



**FOURTH QUARTER
AND PRELIMINARY
FULL YEAR REPORT**

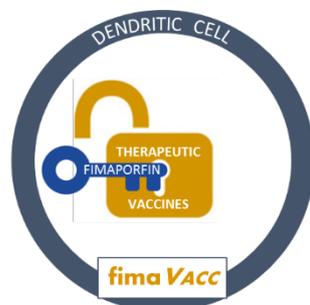
2021

*Enabling
intracellular
delivery*



LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

TRIGGERED ENDOSOMAL RELEASE



Enhancing cellular immune responses important for therapeutic vaccines



Providing a delivery solution for 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 the 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.

PCI Biotech's lead programme fimaVACC 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 were successfully verified in humans through an extensive Phase I study in healthy volunteers and a Phase II study is in planning with the aim to demonstrate enhancement of immunotherapy for treatment of solid tumours. The second programme fimaNAC utilises the proven potential of the PCI technology for intracellular delivery of therapeutic 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 fimaNAC programme is focused on selected applications well suited to the specific strengths of the PCI technology and with several research collaborations established.

Highlights 2021

fimaCHEM

- The RELEASE trial was closed to recruitment in January 2022 due to changes in the competitor situation that renders the trial challenging to complete and potentially inadequate for approval
- Approximately 30% of the 41 enrolled patients will continue to receive study treatments for up to 6 months, enabling a swift wind-down of the trial
- The trial results will be analysed to evaluate how the data can be utilised going forward

fimaVACC

- The programme is progressing towards initiation of a Phase II clinical proof-of-concept study, with product definition and overall study design clarified following comprehensive consultations with international experts
- US patent granted for the use of fimaVACC in combination with immune checkpoint inhibitors

fimaNAC

- Focused development plan initiated based on strategic research and collaborations, targeting applications suited to the specific strengths of the PCI technology
- Encouraging data on enhanced delivery of mRNA for various medical applications presented at the UK based 12th Annual RNA Therapeutics Virtual Conference
- Established extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics
- In January 2022, PCI Biotech entered into a preclinical collaboration with the South Korean company MDimune, developing innovative drug delivery technologies for modifying cellular and disease processes

Corporate

- Significantly strengthened the organisation with three highly skilled individuals; an experienced clinical operational leader, and two key employees within clinical science and business development focusing on fimaVACC and fimaNAC

Key figures

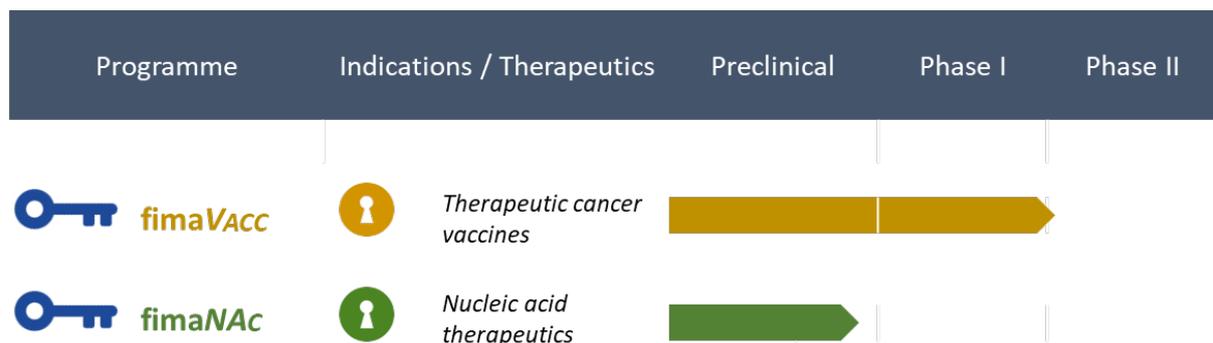
<i>(In NOK 1,000)</i>	2021 Q4	2020 Q4	2021 FY	2020 FY
Other income	1 188	1 567	6 273	7 368
Operating expenses	20 917	22 927	92 302	89 488
Operating results	-23 272	-21 361	-86 029	-82 121
Net financial result	-1 776	-5 104	-2 362	9 881
Comprehensive income	-25 048	-26 464	-88 391	-72 239
Cash & cash equivalents	116 118	187 967	116 118	187 967
Cash flow from operating activities	-17 492	-16 020	-68 307	-77 391

2021 in review – managing RELEASE and preparing the ground for fimaVacc

A lot of effort was put into accelerating the RELEASE study in bile duct cancer last year, as the Covid-19 pandemic continued to have a strong negative impact on study progress with fluctuating recruitment through the year. The strong efforts resulted in enhanced screening and enrolment of bile duct cancer patients towards the end of the year, with the ambitious target of 12 patients included per quarter being reached in Q4. However, the clinical performability and business opportunity for the RELEASE programme changed radically in January 2022 when a clinical pivotal study (TOPAZ-1) with an immune checkpoint inhibitor reported overall positive results, with clinically meaningful benefit on progression free survival and overall survival. The results presented at ASCO GI in January 2022 showed significant clinical benefit in the RELEASE patient population. This is expected to quickly change the standard of care for patients with extrahepatic cholangiocarcinoma. These results are positive news for patients but will unfortunately render the RELEASE study challenging to complete and potentially inadequate for approval, and the study was therefore closed to recruitment late January 2022. Stopping RELEASE was a hard decision to make and we would like to thank all contributors to the study. It has been a tremendous effort, not least by the enrolled patients, the clinical sites, and our investors, willing to contribute to the benefit of future patients and their relatives. We are now focusing on a swift and cost-effective closing of the study, whilst ensuring that any potential residual value is captured.

