Q2 & 1H 2017 PRESENTATION

August 29, 2017

Per Walday, CEO
Ronny Skuggedal, CFO

PCI BIOTECH

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HIGHLIGHTS

► 2017

- Encouraging interim overall survival data from Phase I
- First patient treated in the Phase I extension study

- Tolerability of the vaccination technology established – awaiting initial results on overall T-cell responses

- RXi Pharmaceutical collaboration expanded into the field of immuno-oncology
- Top-10 pharma collaboration extended and entered into *in vivo* studies

- Dr Hans Olivecrona appointed Chief Medical Officer
- Completion of a fully underwritten rights issue of NOK 70 million
- Awarded up to NOK 14.3 million for further development of the vaccination platform

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PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

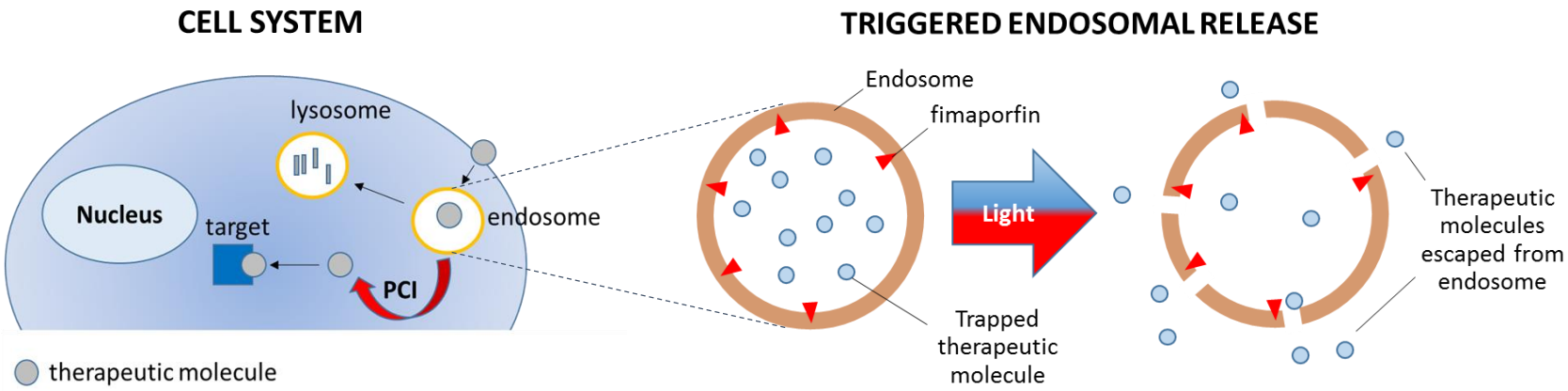
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Norwegian Radium Hospital

Programme	Indications / Therapeutics	Preclinical	Phase I	Phase II	Status
fimaCHEM	*Bile duct cancer / gemcitabine*				Phase I extension initiated to evaluate safety of repeated treatment in the orphan indication bile duct cancer
fimaVACC	*Therapeutic cancer vaccines*				Phase I study in healthy volunteers One active R&D collaboration
fimaNAC	*Nucleic acid therapeutics*				Four active R&D collaborations

An oncology focused company with three well differentiated assets

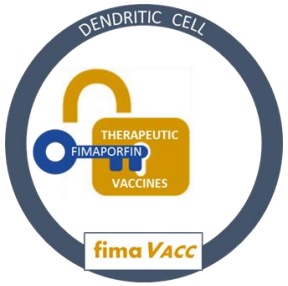
PCI TECHNOLOGY

- Enabling drugs to reach intracellular therapeutic targets

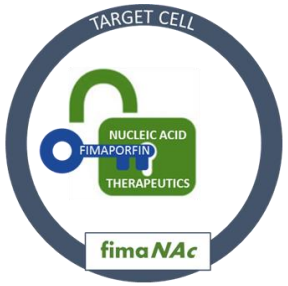


PCI – the solution to a key challenge for several modalities

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

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THE SOLUTION TO A KEY CHALLENGE

