SECOND QUARTER AND FIRST HALF-YEAR REPORT

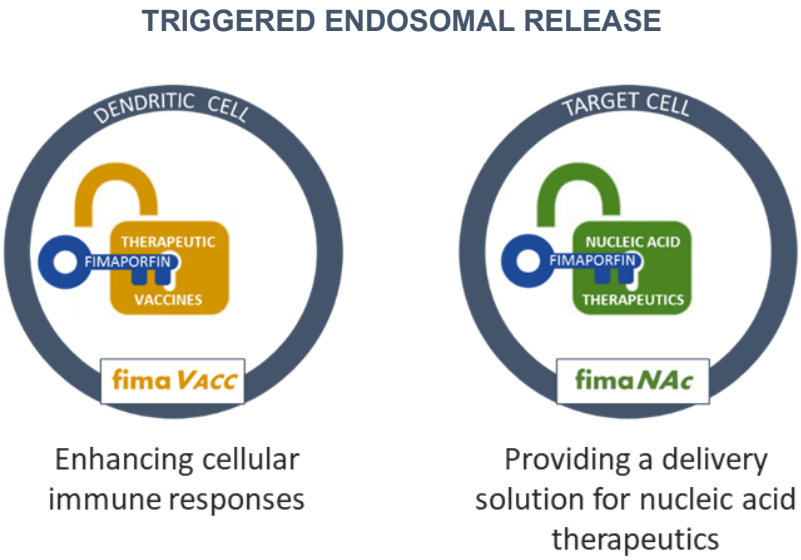
2022

Enabling intracellular delivery

PCI Biotech

Enabling intracellular delivery

LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS



ABOUT PCI BIOTECH

PCI Biotech is an oncology-focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies for the treatment of cancer through its proprietary photochemical internalisation (PCI) technology originating from world-leading research at the Oslo University Hospital – the Norwegian Radium Hospital. The PCI technology works by inducing light-triggered endosomal release, which may unlock the true potential of a wide array of therapeutic modalities, such as vaccines and different classes of nucleic acids.

The **fima*VACC*** programme aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. In preclinical experiments **fima*VACC*** has proven excellent efficacy with protein- and peptide-based vaccines, with particularly strong cytotoxic (CD8) T-cell immune responses, which are crucial in cancer immunotherapy. The beneficial immune characteristics of **fima*VACC*** were successfully verified in humans through a Phase I study with healthy subjects. The **fima*NAC*** programme utilises the proven potential of the PCI technology for intracellular delivery of nucleic acids. The technology can be used for most types of nucleic acids, ranging from oligonucleotides through mRNA and plasmids to some types of viral vehicles. The development of the **fima*NAC*** programme is focused on selected applications well suited to the specific strengths of the PCI technology, with several research collaborations established.

Highlights

Corporate

- The previously reported 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 and PCI Biotech will not conduct a company-sponsored Ph II trial with the fimaVACC technology
- The company will focus its efforts and resources on non-clinical research, developing further the current pipeline opportunities while exploring new fields of use for the PCI technology utilising fimaVACC for intratumoural immunotherapy, and fimaNAC for dermatology and bioprocessing applications

fimaVACC – intratumoural immunotherapy

- The results from preclinical studies on BCG vaccination performed in collaboration with The University of Zurich and ETH Zurich, published in January this year[1], strengthened the understanding of the immunological effects of PCI treatment and its potential for use in intratumoural immunotherapy
- A Ph.D. candidate grant of up to NOK 2.5 million, commencing 1st January 2023, was received from the Research Council of Norway. The grant is dedicated to the development of intratumoural immunotherapy

fimaNAC – dermatology and bioprocessing

- In addition to progressing the current programs we are now also exploring applications specifically suited to the strengths of the PCI technology within bioprocessing
- An overview of PCI Biotech's proprietary platform technology for use in the exciting field of mRNA-based therapies was presented at the TIDES USA 2022 conference in May

fimaCHEM

- The RELEASE trial was terminated due to changes in the competitive landscape that rendered the trial challenging to complete and potentially inadequate for approval. Available data from the RELEASE trial are insufficient to draw conclusions regarding the efficacy or safety of the PCI treatment
- The last patient discontinued the study in May and all clinical sites were closed by the end of June. All major study closure activities are expected to be completed during Q3. The closure process has an expected cash effect, from 1st July 2022, of up to NOK -5 million

