



**Enabling
intracellular
delivery**

PCI Biotech - Q2 and 1H 2022 Interim Report

Presentation August 31, 2022

Ronny Skuggedal, Interim CEO / CFO

Morten Luhr, BD and Scientific Alliance Manager

PCI Biotech

Q&A session through teleconference and webcast console

Norway +47 2195 6342

Sweden +46 4 0682 0620

Denmark +45 7876 8490

United Kingdom +44 2037 696 819

United States +1 646 787 0157

This presentation will also be presented through a teleconference, **mainly facilitated for attendees intending to ask questions verbally during the Q&A session.**

If you plan to use this facility, please join the event 5-10 minutes prior to the scheduled start time. A line mediator will provide information on how to ask questions. If your country is not listed, we recommend that you use the dial-in details for UK.

When prompted, provide the confirmation code or event title.

Confirmation Code: 436187

Event title: PCI Biotech Holding Half-yearly Report

This information is also available in the Q2 Report press release.

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

PCI Biotech

Important notice and disclaimer

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on PCI Biotech's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "programmes", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realised.

Factors that could cause these differences include, but are not limited to, implementation of PCI Biotech's strategy and its ability to further grow, risks associated with the development and/or approval of PCI Biotech's products candidates, ongoing clinical trials and expected trial results, the ability to commercialise fimaporfin (Amphinex®), technology changes and new products in PCI Biotech's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors. No assurance can be given that such expectations will prove to have been correct. PCI Biotech disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The reservation is also made that inaccuracies or mistakes may occur in this information given about current status of the Company or its business. Any reliance on the information is at the risk of the reader, and PCI Biotech disclaims any and all liability in this respect.

Table of Contents

Highlights
Operational review
Key financials
Outlook



Highlights

1H 2022

Corporate

- ▶ The reported efforts to finance a Ph II clinical trial did not under the current market conditions result in a feasible way forward. PCI Biotech will not conduct a company-sponsored Ph II trial with the **fima VACC** technology
- ▶ Focus efforts and resources on non-clinical research, developing further the current pipeline opportunities while exploring new fields of use for the PCI technology
 - **fima VACC** for intratumoural immunotherapy
 - **fimaNAC** for dermatology and bioprocessing applications
- ▶ The decision not to pursue a company-sponsored **fima VACC** Ph II clinical study entails reduction of the clinical team, which will be enacted during the second half of 2022
- ▶ Per Walday stepped down as CEO at the end of May 2022. Ronny Skuggedal, CFO, appointed CEO effective 1st September
- ▶ Financial runway estimated into 2024 and PCI Biotech will continue to explore financing and strategic opportunities as the non-clinical pipeline matures

Highlights

1H 2022

fima VACC Intratumoural immunotherapy

- ▶ The results from preclinical studies on BCG vaccination performed in collaboration with the University of Zurich and ETH Zurich, strengthened the understanding of the immunological effects of PCI treatment and its potential for use in intratumoural immunotherapy
- ▶ Ph.D. candidate grant of up to NOK 2.5 million, received by the Research Council of Norway

Highlights

1H 2022

fimaNAC
Dermatology
Bioprocessing

- ▶ Focused development for applications specifically suited to the strengths of the PCI technology
 - **Dermatology**
 - **Bioprocessing**
- ▶ The platform technology for use in the exciting field of mRNA-based therapies was presented at the TIDES USA 2022 conference in May

Highlights

1H 2022

fima *CHEM*

- ▶ RELEASE terminated due to changes in the competitive landscape that rendered the trial challenging to complete and potentially inadequate for approval
- ▶ Available data are insufficient to draw conclusions regarding the efficacy or safety of the PCI treatment
- ▶ All major study closure activities are expected to be completed during Q3