- Three well-defined development programmes

fima*CHEM*

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

- First-in-man study published in Lancet Oncology*
- Promising tumour responses in Phase I in inoperable extrahepatic bile duct cancer
- Incidence close to 15,000 (Eur.+US), with ≈3,000 assumed eligible for **fima*CHEM***
- Possible upside in distal and metastatic disease, and in Asia
- Orphan disease with high price potential

fima*VACC*

Total sales of cancer vaccines estimated to reach **$7,5bn** in 2022**

- Expected market growth largely driven by therapeutic vaccine combinations with checkpoint inhibitors
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

fima*NAc*

Main **HURDLE IS DELIVERY** into cells

- Estimated sales of $18bn in 2030*** (RNAi alone)
- Opportunistic collaborative approach
- Aim is to out-license the technology on non-/semi-exclusive basis

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

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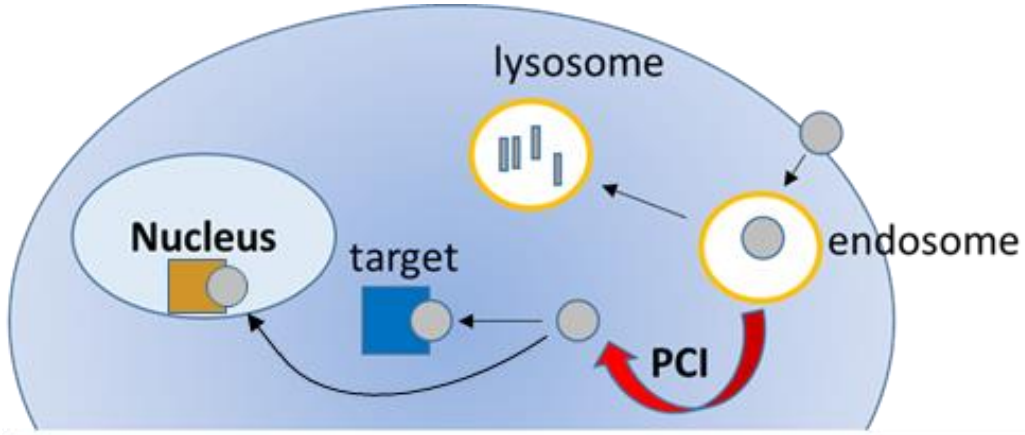
PCI TECHNOLOGY

► fimaCHEM – mode of action

Cancer cell



chemotherapeutic

Chemotherapeutics

Endocytosis

fimaCHEM

Release into cytosol

Lysosomal Breakdown

E.g.

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

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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
- Conjoining localised with systemic therapy

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

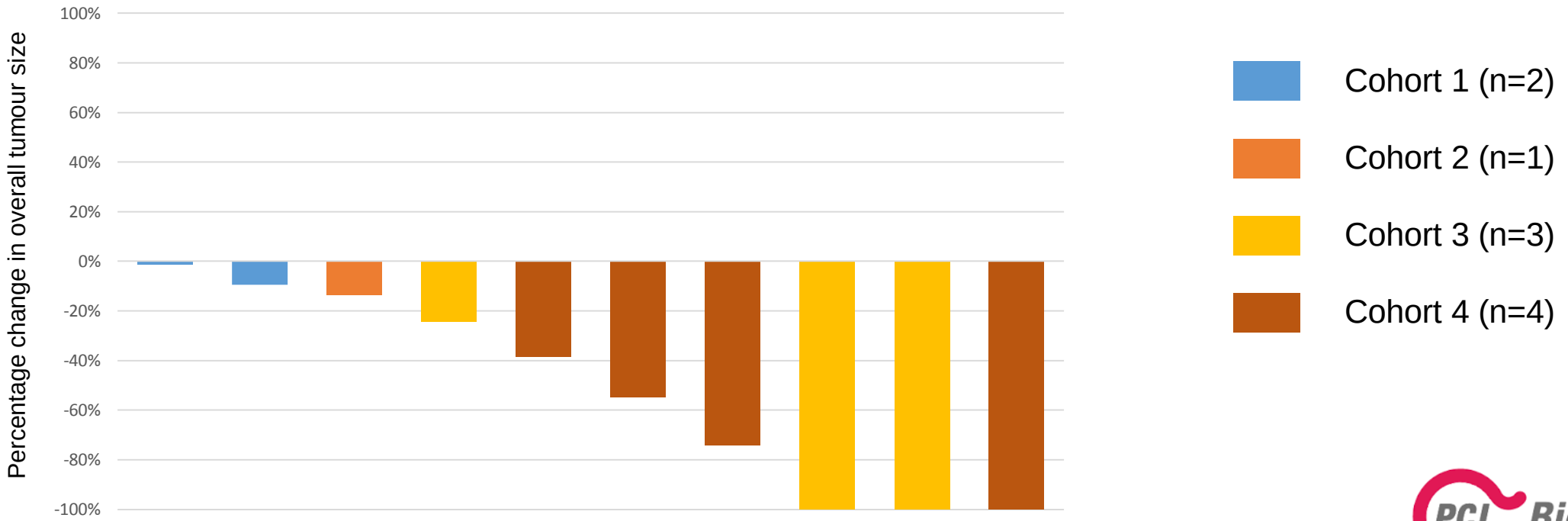
- Preclinical and clinical data supports the notion of potential abscopal effects with fimaCHEM
- May be ideal for combination with checkpoint inhibitors