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

[1] Waeckerle-Men *et al*. (2022) Frontiers in Immunology;13:815609

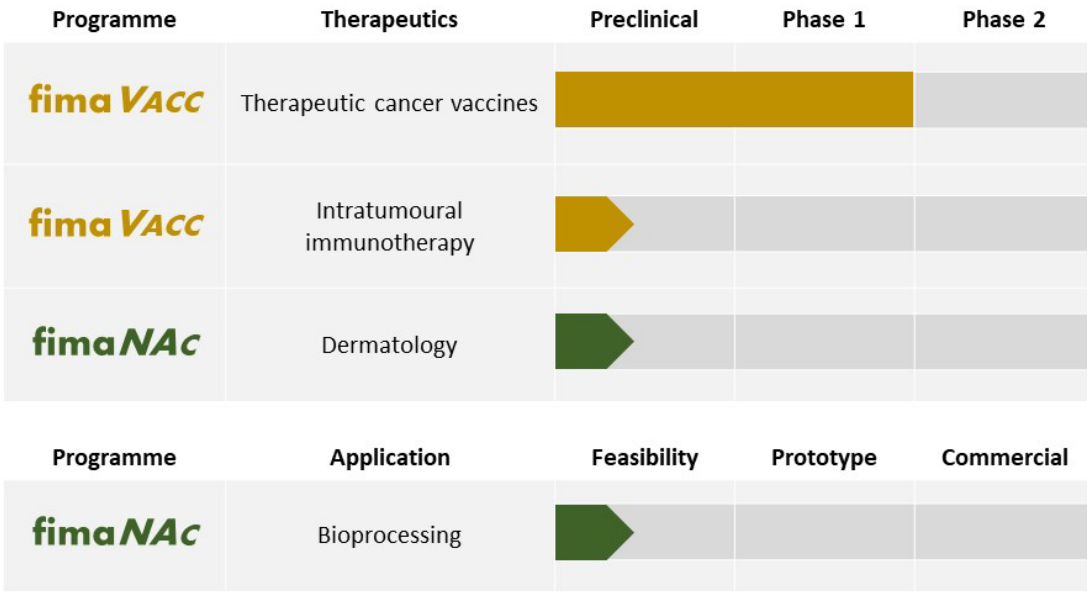
Corporate – other

- Per Walday stepped down as CEO at the end of May 2022. Ronny Skuggedal, CFO, was appointed Interim CEO effective 1st June, and will now be promoted to CEO effective from 1st September 2022
- Following the decision to terminate the RELEASE trial, the clinical organisation was reduced, with last notice period ending August 2022. The decision not to pursue a company sponsored fima VACC Ph II clinical study entails additional reduction of the clinical team staff, which will be enacted during the second half of 2022. The CBO, Ludovic Robin, left the company in May 2022 and the CMO, Amir Snapir, will be leaving the company in September 2022
- The financial runway is now estimated to be into 2024. The company will continue to explore financing and strategic opportunities as the non-clinical pipeline matures
- The Scientific Advisory Committee is further strengthened with Prof. Ernst Wagner at the Ludwig-Maximilians-Universität (LMU) and the Center of Nanoscience in Munich, Germany, contributing with expertise and experience in the field of targeted delivery of nucleic acids and protein therapeutics

Key figures

(In NOK 1,000)	**2022 1H**	**2021 1H**	**2022 Q2**	**2021 Q2**	**2021 FY**
Other income	2 375	3 898	1 188	2 310	6 273
Operating expenses	40 817	44 152	16 829	21 393	92 302
Operating results	-38 442	-40 254	-15 641	-19 083	-86 029
Net financial result	739	-1 665	950	937	-2 362
Comprehensive income	**-37 703**	**-41 919**	**-14 691**	**-18 146**	**-88 391**
Cash & cash equivalents	**76 328**	**147 732**	**76 328**	**147 732**	**116 118**
Cash flow from operating activities	**-39 764**	**-37 843**	**-18 172**	**-14 958**	**-68 307**

Pipeline



Operational review and development programmes overview

fima VACC

The **fimaVACC** technology aims to enhance immunotherapy responses and has shown excellent preclinical efficacy with protein- and peptide-based vaccines. The technology has shown particularly strong CD8 T-cell responses, which are important for therapeutic vaccination, as well as enhanced helper (CD4) T-cell and antibody responses. Immune responses and safety have been successfully translated to healthy subjects in a Ph I study[2]. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based immunotherapy technologies.

The company announced in August 2022 that the previously reported 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 and PCI Biotech will not conduct a company-sponsored Ph II trial with the **fimaVACC** technology. The company will focus its efforts and resources on non-clinical research, developing further the current pipeline opportunities, while exploring new fields of use for the PCI technology utilising **fimaVACC** for intratumoural immunotherapy, with a partnership-driven development strategy.

Intratumoural immunotherapy

Immune checkpoint inhibitors (ICIs) have revolutionised cancer treatment. However, a large proportion of patients do not respond to ICIs, or progress shortly after initial response. As with other systemically administered treatments, safety is a concern, currently preventing increased ICI doses to improve efficacy, as well as combining more than two ICIs together.

Combining ICIs with intratumour immunotherapy is an attractive approach to overcome resistance to ICIs. Intratumour immunotherapy is administered directly into the tumour and constitutes a “local” treatment. As a result, the dose is relatively low, and systemic adverse effects are limited. This in turn enables combination treatments not feasible with systemic treatment.

[2] Otterhaug *et al.* (2021) Frontiers in Immunology;11:576756

PCI is a technology designed for local enhancement of therapeutic effects and is very well suited for delivery of immunotherapy combinations to tumour sites. Thus, PCI can enhance the delivery of proteins, nucleic acids, and small molecules, all of which are relevant for locally-administered immunotherapy. In addition, the PCI technology by itself has a local immunostimulatory effect, e.g. by inducing cytokine production.

PCI Biotech is exploring intratumoural immunotherapy approaches, aiming to identify novel immunotherapy treatment combinations with promising efficacy.