The **fimaVacc** programme is progressing towards development of a defined vaccine product candidate and the next clinical phase. It is now the lead programme in the company and a group of international expert investigators has been established to support the development. The aim is to combine the **fimaVacc** technology with relevant immunomodulation therapy, initially focusing on the most apposite indication before a potential broadening of the deployment of this versatile platform. To this end, another important patent was added to the **fimaVacc** IP portfolio by the US granting a patent covering combination with relevant immune checkpoint inhibitors. Positive collaborative data for the **fimaNac** technology for intracellular delivery of nucleic acid therapeutics were presented in 2021. These data have helped boost further interest in the **fimaNac** technology and two collaborations were initiated with South Korean companies. A strategic review of the **fimaNac** technology and collaborative opportunities resulted in the initiation of a focused development plan targeting applications suited to the specific strengths of the technology. The organisation was also reinforced with specific expertise to support the further development of both **fimaVacc** and **fimaNac**.

Operational review and development programmes overview



Implications of the COVID-19 pandemic

During 2021 the company's operations were affected by the pandemic mainly by challenges with screening of patients into the RELEASE trial. After the decision to close down the RELEASE trial, made in January 2022, there are per date of this report no corporate operations that are materially impacted by the COVID-19 pandemic.

fimaCHEM

The company decided in January 2022 to close the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities with both fimaVACC and fimaNAC assets.

The decision to close the RELEASE study is based on recent 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 is the intended patient population of the RELEASE trial. Such a change in the standard of care treatment will render the RELEASE trial challenging to complete and the clinical results potentially inadequate for approval and significantly diminish the opportunity for PCI Biotech's treatment approach in this patient population.

The impact of the recent clinical trial results presented at ASCO GI has been 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 RELEASE trial has been a tremendous 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 will now focus on a swift and cost-efficient closing process of the RELEASE trial. The efficacy follow-up schedule and closure plan with timelines and costs are currently under evaluation with the CRO. Almost 60% of the sites are being closed immediately, while efficacy will be monitored and collected for ongoing patients for the earliest possible closure of all sites with patients. The trial enrolled a total of 41 patients, of which around 30% will continue to receive the study treatments for a duration of up to six months. This should enable a swift wind-down of RELEASE, allowing the company to reallocate resources to the other drug development programmes. The results of the RELEASE trial will be compiled and analysed for assessment of how they can be utilised going forward.

fimaVACC

The fimaVACC technology aims to enhance immunotherapy responses and has proven 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 volunteers in a Phase I study and the next development step will now be a Phase II clinical proof-of-concept study for enhancement of immunotherapy in a relevant cancer disease with solid tumours. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based immunotherapy technologies.

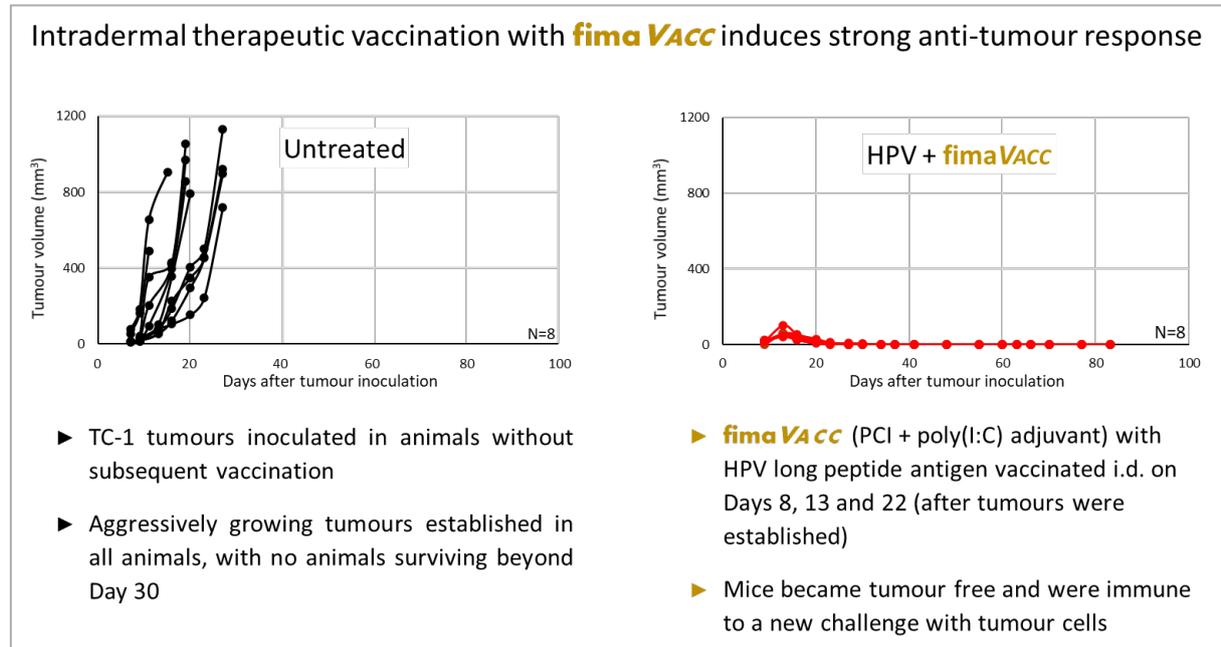
fimaVACC provides highly desired features for therapeutic vaccination technologies:

- ✓ Increased number of responders
- ✓ Enhanced T-cell responses
- ✓ Improved T-cell functionality

Extensive preclinical data suggest strong T-cell induction

The mechanism of action and the effect of the fimaVACC technology with peptide- and protein-based vaccines have been extensively elucidated in preclinical experiments. Strong synergistic effects have been shown in combination with several types of adjuvants, not least toll-like-receptor (TLR) agonists, for which combination PCI Biotech has use patents granted in major markets. Preclinical experiments have shown that intradermal injection of this combination with relevant antigens has the power to

eradicate aggressively growing inoculated tumours in mice, such as the HPV driven TC-1 tumours (see figure below).



Treatment with immune checkpoint inhibitors (ICI) has revolutionised cancer immunotherapy, as this class of drugs may induce long-lasting effects in those patients responding to treatment. Unfortunately, most patients do not respond to ICI therapy and different treatment combination strategies are explored with the aim to increase the number of patients responding. Combining ICIs with therapeutic cancer vaccines that induce relevant immune responses, such as induction of T-cells against the tumour cells, is regarded as one of the most promising strategies. In preclinical studies, adding vaccination with **fimaVACC** to ICIs can significantly improve the anti-tumour effect in tumour-bearing mice and a patent for this combination is granted in the US, while still pending in Europe and Asia.

Successful clinical proof-of-concept for T-cell induction in healthy volunteers

PCI Biotech has successfully translated the immune response characteristics of **fimaVACC** into humans through a Phase I study in healthy volunteers, using both peptide- and protein-based antigens. The immune results provide Proof-of-Concept and clinical support of **fimaVACC**'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. More than 90 subjects were included, and safety and tolerability of intradermal treatment with **fimaVACC** was established across a wide range of doses.

The Phase I results show a substantial increase in number of T-cell responders to HPV peptides already after two vaccinations, and a clear enhancement in the T-cell responses compared to the control group with a state-of-art vaccine adjuvant. The important CD8 responses were also more robust with **fimaVACC** and exhibited increased functionality compared to control.

Phase I in healthy volunteers published

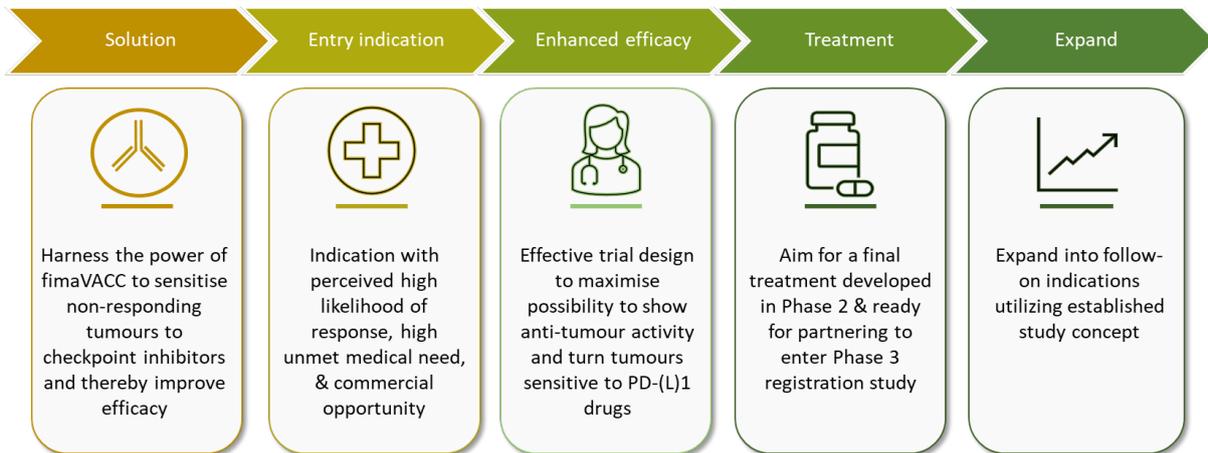
The full study results were published early January 2021 in *Frontiers in Immunology*¹, a high impact immunology journal. The study was performed in collaboration with international experts, including staff at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg.

