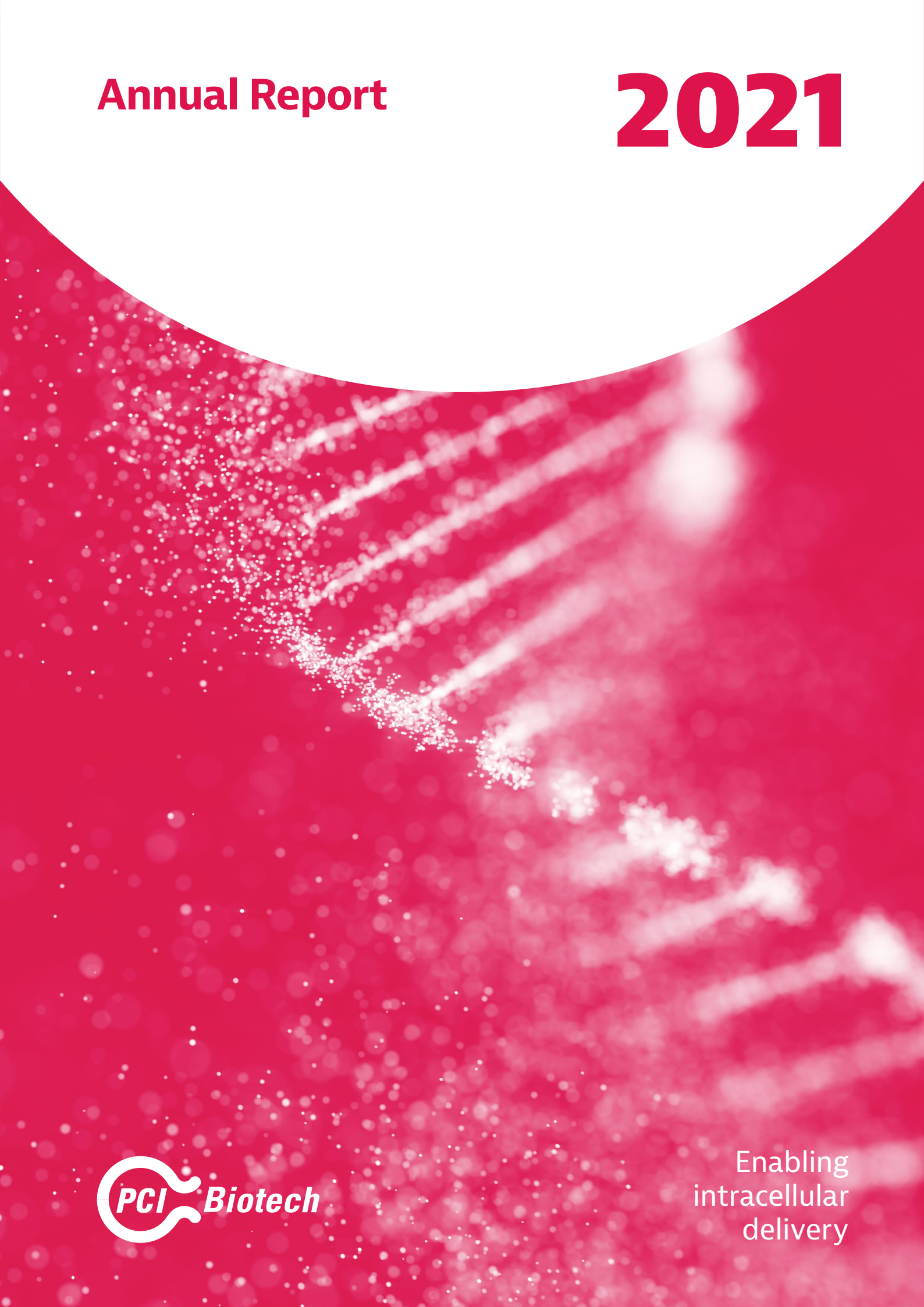
# Annual Report 2021



PCI Biotech

Enabling intracellular delivery

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# INTRODUCTION

## ABOUT PCI BIOTECH

PCI Biotech Holding ASA ("PCI Biotech" or "the Group" or "the Company") is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The Company is developing therapeutic products based on its proprietary photochemical internalisation (PCI) technology, which originates from world leading research at the Norwegian Radium Hospital. PCI Biotech's lead product candidate is the photosensitiser fimaporfin (Amphinex®) and the Company has an extensive collaboration with Norwegian and international hospitals and companies.

