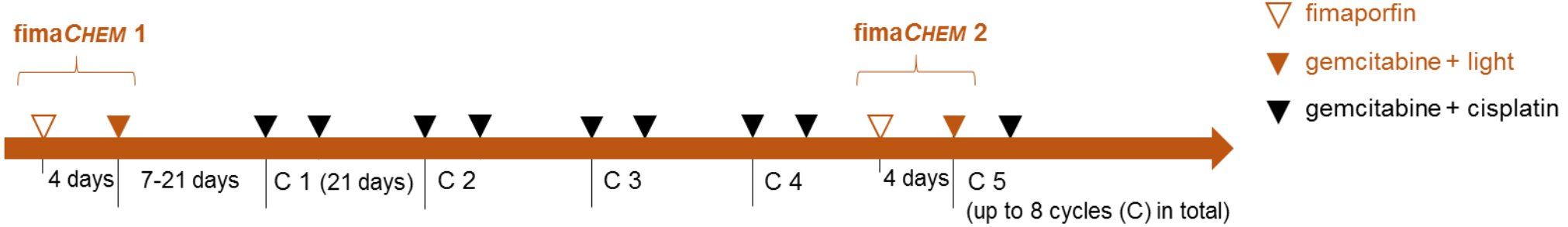
BILE DUCT CANCER – PHASE I EXTENSION STUDY

- Repeating the **fimaCHEM** treatment with the aim to further enhance efficacy

fimaCHEM
A three step treatment procedure



- Exploring safety of repeating the **fimaCHEM** treatment in an extension to Phase I, to allow for repeated treatment in the pivotal study
  - Seven patients have been included in the study
  - Four patients have so far passed the safety window, which includes approx. 3 weeks after the second **fimaCHEM**
  - Data not yet mature enough for efficacy evaluation
- The pivotal study will commence with up to two scheduled treatments, with IDMC[a] performing a safety review when eight pivotal study patients have received two treatments



[a] IDMC: Independent Data Monitoring Committee

INOPERABLE EXTRAHEPATIC BILE DUCT CANCER

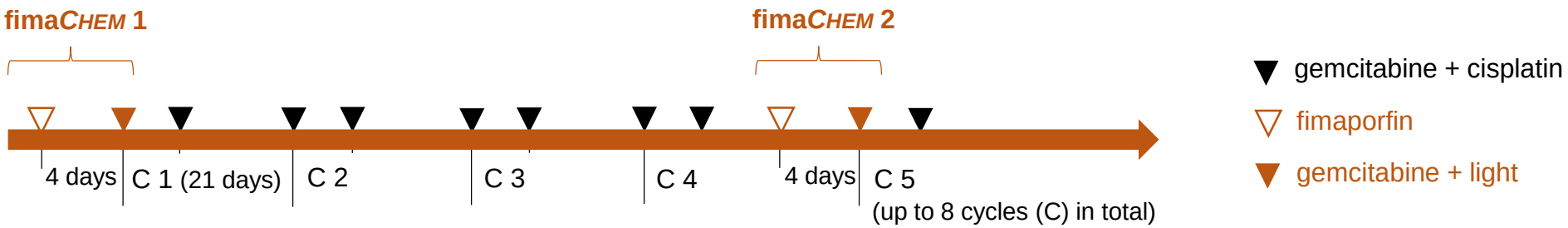
Status and strategy going forward

- **Orphan designation**
  - Granted in both the US and EU, recognising the medical need and potential therapeutic benefits
- **Phase I dose-escalation completed with good tolerability and promising early signs of efficacy**
  - Tumour shrinkage in almost all radiologically evaluable patients
  - Encouraging overall survival data at the selected dose level
- **Fastest way to market determined through regulatory interactions with authorities**
  - Single randomised pivotal study with potential for accelerated / conditional approval based on interim analysis
- **Preparations for pivotal phase progressing towards initiation early 2019**
  - Extensive feasibility study ongoing to aid in the selection of high quality sites with large catchment areas