¹ doi.org/10.3389/fimmu.2020.576756

Development strategy for the **fimaVacc** platform

The Phase I study provided proof-of-concept by demonstrating improvement of vaccine immunogenicity in healthy volunteers applying peptide- and protein-based vaccines. As a next development step, PCI Biotech is actively preparing for a Phase II clinical proof-of-concept study for therapeutic vaccination in a relevant cancer disease. The **fimaVacc** technology has potential to also enhance other vaccination technologies, such as mRNA.

The company has taken advice from a group of international experts to assess the best possible development opportunities across vaccination technologies and diseases. The aim is to leverage the expected strengths of the **fimaVacc** technology, such as combination with relevant immunomodulation therapy and application of both intradermal and intratumoural vaccine delivery, initially focusing on a study in recurrent/metastatic head and neck cancer before a potential broadening of the deployment of this versatile platform. There is a high unmet medical need in head and neck cancer, as most of these patients progress within 6 months of starting first line treatment with a PD-1 immune checkpoint inhibitor. A network of international expert investigators has been established and preparations are currently focused on product activities and the study protocol. Further information will be announced when all key aspects of the study have been discussed and endorsed by the clinical expert group.



To drive and support the development of **fimaVacc** and **fimaNac**, PCI Biotech has in 2021 further strengthened the organisation with a new Clinical Science Director that commenced 1st August. Dr Nina Gustafsson comes from a position as Assistant Professor and Group Leader at the Karolinska Institute (KI) in Stockholm, Sweden. Her research group at KI focused on uncovering novel links between cancer metabolism and genome stability to be exploited therapeutically, with the goal of developing novel anti-cancer therapies. Her R&D expertise and experience will further strengthen the team and she will play a key role in the development of both **fimaVacc** and **fimaNac**.

US patent in combination with checkpoint inhibitors

In June, a new patent was granted by the US Patent and Trademark Office (USPTO). The US patent covers the use of **fimaVacc** in combination with important classes of ICIs and an important type of immunological adjuvants (a class of Toll like receptor agonists). This US patent secure protection until 2036 while the patent application is still pending in Europe and key Asian markets.

Publication of preclinical BCG vaccination results

In January 2022, positive results from preclinical studies on BCG vaccination performed in collaboration with The University of Zurich and ETH Zurich were accepted for publication 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". Infectious diseases are not within PCI Biotech's core focus areas, but the results support our general understanding of **fimaVacc**'s mode of action and the potential of the technology.

Research and development supported by a grant

The **fimaVACC** programme was supported by a government grant from the Research Council of Norway (BIA-programme) distributed over four years, ending first half of 2021, with an accumulated support of NOK 13.4 million.

Immunotherapy with the **fimaVACC** technology

The pharmaceutical industry has long recognised the potential of therapeutic cancer vaccination, i.e. vaccines that treat cancer by inducing or strengthening the body's own immune response. The potential of combining cancer vaccination with immune checkpoint inhibitors has triggered a renewed interest in therapeutic cancer vaccines over the past years.

However, key issues remain to be solved, and the task of improving the immunogenicity of vaccine candidates is a main priority within the immunotherapy field. PCI Biotech believes the **fimaVACC** technology may play a key role in solving this challenge.

Effective induction of cytotoxic T-cells will be critical to realise the potential of therapeutic cancer vaccines, and today's vaccines often fail to generate such responses. One of the main reasons is likely insufficient delivery of vaccine antigens to the appropriate presentation pathway in the immune cells. The **fimaVACC** technology has the potential to effectively enhance intracellular delivery and vaccine presentation through these pathways.

fimaNAC

The **fimaNAC** programme provides a targeted intracellular delivery technology for many potential therapeutic applications with different classes of nucleic acids. It is currently a preclinical stage collaborative programme, with established research collaborations with companies developing nucleic acid based therapies. The results from these collaborations suggest that the **fimaNAC** technology provides an appealing intracellular delivery solution for certain applications within this emerging class of therapeutics. Based on these results and other strategic considerations, the Company focus on selected applications suited to the specific strengths of the PCI technology. The initial focus will primarily be on clinical conditions which are easily illuminable and have supporting preclinical results, such as skin applications where preclinical experiments suggest substantial enhancement of delivery and transfection, with excellent spatial specificity.

