



**FOURTH QUARTER
AND PRELIMINARY
FULL YEAR REPORT**

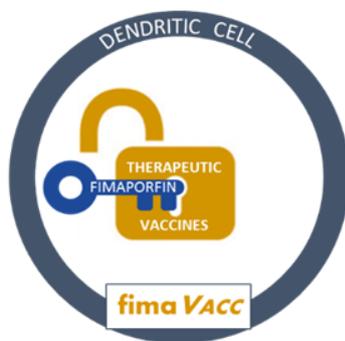
2022

*Enabling
intracellular
delivery*



LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

TRIGGERED ENDOSOMAL RELEASE



Enhancing cellular
immune responses



Providing a delivery
solution for nucleic acid
therapeutics

ABOUT PCI BIOTECH

PCI Biotech is a biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies through its proprietary photochemical internalisation (PCI) platform 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 potential of a wide array of modalities.

The **fimaNAC** programme utilises the proven capability 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 viral vectors. The development of the **fimaNAC** programme is currently focused on selected applications within dermatology and bioprocessing, well suited to the specific strengths of the PCI technology. The **fimaVACC** programme aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. In preclinical experiments **fimaVACC** 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 **fimaVACC** have been successfully verified in humans through a Phase I study with healthy subjects.

Highlights

fimaNAC – dermatology and bioprocessing

- The first phase of the dermatology program, to demonstrate topical **fimaNAC**-mediated nucleic acid delivery in a preclinical wound model, is on track for readout 1H 2023. Positive results will be utilised for seeking co-development with partners having nucleic acid-based drug candidates
- The bioprocessing program has matured, and the first patent application has been filed on use of **fimaNAC** in viral vector manufacturing. Further studies are planned for 1H 2023 to strengthen **fimaNAC**'s value proposition and intellectual property

fimaVACC – intratumoural immunotherapy

- PCI Biotech is exploring approaches aimed at identifying novel immunotherapy treatment combinations, and first patent application for an undisclosed treatment approach is underway for filing in Q1 2023

Corporate

- The cash position of NOK 57 million per year-end enables an extended estimated financial runway towards the end of 2024 with current plans
- All major study closure activities for the RELEASE trial are completed and the estimated remaining cash effect for the closure process is less than NOK -1 million. Downsizing of the full clinical team, reported in August, was enacted during second half of 2022 with full cost reduction effect in Q1 2023
- The company focusses its efforts and resources on pre-clinical research in areas where there is need for novel drug delivery systems, with a partnership-driven development strategy. **fimaNAC** is focussed on dermatology and bioprocessing applications, and **fimaVACC** on intratumoural immunotherapy

Key figures

(In NOK 1,000)	2022 Q4	2021 Q4	2022 FY	2021 FY
Other income	1 188	1 188	4 750	6 273
Operating expenses	8 248	24 460	61 197	92 302
Operating results	-7 061	-23 272	-56 447	-86 029
Net financial result	364	-1 776	1 352	-2 362
Comprehensive income	-6 697	-25 048	-55 095	-88 391
Cash & cash equivalents	56 596	116 118	56 596	116 118
Cash flow from operating activities	-10 439	-17 492	-59 041	-68 307

Pipeline

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

2022 in review: A challenging year - what is next?

The RELEASE trial was terminated in Q1 2022, due to changes in the competitive landscape that rendered the trial challenging to complete and potentially inadequate for approval. PCI Biotech focussed on a swift and cost-efficient closing process of the RELEASE trial, including tailoring the organisation to the new setting. All major study closure activities for the RELEASE trial are completed and the estimated remaining cash effect for 2023 is less than NOK -1 million.

Efforts to finance a Ph II clinical trial in head and neck cancer did not, under the 2022 capital market conditions, result in a feasible way forward and the company reported in August that it will not conduct a company-sponsored Ph II trial with the **fimaVacc** technology. This entailed a full downsizing of the clinical team, which was enacted during the second half of 2022, with full cost reduction effect in Q1 2023.

