



Enabling  
intracellular  
delivery

# PCI Biotech - Q4 2022 Interim Report

Presentation February 17, 2023

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# PCI Biotech

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## Q&A session through teleconference and webcast console

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When prompted, provide the confirmation code or event title.

**Confirmation Code:** 436187

**Event title:** PCI Biotech Q4 2022

This information is also available in the Q4 Report press release.

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

# PCI Biotech

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# Highlights

Q4 2022

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## fimaNAC

Dermatology

Bioprocessing

- ▶ **Demonstrate fimaNAC-mediated nucleic acid delivery for dermatology**
  - First step for the discovery project planned in a wound model
    - External feasibility study on track, expected readout 1H 2023
    - Positive results may trigger collaborative development
  
- ▶ **The bioprocessing discovery project has matured**
  - First patent application filed on use of fimaNAC in viral vector manufacturing
  - Positive initial external feedback, warranting further in-house studies to strengthen
    - fimaNAC's value proposition and intellectual property

# Highlights

Q4 2022

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## **fima VACC** Intratumoural immunotherapy

- ▶ **Exploring approaches aiming to identify novel immunotherapy combinations**
  - A patent application for an undisclosed treatment approach planned to be filed Q1 2023
  - Ph.D. candidate grant of up to NOK 2.5 million over 3 years, commencing Q1 2023

# Highlights

Q4 2022

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## Corporate

- ▶ **Estimated financial runway extended towards end of 2024, with current plans**
  - Estimated remaining cash effect for the RELEASE trial closure is less than NOK -1 million
  - Downsizing, reported Q3, was enacted during 2H-22 with full cost reduction effect in Q1 2023
  - Cash position of NOK 57 million per year-end

# Operational review

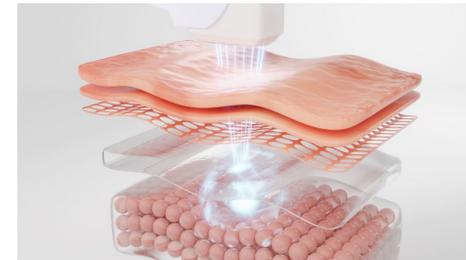
Operational  
review –  
Dermatology

### Background

- ▶ Many skin conditions with large unmet medical needs can potentially be treated with nucleic acid based therapies
  - E.g. chronic ulcers, inflammatory diseases, inherited diseases
- ▶ Many approaches are in early development (clinical and preclinical)
- ▶ Inefficient delivery has severely limited the use of nucleic acid therapies
  - Large body surface areas are particularly challenging

### fimaNAc solution

- ▶ Topical formulation (cream/gel) containing photosensitiser and nucleic acid therapeutic molecule(s)
- ▶ Easy to use light sources for illumination of larger skin areas

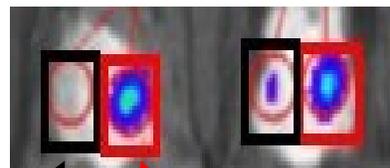


## Demonstrating topical delivery of mRNA in wound model - Performed by a leading CRO

Operational  
review –  
Dermatology

- ▶ Study builds on previous results where **fimaNAc** demonstrated 30x enhanced mRNA delivery by intradermal injection
- ▶ Novel, topical approach: mRNA and fimaporfin applied to wound, followed by illumination
- ▶ First phase has been initiated to test delivery of a model mRNA in *ex vivo* human wound model with a basic formulation