Research collaborations

PCI Biotech has an active collaborative strategy for **fimaNAC** and **fimaVACC**. The collaboration partners include MDimune, OliX Pharmaceuticals, Immunicum, eTheRNA immunotherapies, IMV and Aposense. In these collaborations, partners are exploring synergies between their proprietary technologies and the PCI technology, with potential for further expansion of the partnerships. Previous collaborative interactions and results with other key players 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 February 2021 encouraging collaborative data on the delivery of RNA molecules and on the use of the **fimaNAC** delivery technology in the exciting field of RNA based therapies were presented at the 12th Annual RNA Therapeutics Virtual Conference, a UK based online event. The presented results suggest that the **fimaNAC** technology provides an appealing intracellular delivery solution for certain applications within this class of therapeutics. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of immunotherapy. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAC** programme. In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics. In January 2022, PCI Biotech entered into a research collaboration with MDimune, a South Korean biotech company developing a versatile drug delivery system based on nanosized vesicles obtained from cells. In both these partnerships, the

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

Corporate

Financial review

Income Statement

(Figures in brackets = same period 2020 unless stated otherwise)

The Group has not recorded any revenues for the financial years 2021 or 2020. Grants received from public sources, such as the Norwegian Research Council "BIA" and "SkatteFUNN", are recorded as other income. Q2 2021 represented the end of the BIA grant. Other income for Q4 and full-year (FY) 2021 amounted to NOK 1.2 million (NOK 1.6 million) and NOK 6.3 million (NOK 7.4 million) respectively.

Research and development (R&D) expenses for Q4 and FY 2021 ended at NOK 20.9 million (NOK 21.4 million) and NOK 71.7 million (NOK 75.6 million) respectively. General and administrative (G&A) expense for Q4 and FY 2021 ended at NOK 3.5 million (NOK 1.6 million) and NOK 20.6 million (NOK 13.9 million) respectively. The change in G&A for full-year 2021 compared to last year, is partly driven by the increased number of employees, but mainly due to accounting effect fluctuations for the share option scheme, without direct cash flow effects. Operating expenses for Q4 and full-year 2021 were NOK 24.5 million (NOK 22.9 million) and NOK 92.3 million (NOK 89.5 million) respectively. Operating expenses are mainly driven by the R&D activity level and the pivotal fimaCHEM trial (RELEASE) was the main cost driver for 2021 and 2020.

Net financial results for Q4 and full-year 2021 were NOK -1.8 million (NOK -5.1 million) and NOK -2.4 million (NOK 9.9 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 pivotal RELEASE study.

Net loss for Q4 and full-year 2021 were NOK 25.0 million (NOK 26.5 million) and NOK 88.4 million (NOK 72.2 million) respectively. The main driver of the change for full-year 2021 compared to last year was a net positive financial result in 2020, resulting from the above-mentioned exchange rate fluctuations.

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 116.1 million at year-end 2021, compared to NOK 188.0 million per year-end 2020. 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 -17.5 million for Q4 2021 (NOK -16.0 million), and NOK -68.3 million (NOK -77.4 million) for FY 2021. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 1.7 million negative for Q4 2021 (NOK 5.4 million negative). For the full year, the effect was 2.5 million negative in 2021, compared to 8.5 million positive for 2020.

Other

Risks and uncertainty factors for 2021

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 2020, the most important risks the company is exposed to in 2021 are associated with 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 2020, which also covers implications of the COVID-19 pandemic.

Further strengthening the organisation

The company has strengthened the team for **fimaVacc** with a new Clinical Science Director, Dr Nina Gustafsson, that commenced 1st August, who also will contribute to the further development of **fimaNAC**. For business development purposes a new position as Scientific Alliance and Business Development Manager is established, that commenced 1st October. The company has also strengthened the operational clinical team with an experienced Clinical Project Director, Maria Norling, that commenced 1st July. The full PCI Biotech team counts 17 employees per year-end.

Collaboration with Norwegian Institute for Marine Research (NIMR)

NIMR (Havforskningsinstituttet) received in 2021 NOK 4.5 million 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.

Employee share option scheme

In accordance with the authorisation granted by the Annual General Meeting 28 May 2021, the Board of Directors of PCI Biotech Holding ASA awarded a total of 485,000 share options to key employees in September 2021. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 19.41, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date.

The share options are granted without consideration and are subject to service based vesting conditions, with a three-year vesting term and one-third vest each year. The share options are lapsing in Q3 2026. Further details about the share option program are described in PCI Biotech's remuneration policy.

Post-closing events

The company decided in January 2022 to close the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities with both the **fimaVacc** and **fimaNAC** assets. More details around the decision are described under the operational review for the **fimaCHEM** programme.

PCI Biotech will now focus on a cost-efficient closing process of the RELEASE trial. The trial enrolled a total of 41 patients, of which around 30% will continue to receive the study treatments for a duration of up to six months. This should enable a swift wind-down of RELEASE, allowing the company to reallocate resources to the other drug development programmes. The results of the RELEASE trial will be compiled and analysed for evaluation of how they can be utilised going forward.

The current cost base for the trial will be reduced over time in 2022 and the cash position per year-end 2021 enables an estimated financial run-way for the company well into 2023. From a financial reporting perspective, the stop-decision is a non-adjusting after the reporting date event. There is one balance sheet item under Non-current assets that will be impacted by the decision to close the trial in January 2022. Property, plant and equipment include a device specifically designed to be used in the trial, and the post-decision value of the device is considered low. Per year-end 2021 these devices were recognised with a carrying value of NOK 5.8 million in the balance sheet, which will be depreciated in full in January 2022 without cash-flow effect.