2022 was transformative for PCI Biotech. The company now directs its efforts and resources on pre-clinical research in areas where there is need for novel drug delivery systems, with a partnership-driven development strategy. **fimaNAC** is focussed on dermatology and bioprocessing applications, and **fimaVacc** on intratumoural immunotherapy. The year-end cash position of NOK 57 million enables an extended estimated financial runway towards the end of 2024 with current plans, providing an opportunity window to demonstrate the commercial potential of the technology platform. The company will continue to explore financing and strategic opportunities as the pre-clinical pipeline matures.

In 2022 we initiated a new project within bioprocessing, aimed at using **fimaNAC** for solving challenges with inadequate yields in viral vector manufacturing. This currently serves as a bottleneck for making certain gene therapies available to new indications and larger patient populations. Development of bioprocessing technologies is less complex from a regulatory perspective compared to development of new therapies, allowing shorter timelines and lower costs. A first patent application was filed in 2H 2022 and 1H 2023 will be focussed on in-house generation of proof-of-principle data on a small scale. Initial external feedback on **fimaNAC**'s value proposition has been positive, warranting further studies working towards alpha testing with potential customers.

Nucleic acid therapeutics have the potential to improve treatment of dermatological diseases, but delivery remains an obstacle. PCI Biotech has initiated a project aimed at developing an easy to use topical formulation combined with efficacious delivery of nucleic acids using **fimaNAC**. Readout from the feasibility study for the dermatology program, performed by an expert contract research organisation, is expected 1H 2023. Positive results may provide opportunities for early-stage collaborations with partners developing nucleic acid drug candidates.

PCI Biotech is exploring intratumoural immunotherapy approaches with the **fimaVacc** program, aiming at identifying novel treatment combinations to overcome resistance to immune-checkpoint inhibitors and safety-issues associated with such treatments. A patent application for an undisclosed treatment approach is planned to be filed in Q1 2023. This project is supported by a Ph.D. candidate grant, commencing January 2023.

PCI Biotech continues to pursue new and value-adding collaborative opportunities. Certain research collaborations were ended during 2022, based on review of progress and value, and new collaborations were initiated. The collaboration with the Norwegian Institute of Marine Research, aiming to explore the use of photochemical treatments to combat salmon lice in fish farming, has demonstrated killing of free-swimming sea lice. Refinement of the principle is ongoing to evaluate if sea lice attached to fish can be combated, and a patent application is planned to be filed in Q1 2023. This is an opportunistic, early-stage project, where domain expertise is ensured by collaboration with experts in the field, and further partnership is particularly important for progress.

Operational review and programmes overview

fimaNAC

Nucleic acids have in recent years emerged as a promising class of drugs, exemplified by the mRNA COVID-19 vaccines and several products for the treatment of rare diseases. However, efficient and safe delivery to most tissues is still a major barrier to treating new indications. By achieving site-directed intracellular delivery, this is a challenge **fimaNAC** is uniquely positioned to solve.

The **fimaNAC** programme is a preclinical-stage collaborative programme developing a targeted intracellular delivery technology for different classes of nucleic acids. Results from collaborations and PCI Biotech's own data indicate that the **fimaNAC** technology provides an attractive intracellular delivery solution in this area. PCI Biotech aims to develop the **fimaNAC** technology as a platform for both dermatology and bioprocessing, with a partnership-driven development strategy.

Dermatology

Systemic nucleic acid delivery to skin is largely ineffective. Needle-based delivery may in some cases be effective, but is pharmaceutically sub-optimal and technically cumbersome, especially when larger surface areas are involved. PCI Biotech aims to develop a topical formulation for delivery of nucleic acid therapeutics to skin using **fimaNAC**, to combine the ease of use of topical administration with enhanced delivery from **fimaNAC**. Pre-clinical experiments have demonstrated that the **fimaNAC** technology can substantially enhance nucleic acid delivery to skin, with spatial specificity. PCI Biotech's development plans focus on chronic skin ulcers, with a large unmet medical need, but the technology may also be applied to other dermatological conditions.

Current development aims to demonstrate **fimaNAC**-mediated nucleic acid delivery in an *ex vivo* wound model with topical administration to act as a stepping-stone towards partnership with nucleic acid therapeutics owners. This study, to be performed by an expert contract research organisation, has expected readout in 1H 2023.