Publication of preclinical BCG vaccination results
In January 2022, results from preclinical studies on BCG vaccination performed in collaboration with The University of Zurich and ETH Zurich were published in Frontiers in Immunology, a high-impact immunology journal. The article title is "Photochemically-mediated inflammation and cross-presentation of Mycobacterium bovis BCG proteins stimulates strong CD4 and CD8 T-cell responses in mice". The results strengthened the understanding of immunological effects of **fima*VACC*** and its potential for use in intratumoural immunotherapy.

Ph.D. candidate grant from the Research Council of Norway
A Ph.D. candidate grant of up to NOK 2.5 million, was received from the Research Council of Norway. The three-year grant is dedicated to the development of intratumoural immunotherapy, commencing 1st January 2023. The grant is subject to final contract negotiations.

fima*NAc*

Nucleic acid therapeutics have been established in recent years as an effective treatment approach in many applications, however, efficient and safe delivery to specific tissues is still a major barrier.

The **fima*NAc*** programme is focusing on development of a targeted intracellular delivery technology for different classes of nucleic acids. It is a preclinical-stage collaborative programme with companies developing nucleic acid-based therapies. Results from these collaborations and PCI Biotech's own data indicate that the **fima*NAc*** technology provides an attractive intracellular delivery solution for several applications in this area. Based on these results and other strategic considerations, PCI Biotech aims to develop the **fima*NAc*** technology for selected applications suited to the specific strengths of the PCI technology, with a partnership-driven development strategy.

Dermatology
The Company will focus on skin conditions with substantial unmet need and a good technological fit. Results of non-clinical experiments have demonstrated that the **fima*NAc*** technology can substantially enhance nucleic acid delivery to skin, with spatial specificity. PCI Biotech's development plans focus on chronic skin ulcers, but the technology may also be applied to other conditions. Current development is in the discovery phase with experiments planned to be initiated in 2H 2022.

Bioprocessing
Bioprocessing is a term used for technologies for the manufacturing of biologic drugs ("biologics"). These are often complex processes, and bioprocessing has become a major bottleneck in manufacturing of biologics for treating larger patient populations. There is a great need for new technologies for effective bioprocessing with higher yield as well as increased quality at a lower cost. Development of bioprocesssing technologies is less complex from a regulatory perspective compared to development of new therapies, allowing shorter timelines and lower costs of development.

PCI Biotech has demonstrated the potential of its technology for use in several areas of bioprocessing. Based upon these results, the company has initiated feasibility projects aimed at developing enabling technologies for bioprocessing.

fimaCHEM

The decision, in January 2022, to close recruitment to the RELEASE study was based on randomised Phase III clinical trial results presented at the American Society of Clinical Oncology Gastrointestinal Cancer Symposium (ASCO GI, January 20-22, 2022) from the TOPAZ-1 study, demonstrating that a combination of immune checkpoint inhibition with gemcitabine and cisplatin provides a significant survival benefit to patients with advanced biliary tract cancer compared with placebo plus gemcitabine and cisplatin. These results are expected to rapidly change the first-line standard treatment for patients with unresectable perihilar or distal bile duct cancer, which was the intended patient population of the RELEASE trial. Such a change in the standard of care treatment rendered the RELEASE trial challenging to complete and the clinical results potentially inadequate for approval, and significantly diminished the opportunity for PCI Biotech's treatment approach in this patient population.

The impact of the clinical trial results presented at ASCO GI was discussed with key opinion leaders, confirming an expected rapid change and early adoption of immunotherapy plus chemotherapy as the new standard of care treatment for the RELEASE trial's target population.

The trial enrolled a total of 41 patients, of which 34 patients provided efficacy data. Data collected in the RELEASE trial was insufficient to draw conclusions regarding the efficacy or safety of the PCI treatment.

The RELEASE trial has been a significant effort and the company is obliged to all external contributors, not least the enrolled patients, the clinical sites, and our investors, for their willingness to contribute to the benefit of future patients and their relatives.

PCI Biotech has focused on a swift and cost-efficient closing process of the RELEASE trial. Sites with no ongoing patients (nearly 60%) were closed immediately after the decision to terminate recruitment. The last patient discontinued the study in May and all remaining clinical sites were closed by the end of June. All major study closure activities are expected to be completed during Q3.

The swift wind-down of RELEASE allows the company to reallocate resources to the other development programmes. The future cash effect for the closure process of RELEASE, from 1st July 2022, is estimated up to NOK -5 million. The study results will be published on clincialtrials.gov and in the EU clinical trial database.

Research collaborations

PCI Biotech has an active collaborative strategy for **fimaNAc** and **fimaVACC**. The collaboration partners include MDimune, OliX Pharmaceuticals, Mendus (formerly Immunicum), IMV, and Mymetics. In these collaborations, PCI Biotech and the partners are exploring synergies between their proprietary technologies, with potential expansion of the partnerships. Previous collaborations have provided valuable data and know-how for further development of PCI Biotech's programmes. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAc** and **fimaVACC** programmes.

In January 2022, PCI Biotech entered a new **fimaNAc** research collaboration with MDimune, a South Korean biotech company developing a versatile drug delivery system based on nanosized vesicles obtained from cells. In August 2022 a **fimaVACC** research collaboration was initiated with Mymetics, a company based in Switzerland and a pioneer in the research and development of virosome-based vaccines and immunotherapies against infectious and life disabling diseases, aiming to explore technological synergies for the possible enhancement of cancer therapy.