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. Supported also by external collaboration partners' opinion, the PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (**fimaVACC**) and nucleic acid therapeutics (**fimaNAC**).

An extensive Phase I study in healthy volunteers provided affirmative results on translation of the **fimaVACC** technology into humans and key data to support the programme's further development. A Phase II study is in planning for development of a defined **fimaVACC** product, aiming to demonstrate enhanced response to immunotherapy in patients with recurrent/metastatic head and neck cancer.

The **fimaNAC** programme continues to follow a collaborative approach, by development of treatment applications in the most attractive areas for the technology and pursuing out-licensing opportunities.

The **fimaCHEM** programme was in 2021 in pivotal clinical development for the treatment of inoperable extrahepatic bile duct cancer in the RELEASE study. Recently announced positive pivotal clinical results with an immune checkpoint inhibitor are expected to quickly change the standard of care, which will render RELEASE challenging to complete. The study was therefore closed to recruitment in January 2022 and results will be compiled and analysed for evaluation of how they can be utilised going forward.

In short, the main priorities of PCI Biotech at this time are to:

- Implement the strategy for the next phase of development for **fimaVACC**, towards clinical proof-of-concept in recurrent/metastatic head and neck cancer patients
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform
- A swift and cost-efficient closing process of the RELEASE study, with compilation and analysis of the results for evaluation of potential value to the company

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 17 February 2022

Hans Peter Bøhn
Chairman (sign)

Christina Herder
Director (sign)

Hilde Furberg
Director (sign)

Andrew Hughes
Director (sign)

Lars Viksmoen
Director (sign)

Per Walday
CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS (in NOK '000)	Note	Q4 2021	Q4 2020	FY 2021	FY 2020
Other income	6	1 188	1 567	6 273	7 368
Research and development	8,16	20 917	21 373	71 707	75 571
General and administrative	15	3 543	1 554	20 595	13 917
Operating expenses		24 460	22 927	92 302	89 488
Operating results		-23 272	-21 361	-86 029	-82 121
Financial income and expenses					
Financial income		175	362	752	10 796
Financial expenses		1 951	5 466	3 113	915
Net financial result	7	-1 776	-5 104	-2 362	9 881
Profit/Loss before income tax		-25 048	-26 464	-88 391	-72 239
Income tax	9	0	0	0	0
Net profit/loss		-25 048	-26 464	-88 391	-72 239
Other comprehensive income		0	0	0	0
Total comprehensive income	5	-25 048	-26 464	-88 391	-72 239

Balance sheet (in NOK '000)	Note	31.12 2021	31.12 2020
Non-current assets			
Property, plant and equipment	16	5 806	7 388
Right to use asset	15	1 854	605
Total non-current assets		7 660	7 994
Current assets			
Short term receivables	7	12 200	13 162
Cash & cash equivalents	7	116 118	187 967
Total current assets	14	128 318	201 129
Total assets		135 978	209 123
Equity and liabilities			
Equity			
Paid in capital	10,11	562 443	562 443
Other reserves		-448 651	-373 199
Total equity		113 792	189 244
Long-term liabilities			
Other long-term liabilities		0	32
Lease liabilities	15	1 277	0
Total long-term liabilities	13	1 277	32
Short term liabilities			
Trade debtors		3 745	5 191
Lease liabilities	15	629	673
Other short-term liabilities	7,12	16 535	13 983
Total short-term liabilities		20 909	19 847
Total liabilities	14	22 186	19 879
Total equity and liabilities		135 978	209 123

CHANGE IN EQUITY

<i>(in NOK '000)</i>	Q4 2021	Q4 2020	FY 2021	FY 2020
Equity at beginning of the period	136 136	212 080	189 244	254 828
Capital increase	0	0	0	316
Share option scheme	2 704	3 629	12 939	6 339
Comprehensive income in the period	-25 048	-26 464	-88 391	-72 239
Equity at end of the period	113 792	189 244	113 792	189 244

CASH FLOW

<i>(in NOK '000)</i>	Q4 2021	Q4 2020	FY 2021	FY 2020
Ordinary profit before taxes	-25 048	-26 464	-88 391	-72 239
Depreciation, amortisation and write off	649	616	2 541	2 208
Leasing interest cost	10	19	38	75
Share options	2 704	3 629	12 939	6 339
Currency gain (-) / loss (+) not related to operations	1 735	5 356	2 529	-8 526
Changes in working capital and other non-cash adjustments	2 458	824	2 036	-5 248
Cash flow from operating activities	-17 492	-16 020	-68 307	-77 391
Acquisition of non-current assets	0	-722	-341	-3 919
Net cash flow from investing activities	0	-722	-341	-3 919
Cash flow from financial activities				
Payment principal portion of lease liabilities	-168	-167	-673	-668
Net proceeds from share issues	0	0	0	316
Net cash flow from financial activities	-168	-167	-673	-352
Net change in cash during the period	-17 660	-16 910	-69 321	-81 662
Exchange rate effect on bank deposits in foreign currency	-1 735	-5 356	-2 529	8 526
Cash and cash equivalents at the beginning of the period	135 513	210 233	187 967	261 103
Cash and cash equivalents at the end of the period	116 118	187 967	116 118	187 967