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 was 15.6 months at end of July 2017, with 25% of the patients still being alive. Median OS ended at 14.4 months.

- Best Overall Response (all radiologically evaluable patients) – 90% showed tumour reduction



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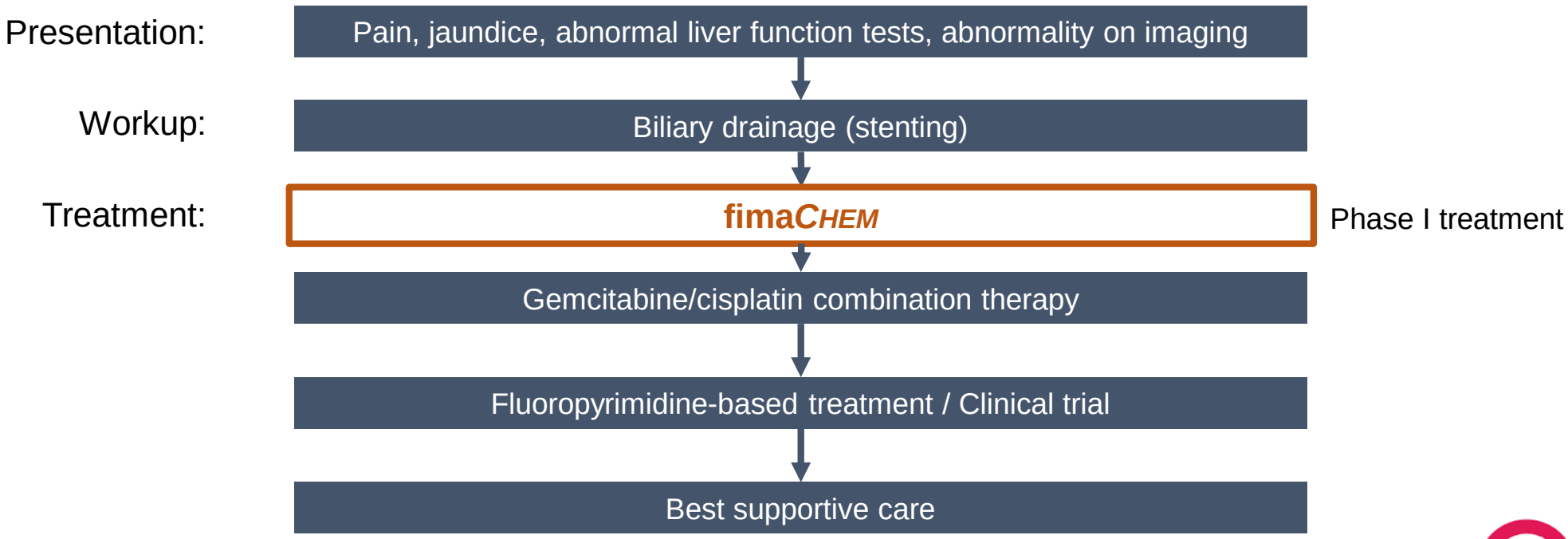
INOPERABLE EXTRAHEPATIC BILE DUCT CANCER