BILE DUCT CANCER – PIVOTAL STUDY

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

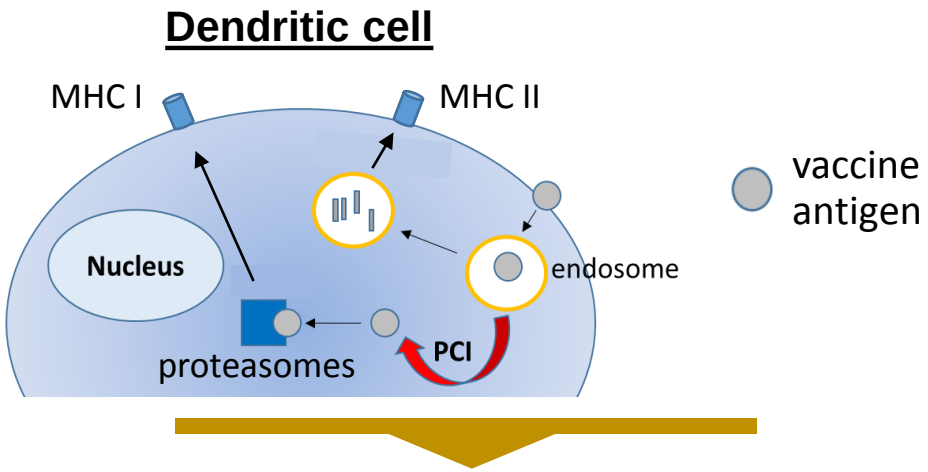
- Randomised pivotal study in newly diagnosed patients with inoperable extrahepatic bile duct cancer +/- liver metastases
- Study design based on thorough discussions with the EMA[a] and the US FDA[b]
- Will involve approx. 40 key hospital sites across Europe and USA
- Approx. 36 months to interim and 50 months to final analysis
- Randomisation (1:1) of 186 patients to treatment with either fima*CHEM* + SoC[c] *or* SoC only
- Primary endpoint: Progression Free Survival (PFS), with Overall Survival (OS) as key secondary
- Interim analysis primary endpoints: PFS followed by Objective Response Rate (ORR)
- Regular IDMC[d] review, but no formal futility stop



[a] EMA: European Medicines Agency; [b] FDA: Food and Drug Administration; [c] SoC: standard of care treatment with gemcitabine + cisplatin;
[d] IDMC: Independent Data Monitoring Committee

PCI TECHNOLOGY

fima VACC – mode of action



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

fima VACC – strong 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
  - Prophylactic & therapeutic vaccination
- Excellent stability
  - Few logistical challenges (stable at room temperature in solution and can be autoclaved)
- Important recent IP generation

PROGRESSING CLINICAL TRANSLATION

▶ Phase I study in healthy volunteers

- Overall objective:
  - Determine the safety, tolerability and immune response of **fimaVACC** in healthy subjects
- Study consists of three parts:
  1. Tolerability of intradermal fimaporfin, adjuvant and light (without vaccine)
  2. **fimaVACC** vaccination: dose finding (fimaporfin and light) and cohort expansion
  3. Optimisation of the **fimaVACC** regimen
- Status:
  - More than 90 subjects have so far been treated
  - Part 1 is completed
  - Part 2 is completed
    - Initial data suggest enhancement of antigen specific T-cell response at tolerable doses, with earlier responses and higher response rates
    - Vast number of study samples available – near-term focus on characterisation of the immune response
  - Part 3 TBD
  - Expected study completion: 2H 2018

Vaccination features: fimaVACC

Enhanced T-cell responses ✓

High T-cell response rates ✓

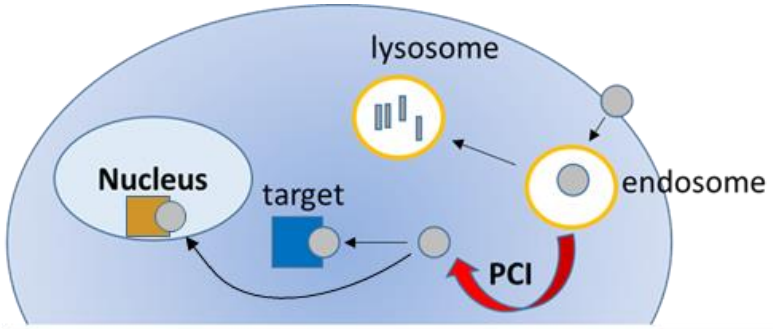
Early T-cell responses ✓

Patented disposable "band-aid-like" device for user-friendly illumination of the vaccination site