Bioprocessing

Bioprocessing is the manufacturing of biologic drugs ("biologics"). This involves complex processes and bottlenecks in the endeavour to offer breakthrough therapies to new and larger patient populations. There is a great need for technologies that enable more effective bioprocessing with higher yield as well as increased quality at a lower cost. Development of bioprocessing 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 identified the potential of its technology for use in several areas of bioprocessing, and 1H 2023 will be focussed on in-house feasibility studies of **fimaNAC** for use in viral vector manufacturing and thereafter on getting feedback from potential customers by performing alpha testing.

fimaVACC

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 study¹. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid-based immunotherapy.

¹ Otterhaug *et al.* (2021) *Frontiers in Immunology*;11:576756

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. Combining ICIs with intratumour immunotherapy is an attractive approach to increase the response rate to ICIs. Here 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 expected to be limited, which in turn may enable novel combination treatments.

PCI is a technology designed for local enhancement of therapeutic effects and is well suited for delivery of immunotherapy combinations to tumour sites. As such, PCI can enhance the delivery of proteins, nucleic acids, small molecules, and viral vectors, 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. A Ph.D. candidate grant of up to NOK 2.5 million over 3 years is granted by the Research Council of Norway, dedicated to the development of intratumoural immunotherapy and commencing 1st January 2023.

Research collaborations

PCI Biotech has an active collaborative strategy for **fimaNAC** and **fimaVacc**. The collaboration partners include MDimune, OliX Pharmaceuticals, IMV, and Mymetics. In these collaborations, PCI Biotech and the partners are exploring synergies between their proprietary technologies, with potential expansion of the partnerships. 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 to explore synergies. The partnerships are governed by research collaboration agreements, under which evaluations of technology compatibility and synergy will be assessed.

All collaborations have during 2022 been reviewed for progress and value, and priorities are set by both parties. Three previous collaborations (eTheRNA, Aposense and Mendus) have been closed as a result of such evaluations.

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 2-year collaboration project with PCI Biotech ending June 2023. The project aims to explore 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.

Corporate

The RELEASE trial – terminated

The RELEASE trial was terminated in Q1 2022, due to changes in the competitive landscape that rendered the trial challenging to complete and potentially inadequate for approval. The trial enrolled a total of 41 patients, of which 34 patients provided efficacy data. Data collected in the study was insufficient to draw conclusions regarding efficacy of the PCI treatment. All major study closure activities were completed during 2022, except publishing the study results on clinicaltrials.gov.

The swift and cost-efficient closing process allowed reallocation of resources to the other development programmes, and the remaining cash effect for the closure process is estimated to be less than NOK - 1 million, from 1st January 2023.

Organisational changes

Following the termination of RELEASE the clinical team was reduced during the first half of 2022. The decision in August 2022 not to pursue a PCI Biotech-sponsored **fimaVacc** Ph II study entailed full disbandment of the clinical team, which was enacted during the second half of 2022 with a full cost reduction effect in Q1 2023.

Per Walday (former CEO), resigned in March to assume a new position and it was mutually agreed that he stepped down from his position at the end of May. Ludovic Robin (former CBO), left the company in May 2022. Amir Snapir (former CMO), left the company in September 2022. Ronny Skuggedal (CFO), was appointed Interim CEO effective 1st June, and promoted to CEO effective 1st September 2022, holding both positions.

The PCI Biotech team count 7 employees at the end of 2022, compared to 17 employees at the beginning of the year.

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 1.2 million) for Q4 and NOK 4.8 million (NOK 6.3 million) for the full year of 2022. The current SkatteFUNN grant project (tax incentive scheme) ends 2022.

Research and development (R&D) expenses for Q4 and FY 2022 ended at NOK 5.1 million (NOK 20.9 million) and NOK 44.8 million (NOK 71.7 million) respectively, including a write-down of the carrying value of NOK 5.8 million for devices following the decision to terminate the RELEASE trial in Q1 2022.

General and administrative (G&A) expenses for Q4 and FY 2022 ended at NOK 3.1 million (NOK 3.5 million) and NOK 16.4 million (NOK 20.6 million) respectively. The change in G&A for FY 2022 compared to last year, is mainly driven by accounting effect fluctuations for the share option scheme, without direct cash flow effects, and the staff downsizing.