► An underserved patient population

- ► No approved medical treatment
- ► Combination therapy with gemcitabine and cisplatin recommended



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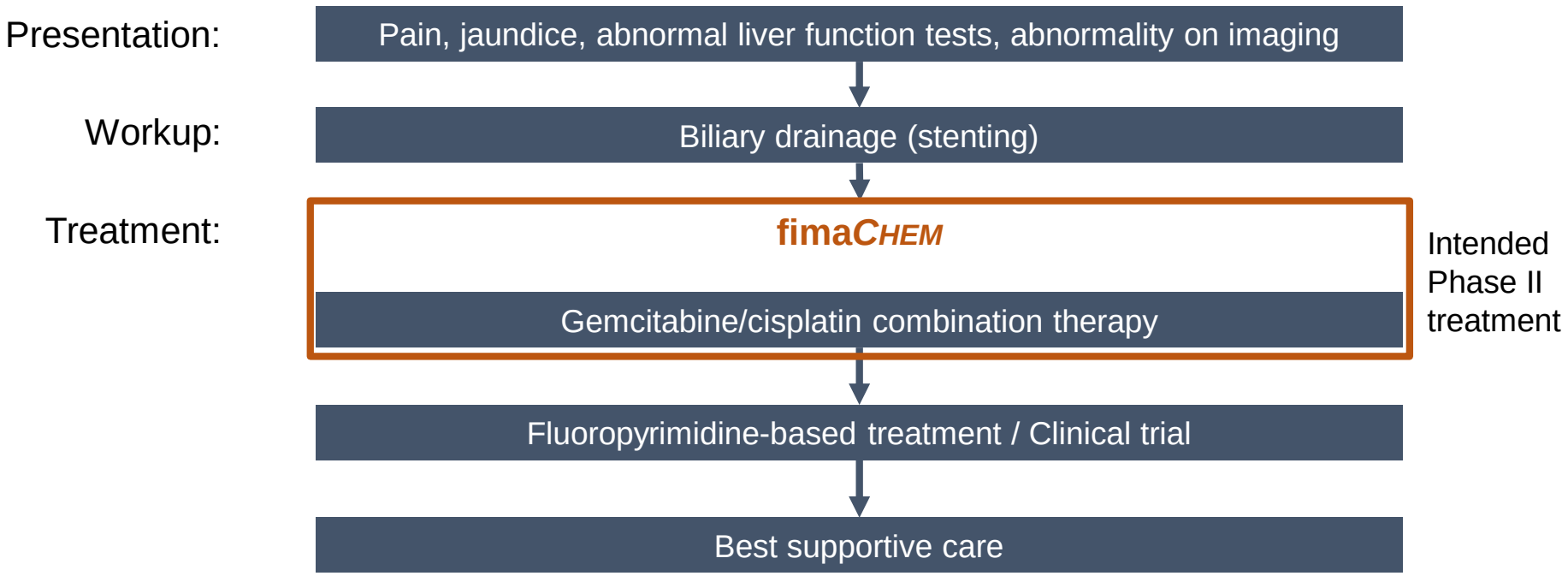
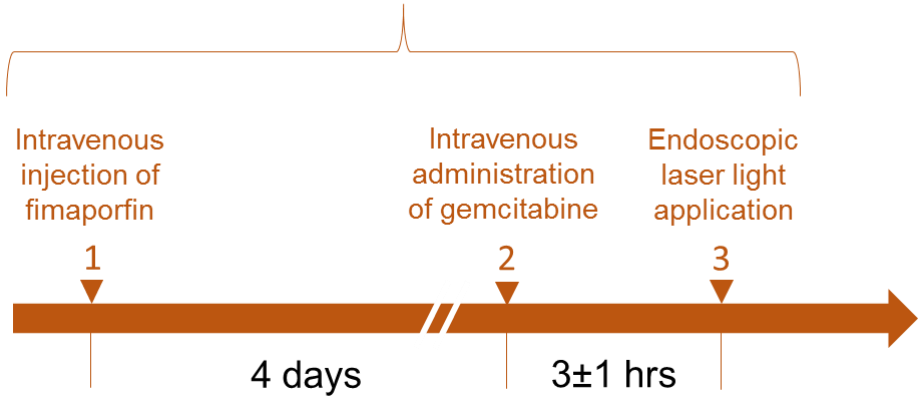