In these collaborations, the companies will combine their know-how and technology platforms to explore synergies. The partnerships are governed by research collaboration agreements, under which evaluations of technology compatibility and synergy will be performed using preclinical studies to explore the potential for further development and partnership.

All collaborations are reviewed for progress and value, and priorities are set by both parties. Two previous collaborations (eTheRNA and Aposense) have been closed as a result of such evaluations.

Corporate

Organisational changes

Per Walday stepped down as CEO at the end of May 2022. Ronny Skuggedal, CFO, was appointed Interim CEO effective 1st June, and will be promoted to CEO effective 1st September 2022, holding both positions.

Following the termination of RELEASE the clinical team was reduced during the first half of 2022. The decision not to pursue a PCI Biotech-sponsored **fima*VACC*** Ph II study entails additional reduction of the clinical team staff numbers, which will be enacted during the second half of 2022. The CBO, Ludovic Robin, left the company in May 2022, and the CMO, Amir Snapir, will be leaving the company in September 2022.

Financial review

Income Statement

(Figures in brackets = same period 2021 unless stated otherwise)
The Group has not recorded any revenues for the financial years 2022 or 2021. Grants received from public sources, such as the Norwegian Research Council, are recorded as other income. Other income amounted to NOK 1.2 million (NOK 2.3 million) for Q2 and NOK 2.4 million (NOK 3.9 million) for 1H 2022.

Research and development (R&D) expenses for Q2 and 1H 2022 ended at NOK 11.7 million (NOK 15.5 million) and NOK 33.5 million (NOK 32.2 million) respectively, including a write-down of devices following the decision to terminate the RELEASE trail. These devices were recognised with a carrying value of NOK 5.8 million at the start of the year and were depreciated in full without cash-flow effect.

General and administrative (G&A) expenses for Q2 and 1H 2022 ended at NOK 5.1 million (NOK 5.9 million) and NOK 7.3 million (NOK 12.0 million) respectively. The change in G&A for 1H 2022 compared to last year, is mainly driven by accounting effect fluctuations for the share option scheme, without direct cash flow effects. In Q1 2022 a total number of 520,000 outstanding share options lapsed, resulting in a reversal of cost from previous periods of NOK 4 million.

Operating expenses for Q2 and 1H 2022 were NOK 16.8 million (NOK 21.4 million) and NOK 40.8 million (NOK 44.2 million) respectively. Operating expenses are mainly driven by the R&D activity level and the fima*CHEM* RELEASE trial was the main cost driver in both 2022 and 2021. There were two non-recurring items in the first half of 2022, write-down of lasers and reversal of costs related to the share option scheme, with a net accounting effect of NOK 1.8 million in operating expenses.

Net financial results for Q2 and 1H 2022 were NOK 0.9 million (NOK 0.9 million) and NOK 0.7 million (NOK -1.7 million) respectively. The variations in net financial results are mainly driven by exchange rate fluctuations on bank deposits placed in foreign currency, as a hedge of the foreign currency risk for the clinical RELEASE trial.

Net loss for Q2 and 1H 2022 were NOK 14.7 million (NOK 18.1 million) and NOK 37.7 million (NOK 41.9 million) respectively.

Cash flow and balance sheet

The decision to terminate the RELEASE trial impacted property, plant and equipment as this balance sheet item includes a device specifically designed to be used in the trial. The post-decision value of the device is considered to be low or of no value and the devices were depreciated in full in Q1 2022 without cash-flow effect.

The Group held cash and cash equivalents of NOK 76.3 million at end of Q2 2022, compared to NOK 116.1 million per year-end 2021. Cash flow from operations is mainly dependent on R&D activities and may vary between periods due to ordinary timing differences. Cash flow from operating activities was NOK -18.2 million for Q2 2022 (NOK -15.0 million), and NOK -39.8 million (NOK -37.8 million) for 1H 2022. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 1.0 million (NOK 0.8 million) positive for Q2 2022. For the first half year, the effect was 0.3 million positive in 2022, compared to 1.9 million negative in 2021.

Based on the decision to terminate the RELEASE trial, and the reported organisational changes the current cost base for the company will be reduced. The future cash effect for closure of RELEASE is estimated up to NOK -5 million from 1st July 2022. The cash position by the end of June 2022 enables an estimated financial run-way for the company into 2024, with current plans. The company continues to explore financing and strategic opportunities as the non-clinical pipeline matures.

Other

Risks and uncertainty factors for 2022

PCI Biotech is exposed to uncertainties and risk factors, which may influence some or all of the company's activities. As described in the Annual Report 2021, the most important risks the company is exposed to in 2022 are associated with financial risk, progress and performance of R&D programmes, and the associated regulatory affairs and market risk. No circumstances have been identified that significantly changes the uncertainties and risk factors described in the Annual Report 2021, which also covers implications of the COVID-19 pandemic and the war in Ukraine.

Changes to the Scientific Advisory Committee (SAC)

To tailor the collective competence of the SAC members to PCI Biotech's strategy we are delighted to announce that Prof. Ernst Wagner has been appointed as a new SAC member. Prof. Wagner is a professor of Pharmaceutical Biotechnology at the Ludwig-Maximilians-Universität (LMU) and the Center of Nanoscience in Munich, Germany. Previously (1991-2001), he was the Director Cancer Vaccines & Gene Therapy at Boehringer Ingelheim in Vienna, Austria, where he supervised the first-in-world polymer-based human gene therapy trial in 1994. Prof. Wagner is an Academician of European Academy of Sciences, a member of the Controlled Release Society (CRS) College of Fellows, and a board member of German Society for Gene Therapy. Prof. Wagner has authored more than 485 publications with more than 45 000 citations. His current academic research projects focus on the targeted delivery of nucleic acids (including mRNA) and protein therapeutics.