Operating expenses for Q4 and FY 2022 were NOK 8.2 million (NOK 24.5 million) and NOK 61.2 million (NOK 92.3 million) respectively. Operating expenses are mainly driven by the R&D activity level and the RELEASE trial was the main cost driver in both 2022 and 2021.

Net financial results for Q4 and FY 2022 were NOK 0.4 million (NOK -1.8 million) and NOK 1.4 million (NOK -2.4 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 Q4 and FY 2022 were NOK 6.7 million (NOK 25.0 million) and NOK 55.1 million (NOK 88.4 million) respectively.

Cash flow and balance sheet

The decision to terminate the RELEASE trial impacted property, plant and equipment as this balance sheet item included a medical device specifically designed to be used in the trial. The post-decision value of the device was considered negligible, and the devices were depreciated in full in Q1 2022 without cash-flow effect.

The Group held cash and cash equivalents of NOK 56.6 million at end of the year, 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 -10.4 million for Q4 2022 (NOK -17.5 million), and NOK -59.0 million (NOK -68.3 million) for FY 2022. All cash and cash equivalents are placed as bank deposits. Bank deposits in foreign currency was originally established in 2018 as a hedge of the foreign currency risk for the RELEASE trial. At year-end 2022 the foreign currency balance was minimal. For 2022 a positive accounting effect of 0.2 million (NOK -2.5 million) has been reported as financial income, resulting from converting Euro cash deposits into NOK as functional currency for the interim report.

The cash position by the end of 2022 enables an estimated extended financial runway for the company towards the end of 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 change 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.

Post-closing events

PCI Biotech is not aware of any 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 nucleic acid therapeutics (**fimaNAc**) and immunotherapy (**fimaVacc**).

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

The main current priorities of PCI Biotech are to:

- Focus efforts and resources on pre-clinical research, for technology platform development
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 16 February 2023

Hans Peter Bøhn
Chairman (sign)

Christina Herder
Director (sign)

Hilde Furberg
Director (sign)

Andrew Hughes
Director (sign)

Lars Viksmoen
Director (sign)

Ronny Skuggedal
CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS (in NOK '000)	Note	Q4 2022	Q4 2021	FY 2022	FY 2021
Other income	6	1 188	1 188	4 750	6 273
Research and development	7,8	5 100	20 917	44 756	71 707
General and administrative		3 148	3 543	16 441	20 595
Operating expenses		8 248	24 460	61 197	92 302
Operating results		-7 061	-23 272	-56 447	-86 029
Financial income and expenses					
Financial income		470	175	1 711	789
Financial expenses		106	1 951	359	3 151
Net financial result	7	364	-1 776	1 352	-2 362
Profit/Loss before income tax		-6 697	-25 048	-55 095	-88 391
Income tax	9	0	0	0	0
Net profit/loss		-6 697	-25 048	-55 095	-88 391
Other comprehensive income		0	0	0	0
Total comprehensive income	5	-6 697	-25 048	-55 095	-88 391
Balance sheet (in NOK '000)					
	Note	31.12 2022	31.12 2021		
Non-current assets					
Property, plant and equipment	16	18	5 806		
Right to use asset	15	705	1 854		
Total non-current assets		723	7 660		
Current assets					
Short term receivables	7	6 162	12 200		
Cash & cash equivalents	7	56 596	116 118		
Total current assets	14	62 758	128 318		
Total assets		63 482	135 978		
Equity and liabilities					
Equity					
Share capital	10,11	111 979	111 979		
Other reserves		-54 576	1 813		
Total equity		57 403	113 792		
Long-term liabilities					
Other long-term liabilities	13	0	0		
Lease liabilities	15	327	1 277		
Total long-term liabilities		327	1 277		
Short term liabilities					
Trade debtors		495	3 745		
Lease liabilities	15	443	629		
Other short-term liabilities	7,12	4 814	16 535		
Total short-term liabilities		5 752	20 909		
Total liabilities	14	6 079	22 186		
Total equity and liabilities		63 482	135 978		