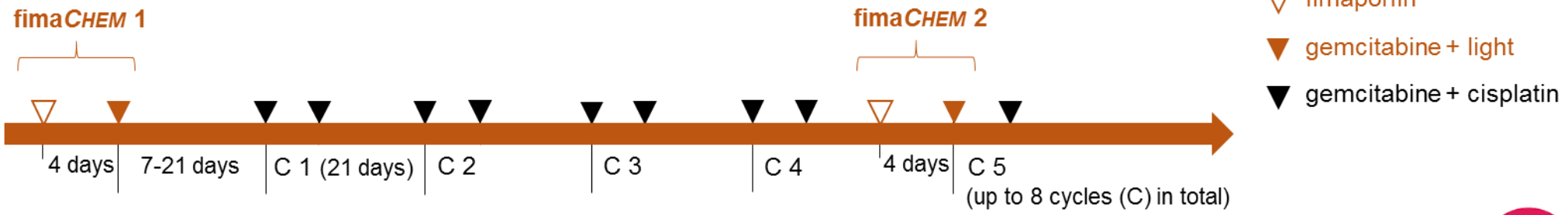
BILE DUCT CANCER – PHASE I EXTENSION STUDY

- 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
- The study is done in parallel with other preparations for the next phase
- May allow for repeated treatment in a potential pivotal Phase II study



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INOPERABLE EXTREHEPATIC BILE DUCT CANCER

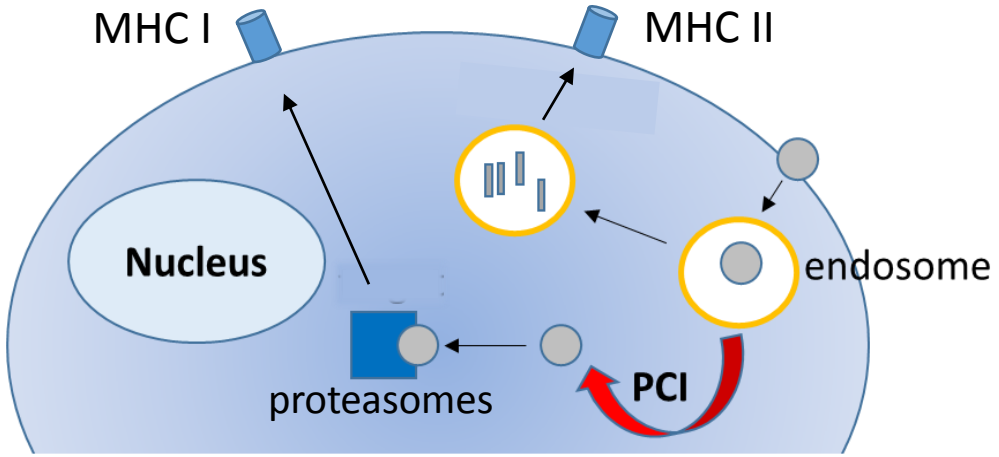
Status and strategy going forward

- **Phase I completed with good tolerability and promising early signs of efficacy**
  - Tumour shrinkage in almost all radiologically evaluable patients
  - Interim average overall survival (OS) of 15.6 months with 25% of patients still alive; median OS ended at 14.4 months
- **Exploring safety of repeated treatment as a Phase I extension**
  - First patient included in August 2017
- **Regulatory interactions with authorities to determine fastest way to market**
  - The interactions are continuing into 2H 2017
- **Orphan designation**
  - Granted in EU
  - US application submitted – interaction with the FDA to ensure a quickest possible process
- **Engaging US key opinion leaders (KOL's)**
  - Involving US KOL's in the study design discussion for Phase II