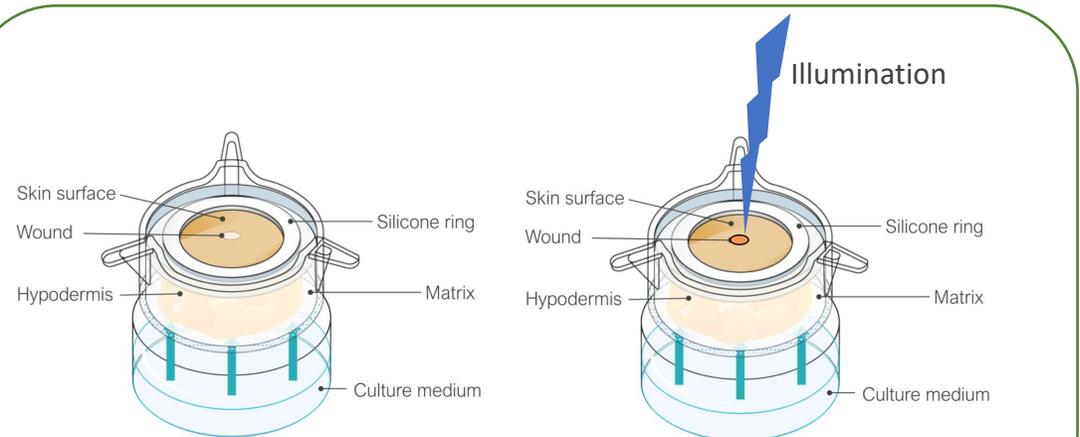
### Intradermal mRNA delivery



Control PCI

**fimaNAc** enhanced  
delivery up to 30x

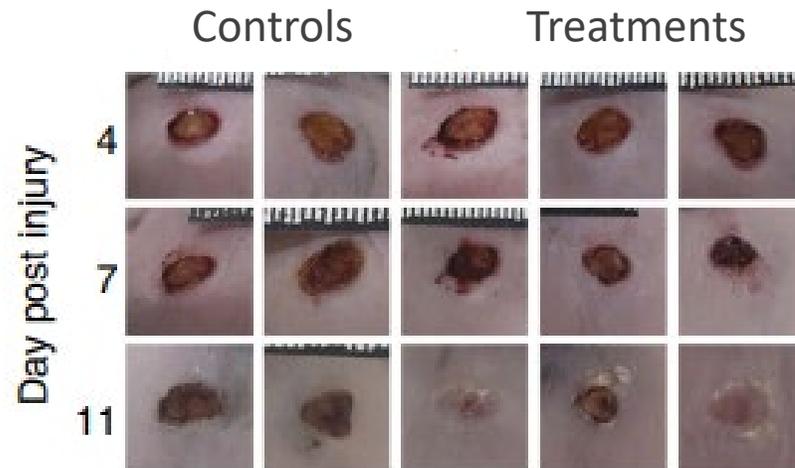
### Topical mRNA delivery



Live human skin with induced wound

## Dermatology – further plans

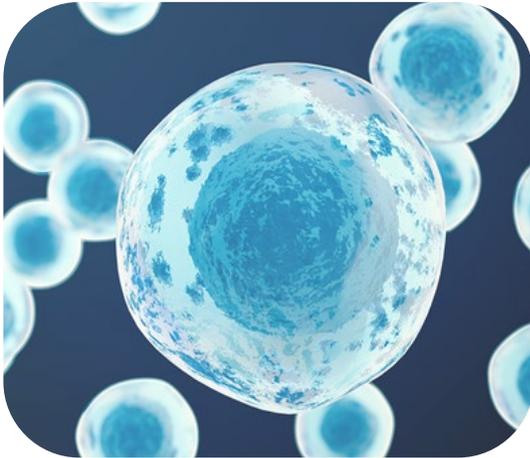
- ▶ Use data from first phase for early-stage partnering
  - Show effect in wound healing model, i.e. that **fimaNAc** treatment accelerates healing of wounds with partner's nucleic acid molecule
  - Alternatively - continue preclinical platform development with model therapeutic RNA



Example animal wound healing model  
Monitoring kinetics of wound closure

## Maximising yield in gene therapy manufacturing

Operational  
review –  
Bioprocessing



### Cells in culture

- Cell lines
- Range in quantity



### Gene edit and expand

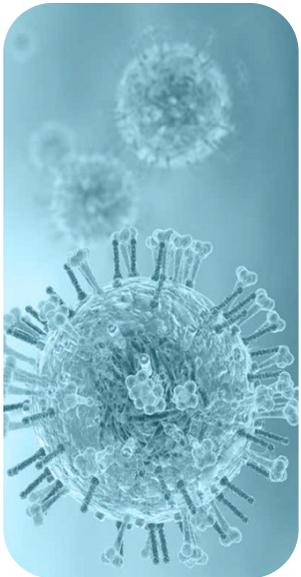
- Nucleic acids
- Enzymes
- Growth factors