## OUR TECHNOLOGY

The PCI technology can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells, and can also be used as a platform that may both potentiate the effect of vaccines and enable macromolecules to reach intracellular targets. During 2021, PCI Biotech applied the technology to three distinct anticancer paradigms: fima*CHEM* (enhancement of chemotherapeutics for localised treatment of cancer), fima*VACC* (T-cell induction technology for therapeutic vaccination), and fima*NAC* (nucleic acid therapeutics delivery).

Several novel classes of drugs (e.g. certain immunotherapeutics) need access to the inside of their human target cells, such as tumour cells or immune cells, in order to be effective. Unfortunately, many of these substances are by nature encapsulated in so-called endosomes as they enter the target cell. Once inside the cell, most of the active compound may hence be trapped in the endosomes and therefore unable to exert its therapeutic effect. Pharmaceutical companies struggle to find effective methods to release drugs that are entrapped in this way and are actively searching for technologies that provide adequate drug release inside the target cells, in order to achieve the full therapeutic and commercial potential of their products.

The PCI technology platform consists of two elements: a proprietary small molecule photosensitiser (named fimaporfin) and a light source. The primary aim of PCI is to introduce drug molecules or macromolecules into the cytosol of the target cells. It is this drug or macromolecule that gives the biological effect in a PCI treatment, and the intended biological effect may range from cell killing (fima*CHEM*), through modification of gene expression (fima*NAC*) to enhanced antigen presentation (fima*VACC*). Needless to say, in the two latter approaches the aim is not to kill the target cells, but PCI is employed to give the cells new properties by modifying the intracellular trafficking of drugs/antigens.

For different applications, fimaporfin will be formulated differently and used at different doses e.g. intravenous injection in localised cancer treatment versus minute amounts administered into the skin in the vaccination setting. The light source may also be different for different applications. Red laser light is used in localised cancer treatment to achieve good tissue penetration, while a LED light may be used in vaccination, as deep light penetration may not be needed to reach antigen presenting cells (APC's) at the site of vaccination.

## BUSINESS AREAS FOR 2021

Recent advancements in cancer therapy, not least owing to the development of new classes of drugs, such as immunotherapeutics, imply a potential to significantly improve the prognosis for millions of patients. The potential of fimaporfin to improve the efficacy of anti-cancer agents has been convincingly shown in well-established preclinical models as well as in clinical trials, with the first clinical results being published in the renowned medical journal the Lancet Oncology. This was followed by a Phase Ib study in bile duct cancer patients that delivered encouraging early signs of tumour response and survival. Based on these positive findings, PCI Biotech focused during 2021 on developing three parallel programmes.

## INOPERABLE BILE DUCT CANCER AND fimaCHEM

The fimaCHEM programme aims to fulfil unmet medical needs by providing localised targeted enhancement of approved chemotherapies for the benefit of the many patients currently left without effective treatment options. Based on findings from a successful Phase Ib study in bile duct cancer patients, a single pivotal clinical trial, named the RELEASE study, was initiated in 2019 for inoperable extrahepatic bile duct cancer, a rare, but fatal disease with no cure.

PCI Biotech decided in January 2022 (after balance sheet date event) to close recruitment to the RELEASE study and focus the development efforts on the promising immunotherapy opportunities within fimaVACC and selected applications for the fimaNAC asset.

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.

These recent clinical trial results, which were presented at ASCO GI, are positive news for patients and the impact 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 would like to thank 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.

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 in 2022. The results of the RELEASE trial will be compiled and analysed for assessment of how they can be utilised going forward.