Highlights

1H 2022

Collaborations

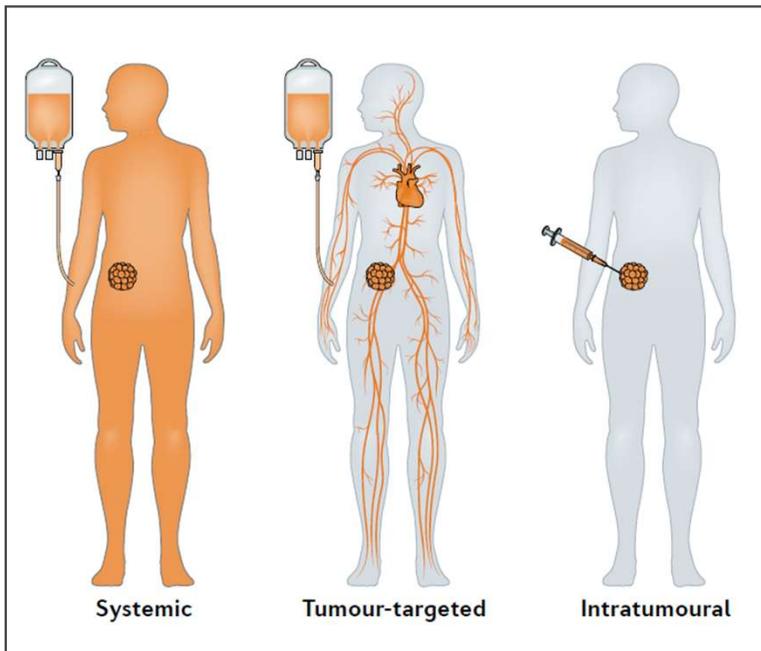
- ▶ Preclinical collaboration established in January with MDimune, developing innovative drug delivery technologies for modifying cellular and disease processes
- ▶ In August 2022, a preclinical collaboration was initiated with Mymetics, aiming to explore technological synergies for possible enhancement of cancer therapy
- ▶ All collaborations are reviewed for progress and value, and priorities have been set. Two of the collaborations (eTheRNA and Aposense) are closed as a result of this evaluation

Operational review

fima VACC

Operational
review

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



Melero *et al.* (2021) *Nat Rev Clin. Oncol.*;18:558–576

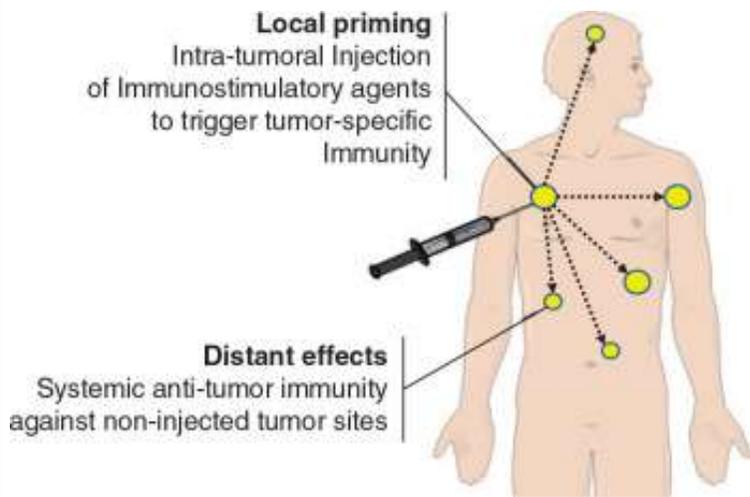
- ▶ Despite representing a major breakthrough in cancer treatment, a large proportion of patients do not respond to immune checkpoint inhibitors (ICIs) or progress shortly after initial response
- ▶ Optimising ICI and combined therapies dosage is difficult to achieve due to systemic side effects
- ▶ Combining ICI with intratumoural immunotherapy may overcome resistance to ICI monotherapy

fima VACC

Operational
review

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

“Treat locally – act globally”



