

## PCI Biotech -Q3 2022 Interim Report

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# **PCI** Biotech

Q&A session through teleconference and webcast console

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When prompted, provide the confirmation code or event title. <u>Confirmation Code:</u> 436187 <u>Event title:</u> PCI Biotech Holding Quarterly Report - Q3 This information is also available in the Q3 Report press release.

It is also possible to post questions through the webcast console.



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Q3 2022

### Corporate

- Reported in August that we will not conduct a company-sponsored Ph II trial with the fime VACC technology
  - Efforts to finance a Ph II clinical trial in head and neck cancer did not, under the current market conditions, result in a feasible way forward

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- The decision entailed downsizing of the clinical team, enacted second half of 2022
  - Full cost reduction effect in Q1 2023
- Cash position of NOK 67 million per end of Q3
  - Enables an estimated financial runway into 2024
- Exploring new fields of use for the PCI technology
  - **fima***NAc* for dermatology and bioprocessing applications
  - fima VACC for intratumoural immunotherapy

Q3 2022

fima*NAC* 

Dermatology Bioprocessing

- ► First step for the dermatology discovery project
  - Demonstrate **fime** NAc-mediated nucleic acid delivery in a wound model
  - External feasibility experiments contracted, expected readout 1H 2023
- ► The bioprocessing discovery project has matured
  - Focus on in-house experiments of **fime NAc** for use in viral manufacturing

Q3 2022

**fima** *VACC* Intratumoural immunotherapy

- Exploring approaches aiming to identify novel immunotherapy treatment combinations
  - Ph.D. candidate grant of up to NOK 2.5 million over 3 years from the Research Council of Norway



Q3 2022

### Collaborations

- In August 2022, a preclinical collaboration was initiated with Mymetics, aiming to explore technological synergies for possible enhancement of cancer therapy
  - The collaborations with Mendus has been reviewed for progress and value. Priorities are set by both parties and the collaboration was closed in November



Q3 2022

### fima CHEM

- All major study closure activities are expected to be completed by the end of the year
  - Study results published in the EU clinical trial database
  - Collected data insufficient to draw conclusions regarding efficacy
  - Remaining cash effect for closure process estimated up to NOK -3 million



## **Operational review**





# Develop a platform technology for PCI-based delivery of nucleic acids to the body surface



- Fimaporfin can be delivered to intact skin in doses sufficient for use in nucleic acid delivery
- Next experiments will be performed by investigating delivery of a model mRNA in an *ex vivo* human skin wound model



## fima*NAC*

Operational review – Dermatology

### Platform technology for delivery of nucleic acids to skin

- **fimaNAc** Excellent technological fit with dermatological diseases
- Chronic skin ulcers (e.g. diabetic ulcers) have large unmet medical need
- Complex biology where fimaNAc can exploit the potential of nucleic acid therapies to affect tissue developmental (regenerative) programs
- Inefficient delivery has severely limited the use of nucleic acid therapies
- Large body surface areas are particularly challenging







Operational review – Bioprocessing



**Bioprocessing** - Manufacturing capacity is a limiting factor to treating more patients

Markets:

Cell culture



Cell and gene therapy



Viral manufacturing









### Maximising yield for viral manufacturing

Operational review – Bioprocessing







• Cells in culture

• Range in quantity

#### Gene edit and expand

- Nucleic acids
- Enzymes
- Growth factors

#### Harvest

- Quantity of material
- Purity of material
- Quality of material



## fima NAC

review –

#### Operational • Pursue applications based on market need and technological fit • Apply **fimaNAc** to viral manufacturing proof-of-concept (alpha prototype) • Perform in-house Bioprocessing Feasibility • Partnerships are sought to improve early (alpha) prototype products or solutions • Targets: • Pharma and Biotech Early prototypes • Contract development and manufacturing organisations (CDMOs, CMOs) (alpha) • Late-stage (beta) prototypes are tested in partnerships to validate that products and solutions are commercially viable • Targets: • Pharma and Biotech Late-stage • Contract development and manufacturing organisations (CDMOs, CMOs) prototypes (beta)

#### **PROTOTYPES WILL BE DEVELOPED FOLLOWING A PARTNERSHIP-DRIVEN STRATEGY**





## fima VACC

Operational review – Intratumoural immunotherapy

### "Treat locally – act globally"



Marabelle et al. (2017) Ann. Oncol.;28:xii33

# Leveraging intratumoural immunotherapy to achieve a systemic anti-tumour immune response

- Despite representing a major breakthrough in cancer treatment, a large proportion of patients do not respond properly to immune checkpoint inhibitors (ICIs)
- Exploiting combinations of ICI and other systemic therapies is often difficult due to systemic side effects
- Local treatment of one tumour lesion can induce specific immune response against other tumour lesions in the body
- Systemic adverse effects are limited, enabling combination treatments not feasible with systemic treatment
- PCI has shown promising effects with several different intratumoural approaches, including principles which are in clinical use
- But; competitive and complex area
- Will mainly be pursued via a PhD grant from the Research Council of Norway
- 3-year project starting end of 2022 collaboration with the Radium Hospital
- Focus on understanding mechanisms, use this to optimally exploit effect of PCI in this area



## **Research collaborations**



- Offer valuable scientific knowhow, encouraging results and intellectual property
- Collaborations span different classes of drugs and applications
- PCI Biotech continues to pursue new and value-adding collaborative opportunities



## RESEARCH COLLABORATION WITH INSTITUTE OF MARINE RESEARCH

### PHOTOLICE - PHOTOCHEMICAL TREATMENT OF SEA LICE

#### Project introduction

- 2-year project fully funded by public grant, ending June 2023
- Work performed by Institute of Marine Research (Havforskningsinstituttet)
- Evaluate if photochemical treatments can be used to combat sea lice in fish farming
- ► <u>Rationale</u>
- Sea lice are flat, transparent and accessible for illumination
- Photochemical reaction in a sea louse may destroy vital functions without harming the salmon

► <u>Status</u>

- Several photosensitizing compounds tested some of them can kill freeswimming sea lice upon illumination
- Refinement of the principle is on-going



HAVFORSKNINGSINSTITUTTET







# Key financials Outlook Q&A



### **Finance**

Key financial figures

#### ► Financial run-way estimated into 2024

- RELEASE closure, estimated remaining cash effect up to NOK -3 million
- Organisational changes will further reduce costs, full effect in Q1 2023
- Explore financing and strategic opportunities as non-clinical pipeline matures

(figures in NOK 1,000)	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Other income (public grants)	1 188	1 187	3 563	5 085	6 273
Operating results	-10 945	-22 503	-49 387	-62 757	-86 029
Net financial result	250	1 080	988	-586	-2 362
Net profit/loss	-10 695	-21 423	-48 398	-63 343	-88 391
(figures in NOK 1,000)	Q3 2022	Q3 2021	YTD 2022	YTD 2021	FY 2021
Cash & cash equivalents	67 224	135 513	67 224	135 513	116 118
Cash flow from operating activities	-8 838	-13 141	-48 602	-50 984	-68 307



### Outlook

# Leveraging the PCI technology platform within immunotherapy, dermatology, and bioprocessing

Therapeutics Preclinical Phase 2 Programme Phase 1 fima NAc Dermatology Intratumoural fima VACC immunotherapy Collaborations Undisclosed Programme Application Feasibility Prototype Commercial fima NAc Bioprocessing

Enabling intracellular delivery





## **PCI** Biotech

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