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 (fimaVACC) and delivery of nucleic acids (fimaNAC). The fimaVACC programme has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. A Phase II study is in planning with the aim to demonstrate enhancement of immunotherapy for treatment of solid tumours. 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. A third development programme (fimaCHEM) had until recently a pivotal clinical trial in inoperable extrahepatic bile duct cancer, the RELEASE trial. This trial was closed to recruitment in 2022 due to a recent announcement of positive pivotal results with an immune checkpoint inhibitor in this patient population, which is expected to change the standard of care and render the trial challenging to complete and potentially inadequate for approval.

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 2020 (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 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 17 February 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 2021 is consistent with the consolidated financial statements for the year ended 31 December 2020.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2021 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the consolidated financial statements for 2020.

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, 2020.

5. Earnings per share

	Q4 2021	Q4 2020	FY 2021	FY 2020
Result allocated to shareholders (in NOK '000)	(25 048)	(26 464)	(88 391)	(72 239)
Weighted average of outstanding shares (in NOK '000)	37 326	37 226	37 326	37 285
Earnings per share (NOK per share)	-0,67	-0,71	-2,37	-1,94

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. Per year-end 2021 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 grants from the Norwegian Research Council (BIA) and 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 2020 and 2021 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	7 068	354	28	4 750	12 200
Total receivables	7 068	354	28	4 750	12 200

Most of the short-term receivables relates to accrued, not received government grants (BIA) and 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.

For the year 2021 a negative accounting effect of NOK 2.5 million has been charged as financial expenses, resulting from converting Euro cash deposits into NOK as functional currency for the interim report. The effect for 2020 was NOK 8.5 million positive.

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 2021	Q4 2020	FY 2021	FY 2020
Clinical studies	17 590	16 618	57 204	57 761
Pre-clinical studies	1 794	1 969	6 966	6 607
CMC and equipment	678	1 612	3 332	6 637
Patents	854	1 174	4 204	4 566
Other costs	0	0	0	0
Total	20 917	21 373	71 707	75 571

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 142.9 million in 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	
		31.12.2020	31.12.2021
2022 - Q3	21.48	325 000	310 000
2024 - Q3	25.78	320 000	300 000
2025 - Q3	50.36	540 000	520 000
2026 - Q3	19.41	0	485 000
Total		1 185 000	1 615 000

The current authorisation, granted by the Annual General Meeting on 28 May 2021, for the employee share option program allows for a total of 2,790,000 share options, of which 1,615,000 have been granted by the Board of Directors per end of the quarter.

In accordance with the authorisation granted by the Annual General Meeting 28 May 2021, the Board of Directors of PCI Biotech Holding ASA awarded a total of 485,000 share options to key employees on 6th September 2021. Each share option gives the right to subscribe for or acquire one share per option

(after PCI Biotech Holding ASA's choice), at a strike price of NOK 19.41, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2026.

The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value was assessed to NOK 7.5 million, which will be charged to the profit and loss statement over the three-year vesting period for the share options.

Of the 485,000 share options, a total of 340,000 share options were allotted to primary insiders as disclosed in the following table.

Overview share options, Senior executives	Total holdings					Total holdings 31.12.2021
	31.12.2020	Allocated	Lapsed	Exercised	Expired	
Per Walday, CEO	225 000	70 000	0	0	0	295 000
Ronny Skuggedal, CFO	140 000	50 000	0	0	0	190 000
Anders Høgset, CSO	150 000	40 000	0	0	0	190 000
Kristin Eivindvik, CDO	70 000	40 000	0	0	0	110 000
Lucy Wabakken, CDO (acting)	120 000	40 000	0	0	0	160 000
Ludovic Robin, CBO	90 000	40 000	0	0	0	130 000
Amir Snapir, CMO	90 000	60 000	0	0	0	150 000
Total	885 000	340 000	0	0	0	1 225 000

11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2020	37 326 390	3.00	111 979 170
Transactions	-	-	-
31.12.2021	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 2021 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 year.

10 largest shareholders per 31 December 2021:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,07 %
MYRLID AS	2 110 501	5,65 %
MP PENSJON PK	1 686 729	4,52 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
NORDNET LIVSFORSIKRING AS	942 333	2,52 %
GRESSLIEN, ODD R.	852 000	2,28 %
NORDNET BANK AB	728 409	1,95 %
JANDERSEN KAPITAL AS	470 000	1,26 %
BERG-LARSEN, ALEXANDER	461 148	1,24 %
FORENEDE FORVALTNING AS	380 467	1,02 %
Total 10 largest shareholders	12 474 445	33,42 %
<i>Others</i>	<i>24 851 945</i>	<i>66,58 %</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	
		31.12.2020	31.12.2021
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	CEO	72 700	72 700
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CFO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Lucy Wabakken, and related parties	CDO (acting)	10 008	10 008
Ludovic Robin	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.