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

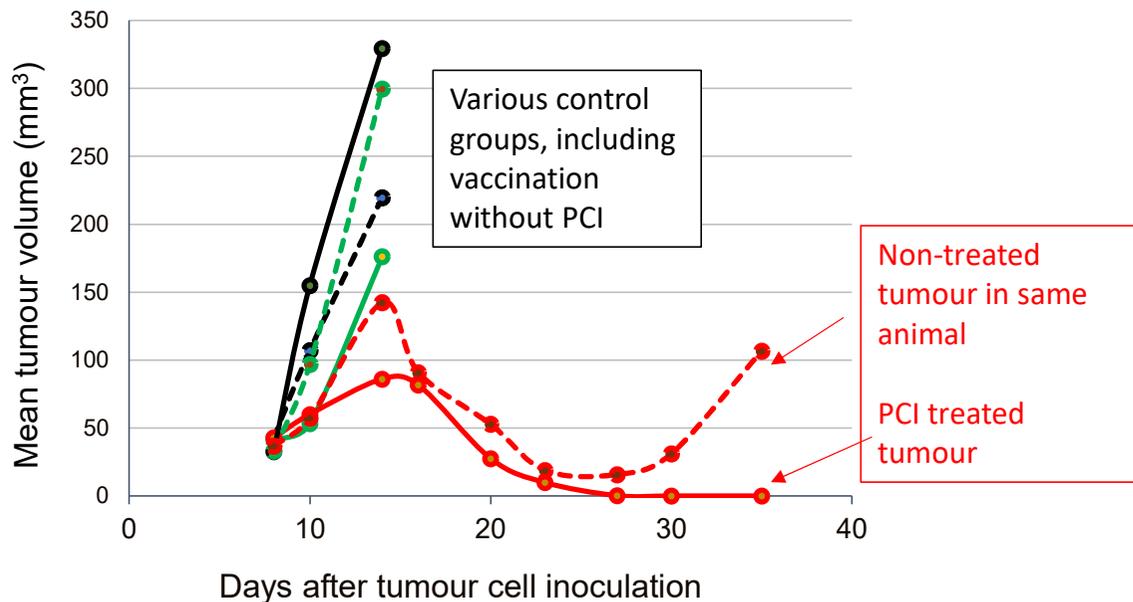
- ▶ For intratumoural treatment, systemic adverse effects are limited, enabling combination treatments not feasible with systemic treatment
- ▶ Therapy may include components that target immunosuppressive mechanisms
- ▶ Exploits patient’s own tumour as a patient-specific therapeutic “cancer vaccine”
- ▶ Treatment of one tumour lesion can induce specific immune response against other tumour lesions in the body

fimaVACC

Intratumoural therapy with **fimaVACC** gives systemic anti-tumour immune response

Operational review

Intratumoural vaccination in animals with two tumours.



► In animal studies, **fimaVACC** gives a very good effect with intratumoural vaccination, also on untreated tumour lesions

► **fimaVACC** has shown to enhance the effect of different types of agents explored in intratumour immunotherapy:

- DNA
- PRR agonists
- Pathogen
- RNA
- Small protein

► **fimaVACC** additionally has an immunostimulatory effect by itself¹

► PCI Biotech will explore novel approaches for intratumoural immunotherapy, supported by PhD project

1. Waeckerle-Men *et al.* (2022) *Front. Immunol.*;13;815609



Diabetic ulcer

Delivery of nucleic acids to skin

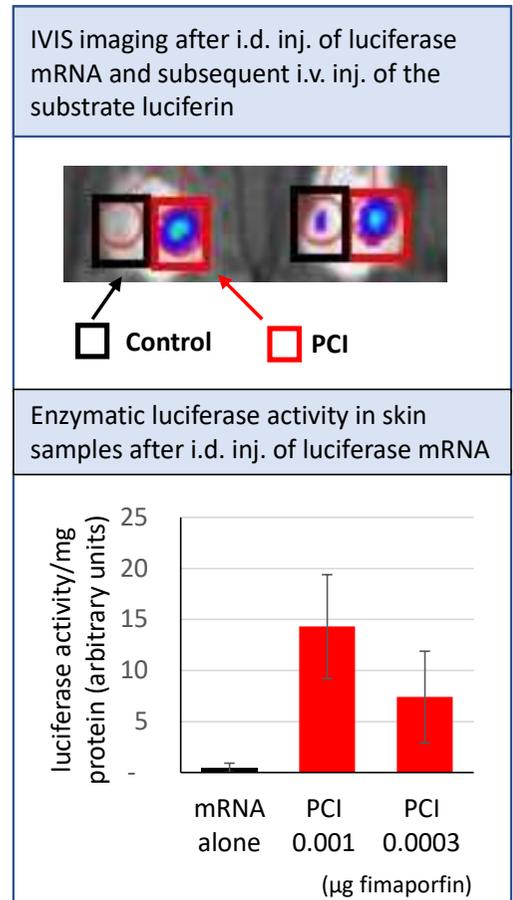
- ▶ Chronic skin ulcers (e.g. diabetic ulcers) have unmet medical need
- ▶ Often complex biology that can benefit greatly from the ability of nucleic acid therapies to affect gene mutations, gene regulation and tissue developmental (regenerative) programs
- ▶ Inefficient delivery has severely limited the use of nucleic acid therapies
- ▶ Large body surface areas are particularly challenging

fimaNAC

Operational review

fimaNAC for delivery of nucleic acids to skin

- ▶ Data from animal experiments indicate that **fimaNAC** can strongly enhance nucleic acid delivery in the skin
 - **fimaNAC** may unlock the therapeutic potential of nucleic acid therapeutics in skin
- ▶ PCI Biotech intends to develop a fit-for-purpose solution with primary focus on treating severe skin conditions with nucleic acid therapeutics
- ▶ Partnership-driven development