Prof. Taskén at Oslo University Hospital has served as a SAC member for PCI Biotech since 2018, and prior to that 10 years as a director, and he will now step out of the SAC. PCI Biotech would like to thank Prof. Taskén for his excellent contributions to PCI Biotech over the years.

Collaboration with Norwegian Institute for Marine Research (NIMR)

NIMR (Havforskningsinstituttet) received in 2021 a NOK 4.5 million grant from the Norwegian Seafood Fund for a collaboration project with PCI Biotech, exploring the use of photochemical treatments to combat salmon lice in fish farming. NIMR will perform the research, and PCI Biotech will provide expertise and compounds and retain commercial rights to the results of the project.

Post-closing events

Except for the decision not to pursue a company-sponsored **fimaVACC** Ph II clinical trial in head and neck cancer and related organisational changes described above, PCI Biotech is not aware of any other post-closing events, which could materially influence this interim financial statement.

Outlook

PCI Biotech's proprietary PCI technology enables intracellular delivery, which provides the possibility to unlock the true potential of certain classes of innovative medicines. The PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (**fima*VACC***) and nucleic acid therapeutics (**fima*NAC***).

The **fima*VACC*** programme aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. The **fima*NAC*** programme follows a collaborative approach, by development of treatment applications in the most attractive areas for the technology and pursuing out-licensing opportunities.

The main current priorities of PCI Biotech are to:

- Focus efforts and resources on non-clinical research, developing further the existing pipeline opportunities while exploring new fields of use for the PCI technology
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform
- Finalise the swift and cost-efficient closing of the RELEASE study

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 30 August 2022

Hans Peter Bøhn Chairman (sign)	Christina Herder Director (sign)	Hilde Furberg Director (sign)
Andrew Hughes Director (sign)	Lars Viksmoen Director (sign)	Ronny Skuggedal Interim CEO (sign)

RESPONSIBILITY STATEMENT

We confirm that, to the best of our knowledge, the unaudited condensed set of financial statements for the first half of 2022 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Group's consolidated assets, liabilities, financial position and results of operations, and that the interim management report includes a fair view of the information required under the Norwegian Securities Trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 30 August 2022

Hans Peter Bøhn Chairman (sign)	Christina Herder Director (sign)	Hilde Furberg Director (sign)
Andrew Hughes Director (sign)	Lars Viksmoen Director (sign)	Ronny Skuggedal Interim CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS *(in NOK '000)*	Note	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Other income	*6*	**1 188**	**2 310**	**2 375**	**3 898**	**6 273**
Research and development	*7,8*	11 681	15 527	33 490	32 179	71 707
General and administrative		5 147	5 866	7 327	11 973	20 595
Operating expenses		**16 829**	**21 393**	**40 817**	**44 152**	**92 302**
Operating results		**-15 641**	**-19 083**	**-38 442**	**-40 254**	**-86 029**
Financial income and expenses		**0**				
Financial income		1 209	999	1 591	1 205	789
Financial expenses		258	63	852	2 869	3 151
Net financial result	*7*	**950**	**937**	**739**	**-1 665**	**-2 362**
Profit/Loss before income tax		**-14 691**	**-18 146**	**-37 703**	**-41 919**	**-88 391**
Income tax	*9*	0	0	0	0	0
Net profit/loss		**-14 691**	**-18 146**	**-37 703**	**-41 919**	**-88 391**
Other comprehensive income		0	0	0	0	0
Total comprehensive income	*5*	**-14 691**	**-18 146**	**-37 703**	**-41 919**	**-88 391**

Balance sheet *(in NOK '000)*	Note	30.06 2022	30.06 2021	31.12 2021
Non-current assets				
Property, plant and equipment	*16*	26	6 774	5 806
Right to use asset	*15*	1 545	2 116	1 854
Total non-current assets		**1 571**	**8 891**	**7 660**
Current assets				
Short term receivables	*7*	15 348	15 259	12 200
Cash & cash equivalents	*7*	76 328	147 732	116 118
Total current assets	*14*	**91 676**	**162 991**	**128 318**
Total assets		**93 248**	**171 881**	**135 978**
Equity and liabilities				
Equity				
Paid in capital	*10,11*	562 443	562 443	562 443
Other reserves		-486 511	-408 482	-448 651
Total equity		**75 932**	**153 961**	**113 792**
Long-term liabilities				
Other long-term liabilities	*13*	0	19	0
Lease liabilities	*15*	962	1 541	1 277
Total long-term liabilities		**962**	**1 560**	**1 277**
Short term liabilities				
Trade debtors		5 408	4 095	3 745
Lease liabilities	*15*	629	627	629
Other short-term liabilities	*7,12*	10 317	11 639	16 535
Total short-term liabilities		**16 354**	**16 361**	**20 909**
Total liabilities	*14*	**17 316**	**17 920**	**22 186**
Total equity and liabilities		**93 248**	**171 881**	**135 978**