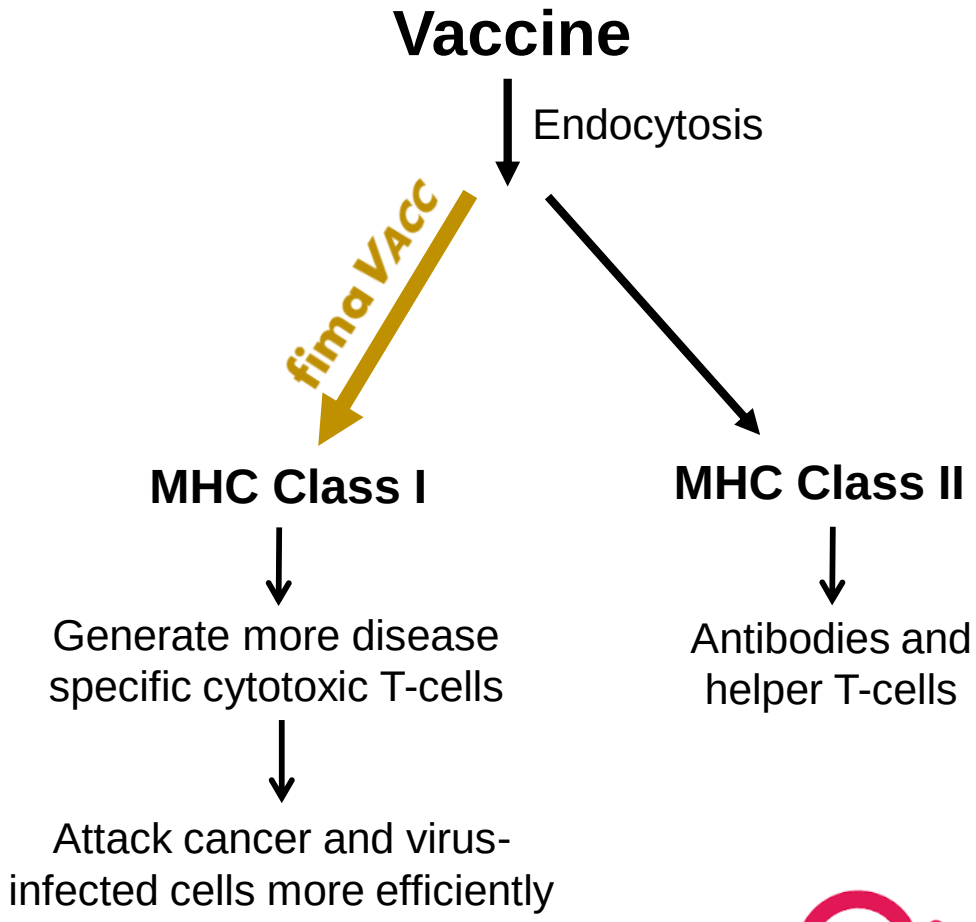
PCI TECHNOLOGY

▶ fima VACC – mode of action

Dendritic cell



vaccine antigen



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PROGRESSING CLINICAL TRANSLATION