## IMMUNOTHERAPY AND fima VACC

Immunotherapy utilises the body's own immune system to fight cancer, which is a radically different approach to treating cancer than chemotherapy. The armamentarium of cancer immunotherapies includes many different therapeutic approaches including antibody-based treatments, cell-based therapies, and therapeutic vaccines. The pharmaceutical industry has long recognised the potential of therapeutic cancer vaccination and the objective of a therapeutic vaccine is to treat an established disease using the body's natural defences. Whereas in a traditional anti-infectious vaccine, the main component of the vaccine is the infectious agent antigen, in the case of a cancer vaccine the main component can be a peptide or protein found on the surface of tumour cells. By vaccinating with such tumour-specific antigens, the body's natural defences can be trained to recognise and destroy cancer cells.

Peptide and protein based vaccines are a subgroup of therapeutic cancer vaccines. There is a broad consensus that therapeutic peptide and protein based cancer vaccines have so far not been able to elicit sufficiently strong immune responses. A fundamental challenge for most existing therapeutic vaccine approaches is to produce a strong and relevant cellular immune response (T-cell activation). Potent induction of Cytotoxic T-cells is considered paramount for successful therapeutic vaccination. This is a main need in the market, which could be addressed by using the fimaVACC technology. In addition to the use in therapeutic vaccination for cancer, fimaVACC also has the potential to be used for the treatment of infectious diseases.

fimaVACC is an endosomal escape technology that may realise the true benefit of innovative therapeutic vaccines by modifying the intracellular machinery of immune cells in such a way that

antigens are more efficiently processed and induce antigen specific cytotoxic T-cells. The innovative and well characterised mode of action of fima*VACC* can be applied to a wide range of cancer vaccine technologies and provide PCI Biotech with a strategic opportunity to enter the field of cancer immunotherapy at a time where the understanding of cancer biology and the potential of modulating the immune response to fight cancer is growing at a rapid pace. The fima*VACC* technology is versatile, as it can be used with several modalities, including nucleic acid based immunotherapy technologies.

In terms of type of vaccination, fima*VACC* is also a versatile technology that can be used in multiple settings including, intradermal, intranodal, and intratumoural administration. Preclinical research has shown that it could also be developed in conjunction with *ex vivo* vaccination. Another promising way forward in the development of therapeutic vaccines is to combine vaccination with other cancer immunotherapy modalities such as checkpoint inhibitors (CPIs). There is a strong scientific rationale for combining CPIs with the fima*VACC* technology: fima*VACC* increases the number of T-cells induced by cancer vaccines while the CPIs prevent the tumour from evading the immune response.

Vaccine technologies commonly utilise adjuvants to enhance immune responses, but the consensus is that each one of the adjuvants available today has shortcomings, like variation in efficacy and toxicity issues. fima*VACC* is expected to increase vaccines' efficacy and generate the immune response faster, and to be user-friendly since illumination of the target area is considered to be a minor inconvenience that potentially can be done without involvement of health personnel. fima*VACC* has the potential to increase patient safety if it can reduce the antigen payload and adjuvant volume per treatment and reduce the number of treatments needed. Increased efficacy for a broad range of peptide and protein based vaccines and patient safety are fima*VACC*'s key competitive differentiators.

The proprietary fima*VACC* technology was successfully translated into humans through a Phase I study in healthy volunteers after having demonstrated strong preclinical efficacy. The immune results in man provide Proof-of-Concept and clinical support of fima*VACC*'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. It is anticipated that several of the cancer vaccines in development could use fima*VACC* to boost their activation of T-cells and increase their efficacy. There are competing peptide vaccine enhancing technology platforms; for example adjuvants, liposomes and nanoparticles. For some of these technologies fima*VACC* has shown synergistic effects in the preclinical setting.