CHANGE IN EQUITY

(in NOK '000)	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Equity at beginning of period	**88 800**	**168 741**	**113 792**	**189 244**	**189 244**
Capital increase	0	0	0	0	0
Share option scheme	1 822	3 366	-157	6 636	12 939
Comprehensive income in the period	-14 691	-18 146	-37 703	-41 919	-88 391
Equity at end of period	**75 932**	**153 961**	**75 932**	**153 961**	**113 792**

CASH FLOW

(in NOK '000)	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Ordinary profit before taxes	-14 691	-18 146	-37 703	-41 919	-88 391
Depreciation, amortisation and write off	158	630	6 089	1 257	2 541
Leasing interest cost	19	19	39	19	38
Share options	1 822	3 366	-157	6 636	12 939
Currency gain (-)/ loss (+) not related to operations	-996	-826	-326	1 883	2 529
Changes in working capital and other non-cash adjustments	-4 485	0	-7 706	-5 719	2 036
Cash flow from operating activities	**-18 172**	**-14 958**	**-39 764**	**-37 843**	**-68 307**
	0				
Acquisition of non-current assets	0	-171	0	-341	-341
Net cash flow from investing activities	**0**	**-171**	**0**	**-341**	**-341**
	0				
Cash flow from financial activities	0				
Payment principal portion of lease liabilities	-175	0	-351	-168	-673
Net proceeds from share issues	0	0	0	0	0
Net cash flow from financial activities	**-175**	**0**	**-351**	**-168**	**-673**
	0				
Net change in cash during the period	**-18 348**	**-17 392**	**-40 115**	**-38 352**	**-69 321**
Exchange rate effect on bank deposits in foreign currency	996	826	326	-1 883	-2 529
Cash and cash equivalents at the beginning of the period	93 680	164 298	116 118	187 967	187 967
Cash and cash equivalents at the end of the period	**76 328**	**147 732**	**76 328**	**147 732**	**116 118**

SELECTED EXPLANATORY NOTES:

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA and the wholly owned subsidiary PCI Biotech AS. The PCI Biotech shares have been listed on Oslo Børs since 27 April 2018 under the ticker PCIB, as a transfer of listing from Oslo Axess. The company is headquartered in Oslo, Norway.

PCI Biotech has developed a unique and patented photochemical intracellular drug delivery technology for use in cancer therapy and other diseases. The technology may also be used to enhance the immunological response of vaccines. The company collaborates closely with The Norwegian Radium Hospital in Oslo, Norway and receives funding on several projects from the Research Council of Norway. The company has an extensive international collaboration network with recognised expert groups in both drug delivery and vaccination. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release.

The PCI technology has potential to improve the efficacy of new classes of drugs, such as therapeutic vaccines, gene therapy and other therapies based on nanotechnology or on biotechnological principles. The company's objective is to prove the clinical usefulness of the technology with various drug classes and subsequently license out the technology to partners for further development and marketing. Revenues will be generated at the time of partnering and onwards from potential up-front payments, milestone payments and royalties from sales. PCI Biotech works on the development of the PCI platform that may both potentiate the effect of vaccines (fima*VACC*) and delivery of nucleic acids (fima*NAC*). The fima*VACC* programme has completed a Phase I study in healthy subjects, which has provided scientific proof-of-concept of fima*VACC'S* ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fima*NAC* programme is in preclinical stage with focused development of selected applications for nucleic acid therapeutics well suited to the specific strengths of the PCI technology. A third development programme (fima*CHEM*) had until recently a pivotal clinical trial, RELEASE, in inoperable extrahepatic bile duct cancer. The RELEASE trial is terminated, and a closing process is ongoing focusing on a swift and cost-effective closure.

2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2021 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim financial report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 30 August 2022.

PCI Biotech has Norwegian kroner (NOK) as its functional currency and presentation currency. In the absence of any statement to the contrary, all financial information is reported in whole thousands. As a result of rounding adjustments, the figures in the condensed interim financial statements may not add up to the totals.

3. Summary of significant accounting policies

The accounting policies applied and the presentation of the interim condensed consolidated financial information for 2022 is consistent with the consolidated financial statements for the year ended 31 December 2021.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2022 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the annual financial statements for 2021.

4. Important accounting valuations, estimates and assumptions

Estimates and judgments are evaluated on an on-going basis and are based on historical experience and other factors, including expectations of future events that are considered to be relevant.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31st, 2021.

5. Earnings per share

	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Result allocated to shareholders (in NOK '000)	-14 691	-18 146	-37 703	-41 919	-88 391
Weighted average of outstanding shares (in NOK '000)	37 326	37 326	37 326	37 326	37 326
Earnings per share (NOK per share)	-0.39	-0.49	-1.01	-1.12	-2.37

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. Per end of Q2 2022 there are no outstanding share options that are in the money.

6. Segment information and Other income

PCI Biotech reports only one segment and had no revenues for the reporting period. Government grants are not recognised until it is probable that the conditions attached to the contribution will be achieved. The grants are recognised in the statement of profit and loss in the same period as the related expenses and are disclosed as other income. The Company has recognised a grant by the Research Council of Norway via the tax incentive scheme (SkatteFUNN) in the period.

7. Credit risk, foreign currency risk and interest risk

Credit risk
PCI Biotech has no sales for 2021 and 2022 and faces therefore no credit risk on trade receivables.