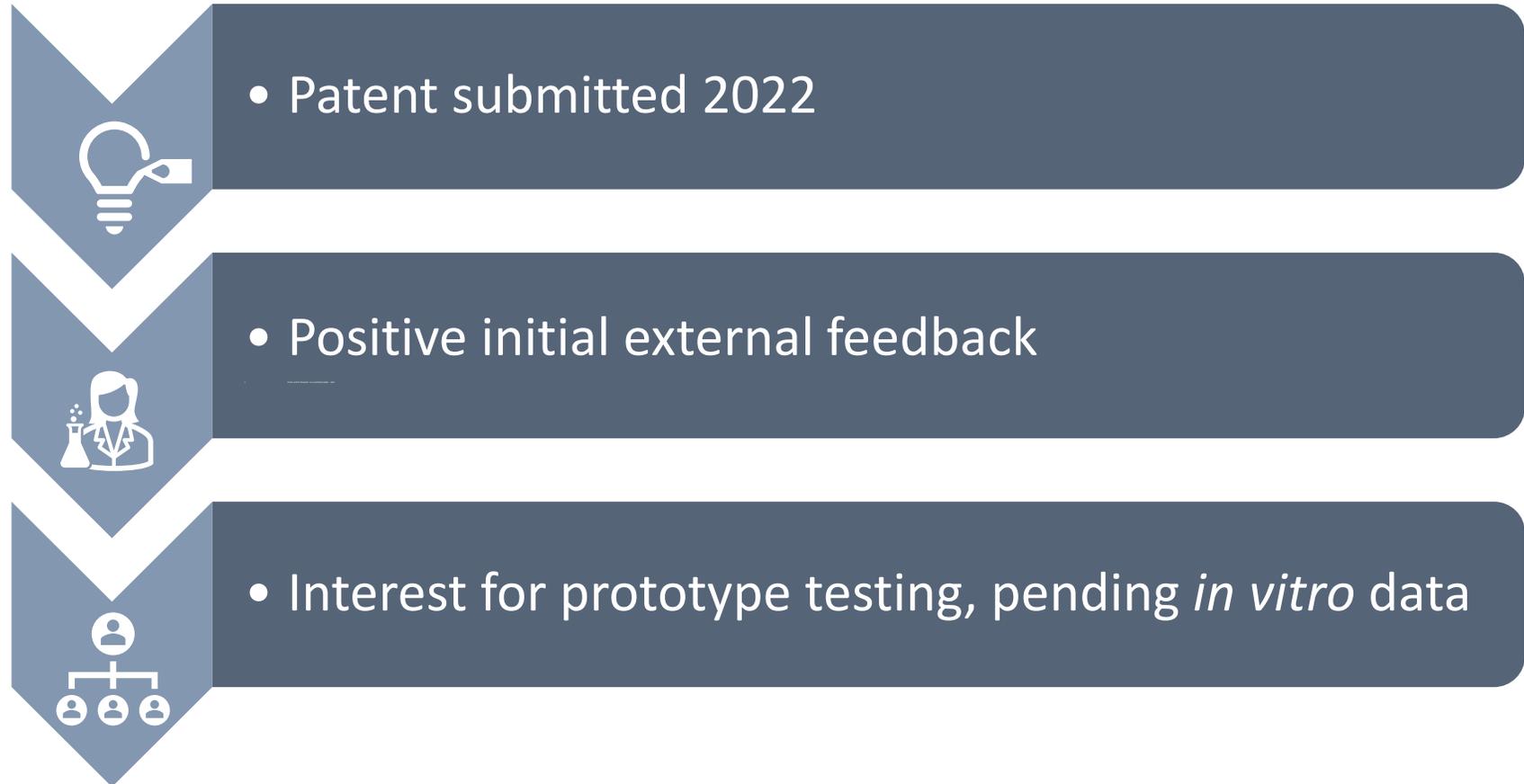
### Harvest

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

Operational  
review –  
Bioprocessing

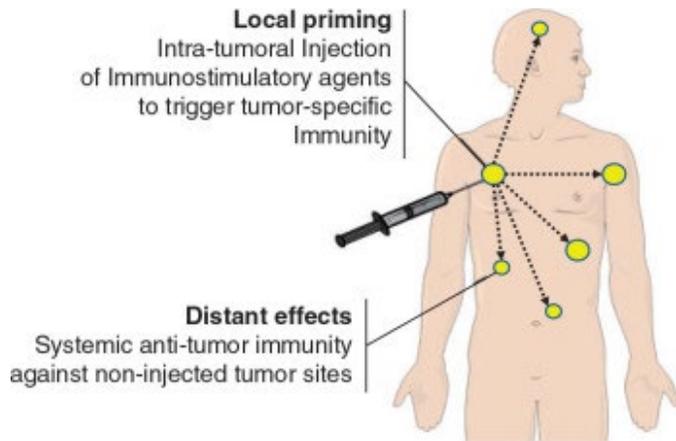


## Maximising yield in gene therapy manufacturing

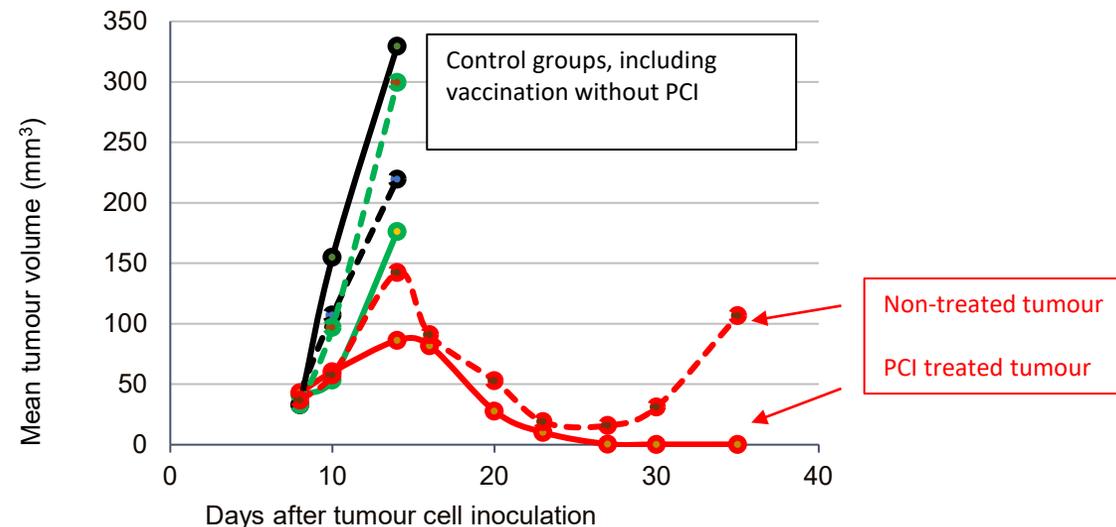


### Operational review – Intratumoural immunotherapy

- ▶ Most patients do not respond properly to current cancer immunotherapies
- ▶ New combination therapies can improve response rates, but are hampered by side effects
- ▶ Induction of an immune response by local treatment of one tumour lesion can allow combination immunotherapy treatments not feasible with systemic treatment