CHANGE IN EQUITY

<i>(in NOK '000)</i>	Q4 2022	Q4 2021	FY 2022	FY 2021
Equity at beginning of period	63 483	136 136	113 792	189 244
Capital increase	0	0	0	0
Share option scheme	617	2 704	-1 294	12 939
Comprehensive income in the period	-6 697	-25 048	-55 095	-88 391
Equity at end of period	57 403	113 792	57 403	113 792

CASH FLOW

<i>(in NOK '000)</i>	Q4 2022	Q4 2021	FY 2022	FY 2021
Ordinary profit before taxes	-6 697	-25 048	-55 095	-88 391
Depreciation, amortisation and write off	158	649	6 406	2 541
Leasing interest cost	19	10	78	38
Share options	617	2 704	-1 294	12 939
Currency gain (-)/ loss (+) not related to operations	37	1 735	-198	2 529
Changes in working capital and other non-cash adjustments	-4 574	2 458	-8 938	2 036
Cash flow from operating activities	-10 439	-17 492	-59 041	-68 307
Acquisition of non-current assets	0	0	0	-341
Net cash flow from investing activities	0	0	0	-341
Cash flow from financial activities				
Payment principal portion of lease liabilities	-152	-168	-678	-673
Net proceeds from share issues	0	0	0	0
Net cash flow from financial activities	-152	-168	-678	-673
Net change in cash during the period	-10 591	-17 660	-59 719	-69 321
Exchange rate effect on bank deposits in foreign currency	-37	-1 735	198	-2 529
Cash and cash equivalents at the beginning of the period	67 224	135 513	116 118	187 967
Cash and cash equivalents at the end of the period	56 596	116 118	56 596	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. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release. The technology may also be used to enhance the immunological response of vaccines and for bioprocessing. 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.

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 enhance the delivery of nucleic acids (fimaNAC) and potentiate the effect of intratumoural immunotherapy (fimaVACC). The fimaVACC programme has completed a Phase I study in healthy subjects, which has provided scientific proof-of-concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fimaNAC 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.

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 16 February 2023.

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 31, 2021.

5. Earnings per share

	Q4 2022	Q4 2021	FY 2022	FY 2021
Result allocated to shareholders (in NOK '000)	-6 697	-25 048	-55 095	-88 391
Weighted average of outstanding shares (in NOK '000)	37 326	37 326	37 326	37 326
Earnings per share (NOK per share)	-0.18	-0.67	-1.48	-2.37

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. Per end of Q4 2022 there are 570k 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	0	1 412	4 750	0	6 162
Total receivables	0	1 412	4 750	0	6 162

Most of the short-term receivables relates to accrued, not received government grants from the tax incentive scheme (SkatteFUNN).

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 December a positive accounting effect of NOK 0.2 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 2021 was NOK 2.5 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

	Q4 2022	Q4 2021	FY 2022	FY 2021
Clinical studies	1 455	17 590	32 442	57 204
Pre-clinical studies	2 334	1 794	7 257	6 966
CMC and equipment	519	678	2 100	3 332
Patents	793	854	2 958	4 205
Other costs	0	0	0	0
Total	5 100	20 917	44 756	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 156.4 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:

Expiry date	Exercise price in NOK per share option	Number of share options	
		31.12.2021	31.12.2022
2022 - Q3	21.48	310 000	-
2024 - Q3	25.78	300 000	150 000
2025 - Q3	50.36	520 000	130 000
2026 - Q3	19.41	485 000	150 000
2027 - Q3	1.90	-	570 000
Total		1 615 000	1 000 000

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 1,000,000 have been granted by the Board of Directors per end of the quarter.

A total of 1,025,000 previously granted share options have lapsed or expired during 2022. The accounting effect of lapsed share options is a cost-reversal of NOK 7.2 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				Total holdings	
	31.12.2021	Allocated	Lapsed	Exercised	Expired	31.12.2022
Ronny Skuggedal, CEO / CFO	190 000	220 000	0	0	50 000	360 000
Anders Høgset, CSO	190 000	120 000	0	0	60 000	250 000
Kristin Eivindvik, CDO	110 000	20 000	0	0	20 000	110 000
Amir Snapir, former CMO*	150 000	0	150 000	0	0	0
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	1 065 000	360 000	575 000	0	130 000	720 000

*Former CMO, Amir Snapir left the company in September

**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	-	-	-
31.12.2022	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 around 5,900 shareholders at end of the year.