## NUCLEIC ACID THERAPEUTICS AND THE fima*NAC* DELIVERY TECHNOLOGY

PCI Biotech's nucleic acid therapeutics program (fima*NAC*) aims at improving the efficacy of novel nucleic acid based therapies. The fima*NAC* technology addresses a main hurdle in the development of nucleic acid based therapies: Sufficient release of therapeutics inside the targeted cells. The therapeutic molecules are, due to their size and charge, notoriously difficult to deliver in large payloads inside cells. Nucleic acids are in most cells taken up by endocytosis, but are then trapped in endosomes, constituting a barrier severely limiting the achievable therapeutic effect. Thus, nucleic acids are very good candidates for enhancement by an endosomal release technology like fima*NAC*, and preclinical experiments have shown that fima*NAC* can give a substantial improvement in the effect of important classes of nucleic acids such as oligonucleotides and mRNA. Nucleic acid therapeutics are widely acknowledged to have a large potential as therapeutic agents, and numerous clinical trials with nucleic acid therapeutics are underway. The commercial exploitation of most such drugs has been hampered by the lack of technologies for efficient delivery of the therapeutic molecules to their molecular targets inside cells. PCI Biotech's fima*NAC* drug delivery technology has the potential to address this issue, as demonstrated in numerous preclinical models.

Nucleic acids have emerged as very promising therapeutic candidates for a wide range of diseases and are now considered the third major drug class, in addition to antibodies and small molecules. Recent progress has been rapid and broad, with several nucleic acid based drugs on the market and with a broad pipeline.

The development of the fima*NAC* programme is focused on selected applications well suited to the specific strengths of the PCI technology and with several collaborations established. It is a preclinical stage programme aiming at improving the efficacy of novel nucleic acid based therapies, where partners are exploring technological synergies, with potential for further deepening of the

partnerships. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of mRNA.

## KEY FIGURES

| *(In NOK 1,000)* | 2021 | 2020 |
|---|---|---|
| Other income | 6 273 | 7 368 |
| Operating expenses | 92 302 | 89 488 |
| Operating results | -86 029 | -82 121 |
| **Comprehensive income** | **-88 391** | **-72 239** |
| **Cash & cash equivalents** | **116 118** | **187 967** |
| **Total liabilities** | **22 186** | **19 879** |
| **Cash flow from operating activities** | **-68 307** | **-77 391** |

# BOARD OF DIRECTORS REPORT

## 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.

During 2021 the company's operations were affected by the COVID-19 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.

## HIGHLIGHTS

fimaCHEM – **The RELEASE trial was closed to recruitment in January 2022 (after balance sheet date event).** The decision was made 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 in 2022, enabling a swift closure 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.** The overall study design is clarified following comprehensive consultations with international experts, and a patent for the use of fimaVACC in combination with immune checkpoint inhibitors were granted in the US. The work towards a Phase II study is based on the Phase I study results, which were published early January 2021 in Frontiers in Immunology[1], a high impact immunology journal.

fimaNAc **- Focused development plan initiated.** The plan is 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 scientific ocnferences and established extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics.

## BUSINESS, LOCATION AND HUMAN RESOURCES

PCI Biotech Holding ASA is a biopharmaceutical company headquartered in Norway and listed on the Oslo Børs, with the ticker PCIB. The company is developing therapeutic products based on its proprietary photochemical internalisation (PCI) technology.

The PCI Biotech group (The Group) comprises PCI Biotech Holding ASA, and the wholly owned Norwegian subsidiary PCI Biotech AS. PCI Biotech is located at Ullernchausséen 64, Oslo, Norway.

The Board of Directors –The Board of Directors consist of Hans Peter Bøhn (Chairman), Hilde Furberg, Christina Herder, Lars Viksmoen and Andrew Hughes, who were all elected for a one-year term at the annual general meeting in May 2021.

Employees - All operations of the Group are managed by PCI Biotech AS and the Group had 17 employees as of 31 December 2021 (2020: 15 employees). The parent company has no employees. The Group mainly uses external service providers for manufacturing, research and development and regulatory work.

The management team consists of Per Walday, Chief Executive Officer, Ronny Skuggedal, Chief Financial Officer, Anders Høgset, Chief Scientific Officer, Kristin Eivindvik, Chief Development Officer, Amir Snapir, Chief Medical Officer and Ludovic Robin, Chief Business Officer.