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



- ▶ Intratumoural **fima VACC** vaccination induces “global” anti-tumour effect

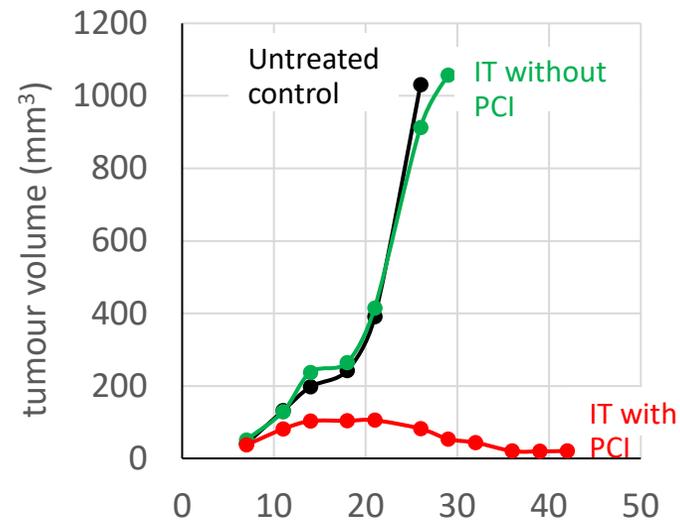
# fima VACC

fima VACC strongly improves effect of clinically explored intratumoural immunotherapy (IT)

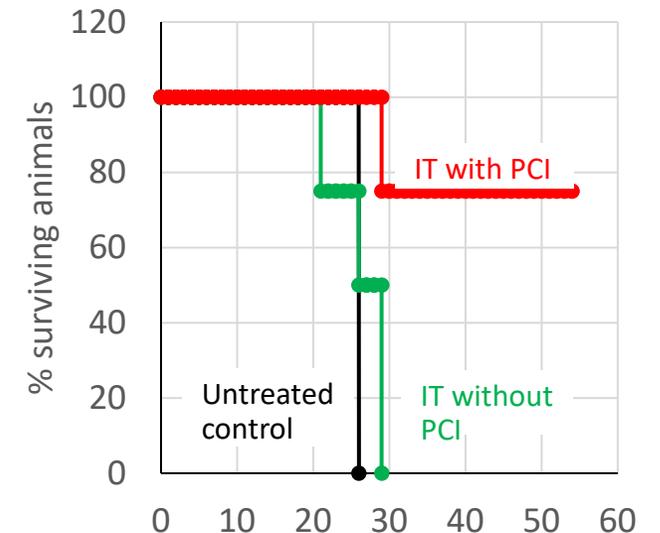
Operational review –  
Intratumoural immunotherapy

- ▶ Seek patent protection
- ▶ PhD grant from the Research Council of Norway for further development and knowledge generation

fima VACC retards tumour growth



fima VACC improves animal survival



**Key financials**

**Outlook**

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**Q&A**

# Finance

## Key financial figures

- ▶ **Financial run-way estimate extended towards the end of 2024**
  - Providing an opportunity window to demonstrate the commercial potential of the platform
  - RELEASE closure, and organisational changes with full cost reduction effect in Q1 2023
  - Other income, current SkatteFUNN grant ending 2022

<i>(figures in NOK 1,000)</i>	<b>Q4 2022</b>	<b>Q4 2021</b>	<b>FY 2022</b>	<b>FY 2021</b>
Other income (public grants)	1 188	1 188	4 750	6 273
Operating results	-7 061	-23 272	-56 447	-86 029
Net financial result	364	-1 776	1 352	-2 362
Net profit/loss	-6 697	-25 048	-55 095	-88 391

<i>(figures in NOK 1,000)</i>	<b>Q4 2022</b>	<b>Q4 2021</b>	<b>FY 2022</b>	<b>FY 2021</b>
Cash & cash equivalents	56 596	116 118	56 596	116 118
Cash flow from operating activities	-10 439	-17 492	-59 041	-68 307

# Outlook

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

Enabling intracellular delivery

Programme	Therapeutics	Preclinical	Phase 1	Phase 2
<b>fimaNAC</b>	Dermatology			
<b>fimaVACC</b>	Intratumoural immunotherapy			
<b>Collaborations</b>	Undisclosed			
Programme	Application	Feasibility	Prototype	Commercial
<b>fimaNAC</b>	Bioprocessing			

**1H 2023 Milestones**

- Data readout from **topical nucleic acid delivery**
- **Advance viral manufacturing** application
- Submit **patent** for novel intratumoural **immunotherapy** approach
- Submit **patent** on refined **sea lice combating** using photochemical treatments

Laying the ground for **partnership-driven development**



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# PCI Biotech

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