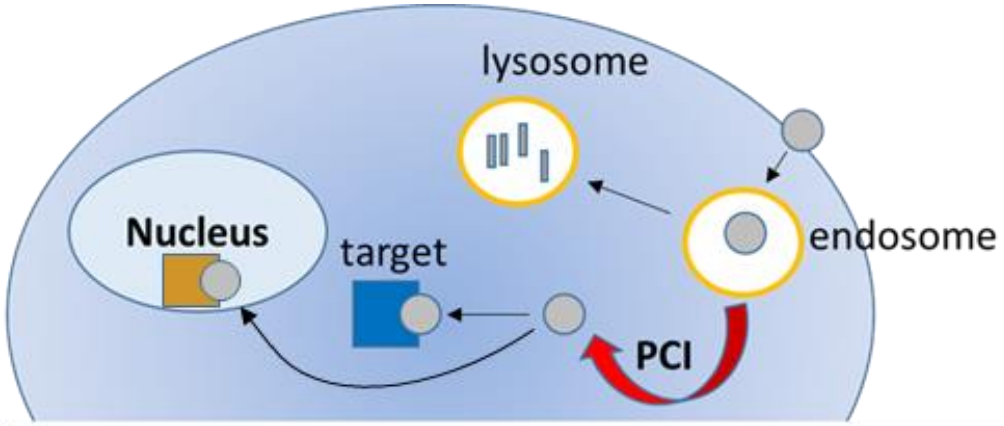
▶ Phase I study in healthy volunteers

- 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 50 subjects have so far been included and treated
  - Part 1 is completed
  - Part 2 is ongoing
    - Maximum tolerated dose not yet identified → total number of subjects may increase with up to 30
    - Delay in establishing immune response assay → initial results will now include a larger proportion of subjects
- Timelines:
  - Q3 2016: First subject dosed
  - 2H 2017: Read-out of initial results on overall T-cell responses – from >50% of subjects in part 2

PCI TECHNOLOGY

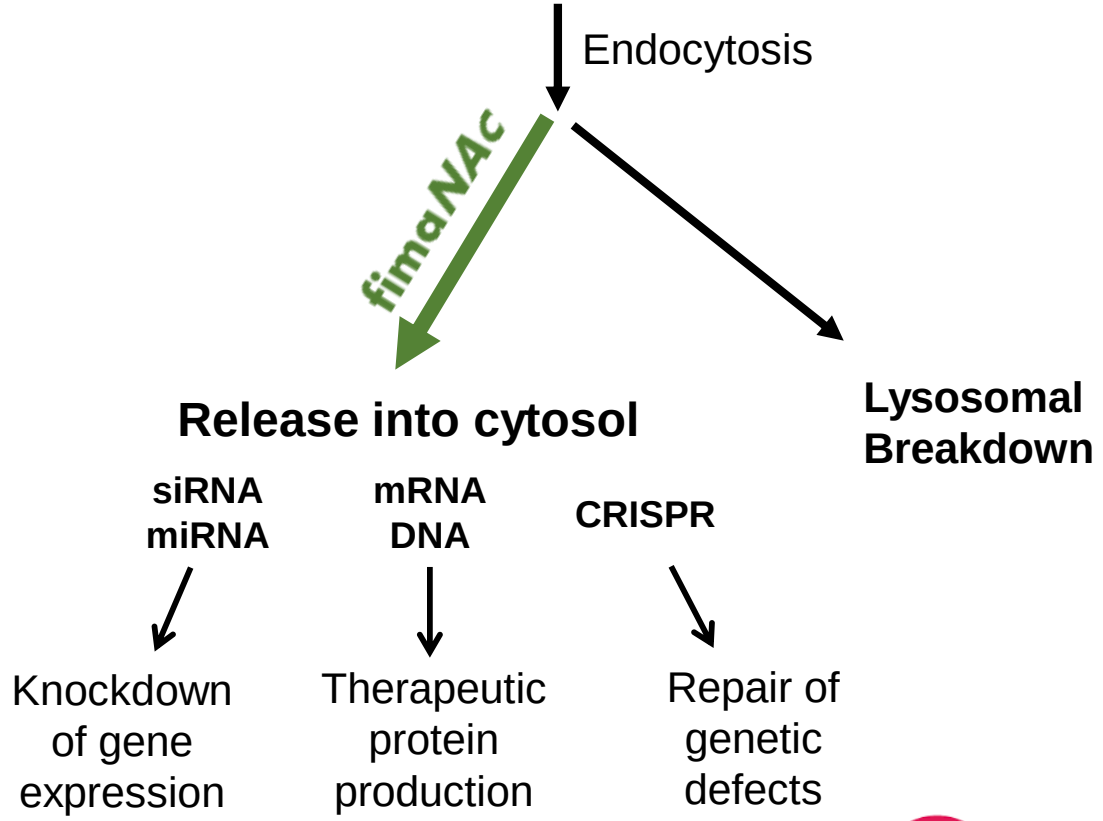
▶ fimaNAc – mode of action

Target cell



nucleic acid therapeutic

Nucleic Acid Therapeutics



RESEARCH COLLABORATIONS

► Five active collaborations within nucleic acid therapeutics and vaccination

fimaNAc

RXi Pharmaceuticals

- Initiated Q2 2015. Listed on Nasdaq, developing innovative therapeutic siRNA
- ➢ ***Q2'17: Collaboration expanded to immuno-oncology following RXi's MirImmune acquisition***