Maturity profile on other receivables at the end of the quarter (all figures in '000 NOK):

	Not due (prepaid expenses)	Less than 3 months	3 to 12 months	More than 12 months	Total
Other receivables	7 296	651	5 026	2 375	15 348
Total receivables	**7 296**	**651**	**5 026**	**2 375**	**15 348**

Most of the short-term receivables relates to accrued, not received government grants from the tax incentive scheme (SkatteFUNN). A major part of prepaid expenses relates to the RELEASE study.

Foreign currency risk
PCI Biotech has transactional currency exposure arising from purchases in currencies other than the functional currency (NOK). PCI Biotech has placed parts of the cash positions in Euro deposits as a

hedge of the foreign currency risk for the pivotal RELEASE study. PCI Biotech has not implemented any other hedging strategy to reduce foreign currency risk.

Per end of June a positive accounting effect of NOK 0.3 million has been reported as financial income for 2022, resulting from converting Euro cash deposits into NOK as functional currency for the interim report. The effect for the same period in 2021 was NOK 1.9 million negative.

Interest risk
PCI Biotech has no interest-bearing debt. PCI Biotech faces interest risk on cash deposits.

8. Research and Development

All figures in '000 NOK

	Q2 2022	Q2 2021	1H 2022	1H 2021	FY 2021
Clinical studies	9 216	11 821	26 862	24 728	57 204
Pre-clinical studies	1 441	2 047	3 735	3 452	6 966
CMC and equipment	356	747	1 338	2 074	3 332
Patents	668	911	1 555	1 925	4 205
Other costs	0	0	0	0	0
Total	**11 681**	**15 527**	**33 490**	**32 179**	**71 707**

PCI Biotech has no development expenditure that qualifies for recognition of an asset under IAS 38 Intangible assets. Expenditure on research activities is recognised as an expense in the period in which it was incurred and all research expenses are recorded in the profit and loss statement, in line with previous years.

9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 151.8 million in estimated non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

10. Share options

Share options outstanding from the company's share option program for employees have the following expiry date and exercise prices:

		Number of share options	
Expiry date	Exercise price in NOK per share option	31.12.2021	30.06.2022
2022 - Q3	21.48	310 000	200,000
2024 - Q3	25.78	300 000	220,000
2025 - Q3	50.36	520 000	340,000
2026 - Q3	19.41	485 000	310,000
Total		**1 615 000**	**1 070 000**

The current authorisation, granted by the Annual General Meeting on 28 May 2022, for the employee share option program allows for a total of 2,790,000 share options, of which 1,070,000 have been granted by the Board of Directors per end of the quarter.

During Q1 2022 a total of 520,000 previously granted share options lapsed, due to employees entering notice periods. The accounting effect of lapsed share options is a cost-reversal of NOK 4 million in the P&L for previously charged costs related to an estimated value for the expected number of share options that will be vested.

Overview share options, Senior executives	Total holdings 31.12.2021	Allocated	Lapsed	Exercised	Expired	Total holdings 30.06.2022
Ronny Skuggedal, CEO	190 000	0	0	0	0	190 000
Anders Høgset, CSO	190 000	0	0	0	0	190 000
Kristin Eivindvik, CDO	110 000	0	0	0	0	110 000
Amir Snapir, CMO	150 000	0	0	0	0	150 000
Ludovic Robin, former CBO*	130 000	0	130 000	0	0	0
Per Walday, former CEO**	295 000	0	295 000	0	0	0
Total	**1 225 000**	**0**	**425 000**	**0**	**0**	**800 000**

*Former CBO, Ludovic Robin left the company in May
**Former CEO, Per Walday left the company in May

11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2021	**37 326 390**	**3.00**	**111 979 170**
Transactions	-	-	-
30.06.2022	**37 326 390**	**3.00**	**111 979 170**

The Company's share capital is NOK 111,979,170 divided by 37,326,390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

The annual general meeting in May 2022 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition, the board of directors were authorised to execute share capital increases with up to NOK 12,034,000 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has more than 6,100 shareholders at end of the quarter.

10 largest shareholders per 30 June 2022:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 910 443	10,48 %
MYRLID AS	2 100 000	5,63 %
MP PENSJON PK	2 055 801	5,51 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
GRESSLIEN, Odd R.	902 700	2,42 %
NORDNET BANK AB	730 528	1,96 %
CLEARSTREAM BANKING S.A.	501 881	1,34 %
RAVI INVESTERING AS	500 000	1,34 %
JANDERSEN KAPITAL AS	470 000	1,26 %
FORENEDE FORVALTNING AS	385 188	1,03 %
Total 10 largest shareholders	**12 638 956**	***33,86 %***
Others	*24 687 434*	*66,14 %*
Total	*37 326 390*	*100,00 %*

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties:

		No. of shares	
Name	**Position**	**31.12.2021**	**30.06.2022**
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)*	Board member	4 000	4 000
Andrew Hughes	Board member	0	0
Per Walday**	Former CEO	72 700	72 700
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CEO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Ludovic Robin***	Former CBO	0	0
Amir Snapir	CMO	0	0
Total		**378 336**	**378 336**

* Hilde Furberg's shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.
**Per Walday, former CEO left the company in May 2022
***Ludovic Robin, former CBO left the company in May 2022

12. Other short-term liabilities

Other short-term liabilities mainly consist of accrued R&D and salary related costs and public duties.