[1] doi.org/10.3389/fimmu.2020.576756

The working environment is considered good. No accidents or injuries were reported in 2021 or 2020. Absence due to illness was 128 days, approximately 4.7% in 2021 (2020: 629 days, approximately 19.2%). The majority of the absence in 2020 was related to long term sick leaves and employees facing responsibilities for home-based school or closed kindergartens for their children during the COVID-19 pandemic.

PCI Biotech's goal is to be a workplace with gender equality and where discrimination is not accepted. As of date of this report the Group has 40% female representation in the board of directors and 20% in the executive management team. 9 out of 17 employees as of year-end 2021 were women (2020: 8 out of 15). Working time and remuneration of the Group employees are not related to gender.

## OPERATIONS

### Operational overview

PCI Biotech is an oncology-focused biopharmaceutical company developing novel therapies 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 fima*VACC* aims to enhance immunotherapy in cancer, by triggered endosomal release of antigens or nucleic acids encoding antigens, or immunostimulatory factors. In preclinical experiments fima*VACC* has proven excellent efficacy with protein- and peptide-based vaccines, with particularly strong cytotoxic (CD8) T-cell immune responses, which are crucial in cancer immunotherapy. The beneficial immune characteristics of fima*VACC* were successfully verified in humans through 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 fima*NAC* 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 fima*NAC* programme is focused on selected applications well suited to the specific strengths of the PCI technology and with several research collaborations established.

### fima*CHEM* – pivotal RELEASE study closed to recruitment in January 2022

The **fima*CHEM*** programme for local enhancement of cancer treatments were the most advanced of PCI Biotech's development programmes in 2021. PCI Biotech decided in January 2022 (after balance sheet date event) to close recruitment to the RELEASE study and redirect the drug development efforts on the promising immunotherapy opportunities **within** fima*VACC* **and selected applications for the** fima*NAC* **asset**. The main focus for 2022 for **fima*CHEM*** is to conduct a swift closure of the RELEASE study, and compile and analyse the results for assessment of how they can be utilised going forward.

### fima *VACC* - lead program for 2022

**fima*VACC* provides highly desired features for therapautic vaccination technologies:**

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

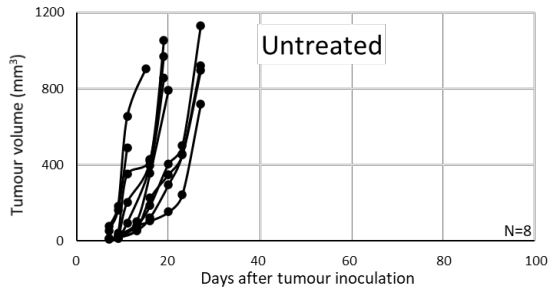
The **fima*VACC*** technology aims to enhance immunotherapy responses and has proven excellent preclinical efficacy with protein- and peptide-based vaccines. The technology has shown particularly strong CD8 T-cell responses, which are important for therapeutic vaccination, as well as enhanced helper (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 intended development step is 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.

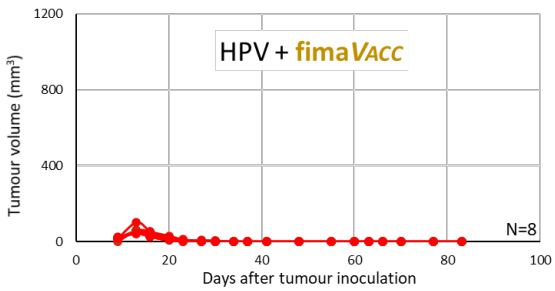
## Extensive preclinical data suggest strong T-cell induction

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).

Intradermal therapeutic vaccination with **fimaVACC** induces strong anti-tumour response




- TC-1 tumours inoculated in animals without subsequent vaccination
- Aggressively growing tumours established in all animals, with no animals surviving beyond Day 30




- **fimaVACC** (PCI + poly(I:C) adjuvant) with HPV long peptide antigen vaccinated i.d. on Days 8, 13 and 22 (after tumours were established)
- Mice became tumour free and were immune to a new challenge with tumour cells

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.