Top-10 large pharma

- Initiated Q3 2015. A global leader in nucleic acid therapeutics
- ➢ ***Q2'17: Collaboration extended to end of 2017 and expanded to in vivo studies***

BioNTech

- Initiated Q3 2016. German biotech company developing individualised cancer immunotherapies
- Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer

eTheRNA

- Initiated Q4 2016. A global leader in mRNA-based immunotherapies
- Evaluate synergistic effects between companies' technologies

fimaVACC

Ultimovacs

- Initiated Q1 2016. Norwegian immunotherapy company
- Therapeutic cancer vaccine against human telomerase

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

FINANCE

- Key financial figures and top 10 shareholders

(In NOK 1,000)	2017 1H	2017 Q2	2016 1H	2016 Q2	2016 FY
Other income	4 833	2 405	4 917	2 332	10 475
Operating costs	21 892	9 611	21 506	11 613	43 502
Operating results	-17 059	-7 205	-16 589	-9 281	-33 027
Financial items	403	181	283	111	843
Comprehensive income	**-16 657**	**-7 024**	**-16 306**	**-9 170**	**-32 184**
Cash & cash equivalents	**60 700**	**60 700**	**31 028**	**31 028**	**14 002**
Net cash flow from operating activities	**-18 334**	**-9 229**	**-18 221**	**-8 607**	**-35 247**

- Close to NOK 10 million in non-dilutive funding for 2017
- Cash burn 1H 2017 in line with last year
- Cash position to reach strategic milestones

Top 10 shareholders per 18 Aug 2017

Name	Number	%
FONDSAVANSE AS	2 540 840	10,20
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 597 274	6,41
MP PENSJON PK	1 447 504	5,81
NORDNET LIVSFORSIKRING	737 618	2,96
GRESSLIEN ODD ROAR	556 000	2,23
MYRLID AS	555 900	2,23
BERG-LARSEN ALEXANDER	509 435	2,05
NORDNET BANK AB	445 312	1,79
SYVERTSEN SVEIN ERIK	437 107	1,76
AASEN KJETIL MYRLID	400 000	1,61
Total 10 largest shareholders	9 226 990	37,05
Total other shareholders	15 673 400	62,95
Total number of shares	24 900 390	100,00

GOOD PROGRESS IN ALL AREAS

► 2017

✓	**fima*CHEM***	Initiated patient enrolment in the extension of Phase I
✓	**fima*VACC***	Tolerability of the vaccination technology established
✓	**fima*NAC***	Preclinical research collaborations entering new stages
✓	**Finance**	Secured financing to reach strategic milestones
✓	**Corporate**	Strengthened the organisation with Dr Olivecrona as CMO

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KEY MILESTONES ANTICIPATED

- Through 1H 2018

2H 2017	➢	**fima*CHEM***	Regulatory clarity on fastest way to market
2H 2017	➢	**fima*VACC***	Initial results on overall T-cell responses in Phase I
1H 2018	➢	**fima*CHEM***	Safety read-out of Phase I extension
1H 2018	➢	**fima*CHEM***	Initiation of Phase II
1H 2018	➢	**fima*VACC***	Phase I in healthy volunteers completed

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▶ Summary and outlook

- **fima*CHEM*** – Progressing development in bile duct cancer
  - Encouraging tumour response and survival data
  - Initiated enrolment into Phase I extension
  - Ongoing regulatory interactions to determine fastest way to market
  - Engaging US KOL's to build awareness and discuss clinical design, preparing for Phase II
- **fima*VACC*** – Clinical validation of the vaccination technology
  - Tolerability established – awaiting initial results on overall T-cell reponses
- **fima*NAC*** – Progressing the research collaborations
  - Focusing the RXi collaboration on immuno-oncology
  - Top-10 pharma collaboration extended and entered into *in vivo* studies
- Cash position to reach strategic milestones

PCI BIOTECH HOLDING ASA

- Enquiries

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