12. Other short-term liabilities

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

13. Long-term liabilities

Total 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

Cash and cash equivalents are measured as financial instruments at fair value through other comprehensive income (OCI). The carrying amount of cash and cash equivalents is applied and disclosed since this approximately equals to fair value since these instruments have a short term to maturity. Financial assets and liabilities related to right to use assets are measured as financial instruments at amortised cost. For all other financial assets and liabilities non-discounted values are applied and disclosed, due to short term to maturity and/or low values.

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

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator at Ullernchausséen 64 Oslo, Norway. The original lease runs to 31 December 2021 with an option for additional three more years. PCI Biotech exercised this lease option in 2021 and the lease now runs to year-end 2024. The lease agreement is subject to annual adjustment according to changes in the consumer price index. The minimum lease after exercise of the lease option for the additional three years is estimated to NOK 1.9 million (discounted contractual payments). Payments of principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects. Lease liabilities due in more than 12 months are disclosed as long-term lease liabilities. PCI Biotech applies the short-term lease recognition exemption for leases related to office equipment, parking facilities at the office and a flat in Oslo available for disposition for foreign employees. Lease payments for this category of leases are consequently charged directly through profit and loss.

All figures in NOK '000

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions Q1 2021	1 867
Acquisitions Q2 2021	0
Acquisitions Q3 2021	0
Acquisitions Q4 2021	0
Acquisition costs 31.12.2021	3 682
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation Q1 2021	155
Depreciation Q2 2021	155
Depreciation Q3 2021	155
Depreciation Q4 2021	155
Accumulated depreciation and impairment as of 31.12.2021	1 828
Total right to use assets - office lease as of 31.12.2021	1 854
Lower of remaining lease term or economic life	3 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	1 813
Payments principal portion of the lease liability Q1 2021	-168
Payments principal portion of the lease liability Q2 2021	-168
Payments principal portion of the lease liability Q3 2021	-168
Payments principal portion of the lease liability Q4 2021	-168
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Interest expenses on the lease liability Q1 2021	10
Interest expenses on the lease liability Q2 2021	10
Interest expenses on the lease liability Q3 2021	10
Interest expenses on the lease liability Q4 2021	10
Total lease liabilities for office as of 31.12.2021	1 906
Whereof:	
Short term lease liabilities < 1 year	629
Long term lease liabilities > 1 year	1 277

(in NOK 1,000)

Income statement effects – office lease	Q4 2021	Q4 2020	FY 2021	FY 2020
Depreciation of right to use asset	-155	-154	-620	-605
Operating expenses for short-term leases	0	0	0	-170
Effect on Operating results net of tax	-155	-154	-620	-775
Interest expenses on the lease liabilities	-10	-19	-40	-144
Effect on Net financial result net of tax	-164	-173	-660	-920
Comprehensive income effect net of tax	-164	-173	-660	-920

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 have been acquired during 2020 and 2021. A linear depreciation method over the expected lifetime of five years for the equipment is applied. A non-adjusting event after the reporting period has made the lasers of no or low value by January 2022 and the carrying amount of NOK 5.8 million will be depreciated in full in 2022. See note 17 Subsequent events for more details.

Equipment	31.12 2021	31.12 2020
Carrying value at the beginning of the period	7 388	5 072
Acquisitions	341	3 919
Depreciation	1 922	1 603
Carrying value at the end of the period	5 806	7 388

17. Subsequent events

The company decided in January 2022 to close the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities with both the fimaVACC and fimaNAC assets. More details around the decision are described under the operational review for the fimaCHEM programme.

PCI Biotech will now focus on a cost-efficient closing process of the RELEASE trial. The trial enrolled a total of 41 patients, of which around 30% will continue to receive the study treatments for a duration of up to six months. This should enable a swift wind-down of RELEASE, allowing the company to reallocate resources to the other drug development programmes. The results of the RELEASE trial will be compiled and analysed for evaluation of how they can be utilised going forward.

The current cost base for the trial will be reduced over time in 2022 and the cash position per year-end 2021 enables an estimated financial run-way for the company well into 2023. From a financial reporting perspective, the stop-decision is a non-adjusting after the reporting date event. There is one balance sheet item under Non-current assets that will be impacted by the decision to close the trial in January 2022. Property, plant and equipment include a device specifically designed to be used in the trial, and the post-decision value of the device is considered low. Per year-end 2021 these devices were recognised with a carrying value of NOK 5.8 million in the balance sheet, which will be depreciated in full in January 2022 without cash-flow effect.

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
fimaCHEM:	PCI Biotech's development program for enhancement of generic chemotherapies
fimaNAC:	PCI Biotech's development program for delivery of nucleic acids
fimaVACC:	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 (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

Annual Report 2021	28 April 2022
Annual General Meeting	25 May 2022
Q1 Report 2022	11 May 2022
Q2 Report 2022	31 August 2022
Q3 Report 2022	23 November 2022

INVESTOR CONTACT

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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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