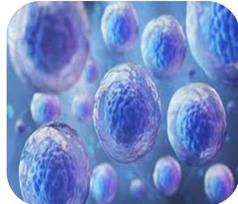


fimaNAC

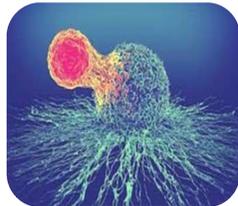
Operational review

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

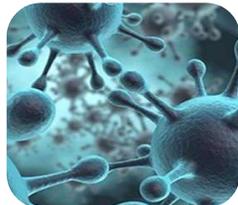
Markets:



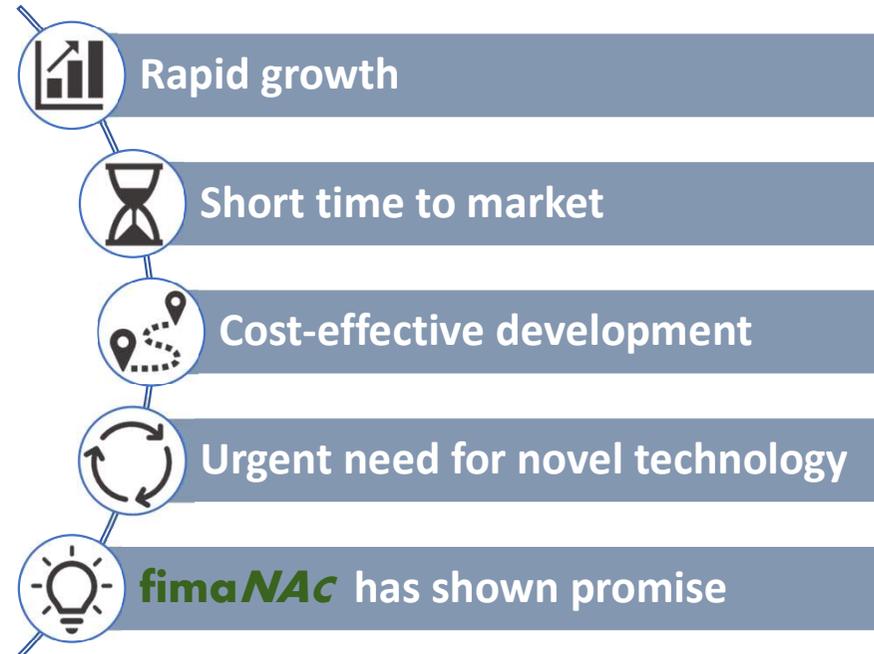
Cell culture



Cell and gene therapy



Viral manufacturing



fimaNAC

Operational
review

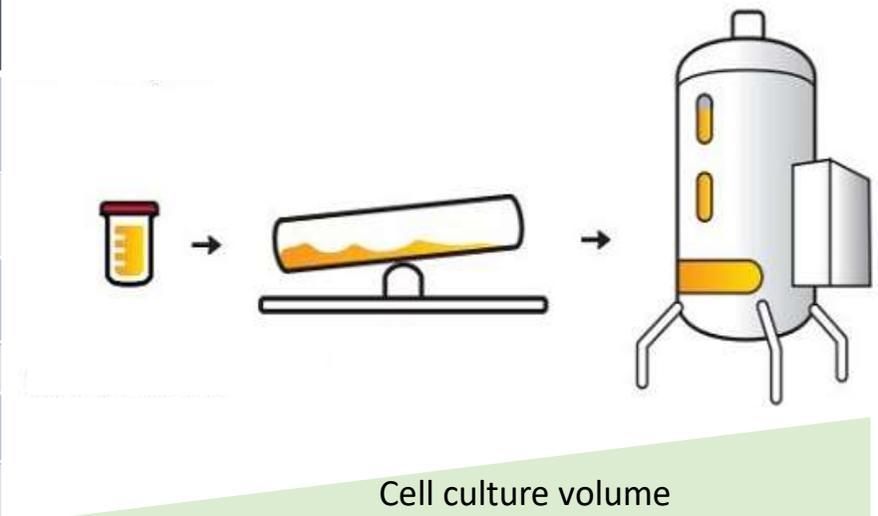
fimaNAC *in vitro* data is highly transferrable to bioprocessing