10 largest shareholders per 31 December 2022:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 910 443	10,48 %
MP PENSJON PK	2 185 801	5,86 %
Myrlid AS	2 034 463	5,45 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
GRESSLIEN, Odd R.	938 800	2,52 %
Nordnet Bank AB	809 677	2,17 %
CLEARSTREAM BANKING S.A.	502 381	1,35 %
RAVI INVESTERING AS	500 000	1,34 %
Jandersen Kapital AS	470 000	1,26 %
BNP Paribas	428 283	1,15 %
Total 10 largest shareholders	12 862 263	34,46 %
<i>Others</i>	<i>24 464 127</i>	<i>65,54 %</i>
<i>Total</i>	<i>37 326 390</i>	<i>100,00 %</i>

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

Name	Position	No. of shares	
		31.12.2021	31.12.2022
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	8 000
Andrew Hughes	Board member	0	0
Per Walday**	Former CEO	72 700	NA
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CEO,CFO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Ludovic Robin***	Former CBO	0	NA
Amir Snapir****	Former CMO	0	NA
Total		378 336	299 628

*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

****Amir Snapir, former CMO left the company in September 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. In December 2022 the lease office space was reduced, and the right to use asset and future lease obligations are reduced accordingly.

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 FY 2022	0
Disposal Q4 2022 at reduction of lease area	-531
Acquisition costs 31.12.2022	3 151
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation FY 2021	620
Depreciation FY 2022	618
Accumulated depreciation and impairment as of 31.12.2022	2 447
Total right to use assets - office lease as of 31.12.2022	705
Lower of remaining lease term or economic life	2 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 FY 2022	-682
Derecognition at reduction of lease area Q4 2022	-531
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 FY 2022	76
Total lease liabilities for office as of 31.12.2022	770
Whereof:	
Short term lease liabilities < 1 year	443
Long term lease liabilities > 1 year	327

(in NOK 1,000)

Income statement effects – office lease	Q4 2022	Q4 2021	FY 2022	FY 2021
Depreciation of right to use asset	-155	-151	-618	-620
Operating expenses for short-term leases	0	0	0	0
Effect on Operating results net of tax	-155	-151	-618	-620
Interest expenses on the lease liabilities	-19	-10	-76	-40
Effect on Net financial result net of tax	-174	-161	-694	-660
Comprehensive income effect net of tax	-174	-161	-694	-660

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 was depreciated in full in 2022.

Equipment	31.12 2022	31.12 2021
Carrying value at the beginning of the period	5 806	7 388
Acquisitions	0	341
Depreciation	16	1 922
Write-down	5 772	-
Carrying value at the end of the period	18	5 806

17. Subsequent events

PCI Biotech is not aware of any post-closing events which could materially influence this interim financial statement.

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
CCA:	Cholangiocarcinoma – Bile duct cancer
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fimaNAC:	PCI Biotech's development program for delivery of nucleic acids
fimaVACC:	PCI Biotech's development program for a vaccination technology
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
RELEASE:	Name of PCI Biotech's study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
NOK:	Norwegian kroner
FY:	Financial year (1 st January – 31 st December)
1H:	First half year (1 st January – 30 th June)
2H:	Second half year (1 st July – 31 st December)
Q1:	First quarter (1 st January – 31 st March)
Q2:	Second quarter (1 st April – 30 th June)
Q3:	Third quarter (1 st July – 30 th September)
Q4:	Fourth quarter (1 st October – 31 st December)
YTD:	Year to date

FINANCIAL CALENDAR

Q4 Report 2022	17 February 2023
Q1 Report 2023	12 May 2023
Q2 Report 2023	31 August 2023
Q3 Report 2023	22 November 2023
Annual Report 2022	28 April 2023

Please note that the financial calendar may be subject to changes. PCI Biotech will for future quarterly reports disclose more condensed financial information, tailored to its operations and effective from Q1 2023.

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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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