PCI TECHNOLOGY

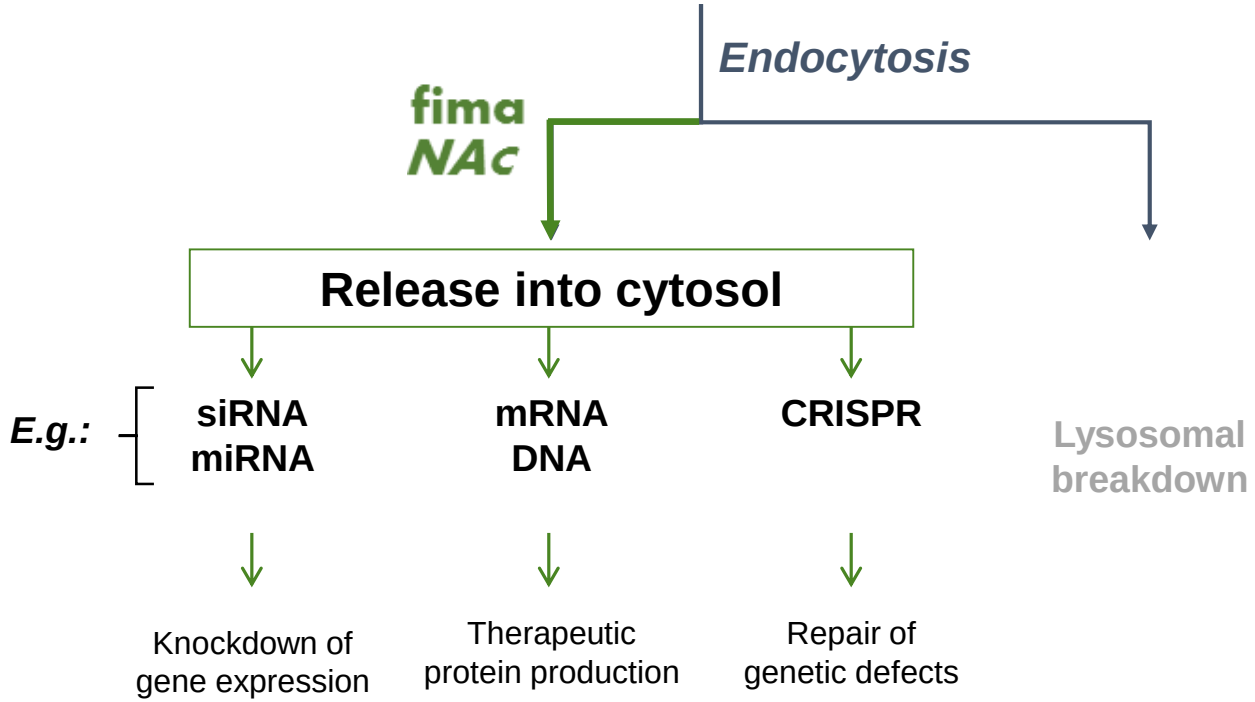
► fimaNAc – mode of action

Target cell



Nucleic acid therapeutic

Nucleic acid therapeutic



RESEARCH COLLABORATIONS

- Six active collaborations within nucleic acid therapeutics and vaccination

fimaNAc

RXi	- Collaboration initiated 2Q 2015 - Listed on Nasdaq, developing innovative therapeutic siRNA - Collaboration expanded to immuno-oncology following RXi's MirImmune acquisition
Top-10 large pharma	- Collaboration initiated 3Q 2015 - A global leader in nucleic acid therapeutics - Collaboration expanded to include *in vivo* studies and duration to end 2018
BIONTECH	- Collaboration initiated 3Q 2016 - German biotech company developing individualised cancer immunotherapies - Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer
eTheRNA	- Collaboration initiated 4Q 2016 - Belgian biotech with proprietary TriMix platform programming dendritic cells - Clinical programmes in melanoma and triple negative breast cancer
IMV IMMUNOVACCINE	- Collaboration initiated 2Q 2018 - A listed Canadian clinical stage immunotherapy biotech - Multiple clinical-stage programmes in cancer and infectious diseases
BAVARIAN NORDIC	- Collaboration initiated 3Q 2018 - A listed Danish clinical stage immunotherapy biotech - Multiple clinical-stage programmes in cancer and infectious diseases

fimaVACC

ultimovacs	- Collaboration initiated 1Q 2016 - Norwegian immunotherapy company - Therapeutic cancer vaccine against human telomerase