13. Other long-term liabilities

Other long-term liabilities include public duties payables due in 1-5 years for potential future exercises of "in-the-money" share options in PCI Biotech's employee share option scheme and lease liabilities for right-to-use assets due in more than 12 months.

14. Financial assets and liabilities

All financial assets and liabilities are classified as financial instruments at amortised costs. Financial assets and liabilities at amortised costs are measured at their nominal amount, as the nominal amount is assessed to be fair value due to the immaterial discounting effect for short-term maturities.

15. Right of use assets and lease liabilities (IFRS 16)

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway, and the lease runs to 31 December 2024. The lease agreement is subject to annual adjustment according to changes in the consumer price index.

Payments for the principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects.

All figures in NOK '000

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions FY 2021	1 867
Acquisitions Q1 2022	0
Acquisitions Q2 2022	0
Acquisition costs 30.06.2022	**3 682**
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation FY 2021	618
Depreciation Q1 2022	155
Depreciation Q2 2022	155
Accumulated depreciation and impairment as of 30.06.2022	**2 137**
Total right to use assets - office lease as of 30.06.2022	**1 545**
Lower of remaining lease term or economic life	2.5 years
Depreciation method	Linear

(in NOK 1,000)

Lease liabilities - office	
Initial recognition 01.01.2019	1 815
Payments principal portion of the lease liability FY 2019	-657
Payments principal portion of the lease liability FY 2020	-668
Recognition at exercise of lease option for 3 more years FY 2021	1 867
Payments principal portion of the lease liability FY 2021	-673
Payments principal portion of the lease liability Q1 2022	-175
Payments principal portion of the lease liability Q2 2022	-175
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Interest expenses on the lease liability FY 2021	40
Interest expenses on the lease liability Q1 2022	19
Interest expenses on the lease liability Q2 2022	19
Total lease liabilities for office as of 30.06.2022	**1 591**
Whereof:	
Short term lease liabilities < 1 year	629
Long term lease liabilities > 1 year	962

Income statement effects – office lease	**Q2 2022**	**Q2 2021**	**1H 2022**	**1H 2021**	**FY 2021**
Depreciation of right to use asset	-155	-154	-308	-309	-618
Operating expenses for short-term leases	0	0	0	0	0
Effect on Operating results net of tax	**-155**	**-154**	**-308**	**-309**	**-618**
Interest expenses on the lease liabilities	-19	-10	-38	-20	-40
Effect on Net financial result net of tax	**-174**	**-164**	**-346**	**-329**	**-658**
Comprehensive income effect net of tax	**-174**	**-164**	**-346**	**-329**	**-658**

16. Property, plant and equipment

PCI Biotech acquired the first lots of lasers to be used in the RELEASE study during 2019 and further lasers were acquired during 2020 and 2021. A linear depreciation method over the expected lifetime of five years for the equipment was applied. The decision made in Q1 2022 to stop the RELEASE trial made the lasers of no or low value and the carrying amount is depreciated in full in 2022.

Equipment	**30.06 2022**	**30.06 2021**	**31.12 2021**
Carrying value at the beginning of the period	**5 806**	**7 388**	**7 388**
Acquisitions	-	341	341
Depreciation	8	955	1 922
Write-down	5 772	-	-
Carrying value at the end of the period	**26**	**6 774**	**5 806**

17. Subsequent events

Except for the decision not to pursue a company-sponsored fima*VACC* Ph II clinical trial in head and neck cancer and related organisational changes described herein, PCI Biotech is not aware of any other post-closing events, which could materially influence this interim financial statement.

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
FDA:	US Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fima*CHEM*:	PCI Biotech's development program for enhancement of generic chemotherapies
fima*NAC*:	PCI Biotech's development program for delivery of nucleic acids
fima*VACC*:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
ODD:	Orphan Drug Designation
ORR:	Overall Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
PFS:	Progression Free Survival
RELEASE:	Name of PCI Biotech's pivotal study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
SoC:	Standard of Care
NOK:	Norwegian kroner
FY:	Financial year (1st January – 31st December)
1H:	First half year (1st January – 30th June)
2H:	Second half year (1st July – 31st December)
Q1:	First quarter (1st January – 31st March)
Q2:	Second quarter (1st April – 30th June)
Q3:	Third quarter (1st July – 30th September)
Q4:	Fourth quarter (1st October – 31st December)
YTD:	Year to date

FINANCIAL CALENDAR

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FORWARD LOOKING STATEMENTS

This Report contains certain forward-looking statements relating to the business, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, and are sometimes identified by the words “believes”, expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. The forward-looking statements contained in this Report, including assumptions, opinions and views of the Company or cited from third party sources, are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements that are expressed or implied by statements and information in the Report, including, among others, risks or uncertainties associated with the Company’s business, segments, development, growth management, financing, market acceptance and relations with customers, and, more generally, general economic and business conditions, changes in domestic and foreign laws and regulations, taxes, changes in competition and pricing environments, and fluctuations in currency exchange rates and interest rates. None of the Company or any of its subsidiaries or any such person’s directors, employees or advisors provide any assurance that the assumptions underlying forward-looking statements expressed in this Report are free from errors nor does any of them accept any responsibility for the future accuracy of such forward-looking statements.

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