Nucleic acids successfully delivered by **fimaNAC**

Type of nucleic acid	Delivery vehicle
Plasmids	PEI, cationic peptides, cationic lipids, polylysine ++ Targeting to EGF-R, transferrin-R
siRNA	None, PEI, cationic peptides, dendrimers, lipofectamine, DOTAP, nanogels, chitosan ++
PNA (peptide nucleic acids)	None, cationic amino acids attached
mRNA	None, PEI, Protamine, Lipofectamine
Adenoviral vectors	None, cationic polymers
AAV vector	None

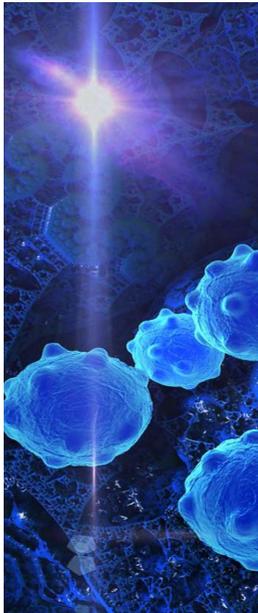
fimaNAC
(In vitro)

Bioprocessing



fimaNAC

Operational review



Capitalising on developments

Feasibility

- ▶ Perform in-house
- ▶ Pursue multiple applications

Prototype

- ▶ Partnership-driven development
- ▶ Targets:
 - Biotech
 - Contract development and manufacturing organisations (CDMOs, CMOs)

Programme	Application	Feasibility	Prototype	Commercial
fimaNAC	Bioprocessing			

- ▶ **RELEASE study terminated**
 - Expected rapid change in SoC → trial challenging to complete and likely inadequate for approval
- ▶ **Available data reviewed**
 - Radiographic data from 34 out of 41 enrolled patients evaluated for PFS/ORR
 - Data are insufficient to allow drawing conclusion regarding efficacy or safety
- ▶ **Swift closure of the RELEASE study**
 - Last patient discontinued the study in May 2022
 - All clinical sites were closed by the end of June 2022
 - All major study closure activities expected to be complete Q3 2022

Research collaborations



- ▶ Offer valuable scientific knowhow, encouraging results and intellectual property
- ▶ Collaborations span different classes of drugs and applications
- ▶ Two collaborations closed and two new established in 2022
- ▶ PCI Biotech continues to pursue new and value-adding, collaborative opportunities

Corporate
Key financials
Outlook

Q&A

Corporate

Organisational changes

- ▶ Organisational changes
 - Consolidation of management team
 - Former CEO and CBO left in May
 - CMO to leave in September
 - Ronny Skuggedal, CFO and CEO effective 1st September
 - R&D team fit for purpose
 - Downsizing of clinical team to be enacted during 2H 2022

Finance

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

- RELEASE closure, estimated future cash effect up to NOK -5 million
- Organisational changes will further reduce costs over time
- Explore financing and strategic opportunities as non-clinical pipeline matures

Key financial figures

<i>(figures in NOK 1,000)</i>	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Other income (public grants)	1 188	2 310	2 375	3 898	6 273
Operating results	-15 641	-19 083	-38 442	-40 254	-86 029
Net financial result	950	937	739	-1 665	-2 362
Net profit/loss	-14 691	-18 146	-37 703	-41 919	-88 391

<i>(figures in NOK 1,000)</i>	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Cash & cash equivalents	76 328	147 732	76 328	147 732	116 118
Cash flow from operating activities	-18 172	-14 958	-39 764	-37 843	-68 307

Outlook

Enabling
intracellular
delivery

Leveraging the PCI technology platform within
immunotherapy, nucleic acid therapeutics, and bioprocessing

Programme	Therapeutics	Preclinical	Phase 1	Phase 2
fima VACC	Intratumoural immunotherapy			
fima NAC	Dermatology			

Programme	Application	Feasibility	Prototype	Commercial
fima NAC	Bioprocessing			



Enabling
intracellular
delivery

PCI Biotech

For enquiries:

Ronny Skuggedal, CFO
Mobile phone: +47 940 05 757
E-mail: rs@pcibiotech.com