FINANCE

- Proposed fully underwritten rights issue of NOK 360 million

- Important milestone for the **fimaCHEM** development programme
  - fully funded until interim read-out of pivotal study
  - enables the company to reach potential marketing authorisation through accelerated approval

- The underwriting syndicate
  - supported by major shareholders
  - significant interest from external investors
  - international specialist investor

FINANCE

► Use of Proceeds

Estimated uses per programme 2019-2022 (NOK million)				
fimaCHEM	fimaVACC	fimaNAC	General corporate purposes	Total
270-290*	**22-25****	**3-5**	**15-20**	**310-340*****

fimaCHEM – expected to cover financing need to interim read of pivotal study, including marketing application filing (conditional / accelerated approval)

– additional funding requirement to final analysis is estimated to NOK 80-90 million

fimaVACC – commercial optimisation and partnering activities

fimaNAC – collaborative strategy, with focus on business development activities and alliance management

* Annual SkatteFUNN grant of NOK 9 million included

** Annual BIA grant of NOK 4 million for year 2019-2020 included

*** Estimated figures are subject to several risk factors (foreign exchange rate, patient inclusion rate, number- and location of sites etc). Transaction costs not included

TIMELINE FOR THE RIGHTS ISSUE

- Key information relating to the proposed preferential rights issue

September 2018

W	M	T	W	T	F	S	S
35						1	2
36	3	4	5	6	7	8	9
37	10	11	12	13	14	15	16
38	17	18	19	20	21	22	23
39	24	25	26	27	28	29	30

October 2018

W	M	T	W	T	F	S	S
40	1	2	3	4	5	6	7
41	8	9	10	11	12	13	14
42	15	16	17	18	19	20	21
43	22	23	24	25	26	27	28
44	29	30	31				

Key dates Subscription period

Key dates

Date	Event
14-Sep	Extraordinary General Meeting to resolve on the rights issue
14-Sep	Last day of trading including subscription rights
17-Sep	Ex-rights date – First day of trading excluding subscription rights
18-Sep	Record date
On or about 19-Sep	Publication of prospectus
On or about 19-Sep	First day subscription period
On or about 19-Sep	First day of trading in subscription rights on the Oslo Stock Exchange
On or about 1-Oct	Last day of trading in subscription rights on the Oslo Stock Exchange
On or about 3-Oct	End of subscription period
On or about 4-Oct	Allocation
On or about 8-Oct	Payment date
On or about 9-Oct	Registration of share capital increase

NB!

Important note to all shareholders: *Subscription rights that are not used to subscribe for new shares before the expiry of the subscription period, or that are not sold before the trading of the subscription rights lapses, will have no value and will lapse without compensation to the holder. Be aware that the subscription period is expected to end on 3-Oct, while the trading of the subscription rights is expected to end on 1-Oct at 16.30 CEST (two days prior to the end of the subscription period)*

FINANCE

- Key financial figures

- Oslo Børs listing – transfer from Oslo Axess in April 2018
- Public grants (Other income) in line with last year
- Operating result impacted by increased clinical activity for **fimaCHEM** and **fimaVACC**

(in NOK 1,000)	Q2 2018	Q2 2017	1H 2018	1H 2017
Other income	2,137	2,405	4,375	4,833
Operating results	-7,193	-7,205	-21,855	-17,059

(in NOK 1,000)	Q2 2018	Q2 2017	1H 2018	1H 2017
Cash flow operating activities	-10,142	-9,410	-22,633	-18,737

(in NOK 1,000)	30.06 2018	31.12 2017
Cash	28,405	50,789

KEY NEAR-TERM MILESTONES ANTICIPATED

1H 2018	✓	**Corporate**	Transfer of listing from Oslo Axess to Oslo Børs
2H 2018	✓	**Corporate**	Financing for pivotal **fimaCHEM** study
2H 2018	✓	**fimaCHEM**	Design of pivotal study finalised
2H 2018	➢	**fimaCHEM**	Safety of repeated treatment
2H 2018	➢	**fimaVACC**	Phase I in healthy volunteers completed
1H 2019	➢	**fimaCHEM**	Initiation of pivotal bile duct cancer study

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	**Promising 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 promising 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 approval potential**
Leadership	Management team, Board of Directors and advisors with **extensive pharmaceutical industry experience** across a range of medical development and commercial areas

PCI Biotech Holding ASA

- Enquiries

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