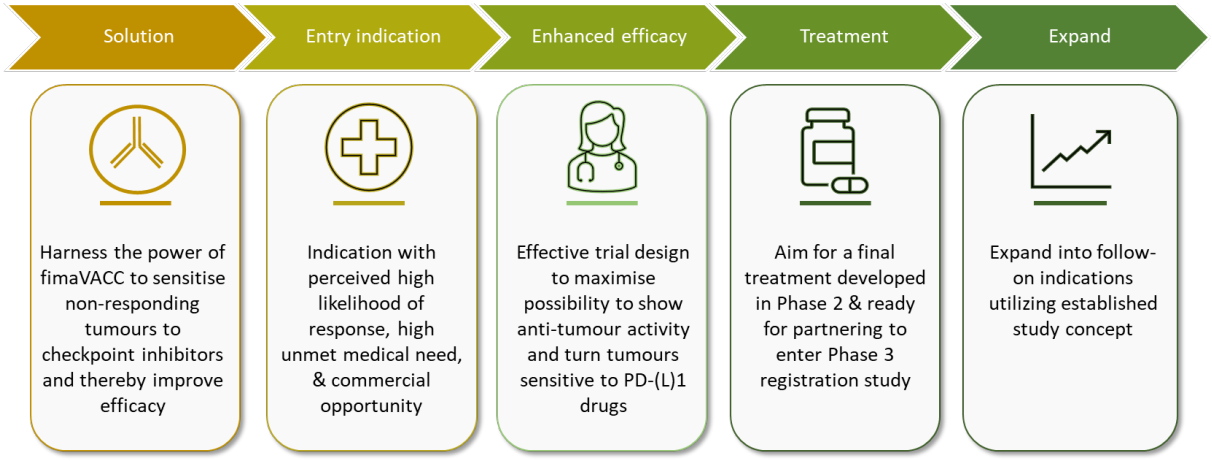
**Phase I in healthy volunteers published**

The full study results were published early January 2021 in Frontiers in Immunology[2], 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.

## 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**.

[2] doi.org/10.3389/fimmu.2020.576756

**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 presently 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.

## fimaNAc - delivery of nucleic acid therapeutics

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 PCI 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 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. 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

## Further strengthening the organisation

The company has strengthened the team for **fima*VACC*** with a new Clinical Science Director, Dr Nina Gustafsson, that commenced 1st August, who also will contribute to the further development of **fima*NAC***. For business development purposes a new position as Scientific Alliance and Business Development Manager commenced 1st October. The company also strengthened the operational clinical team with an experienced Clinical Project Director 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 scheme are described in PCI Biotech's remuneration policy.

**Business development**

PCI Biotech's strategy is to create value by effectively progressing development of the business areas towards commercialisation. The commercialisation of products is intended primarily through agreements with external partners. PCI Biotech believes that the PCI technology has the potential to play a role in the realisation of several new therapeutic modalities, including cancer immunotherapy and mRNA therapeutics.

The Company's lead programme for 2022 is the clinical stage **fima*VACC*** programme, with a successful clinical translation through a Phase I study in healthy volunteers. These results are published in the high-impact immunology journal Frontiers in Immunology. PCI Biotech pursues two development strategies in parallel for **fima*VACC***, utilising the Phase I results both in direct partnering efforts and planning for clinical Proof-of-Concept in a disease setting.

The **fima*NAC*** programme has during 2021 gone through an evaluation for a more focused development strategy towards the application most suited for the PCI-technology, and the initial focus will be on dermatological indications.

## FINANCIAL REVIEW

*(All amounts in brackets are comparative figures for 2020 unless otherwise specifically stated)*

**Profit and loss**
The Group did not record revenues in 2021 or 2020. Grants received from various public sources such as the Research Council of Norway and "SkatteFUNN" were recorded as other operating income amounting to NOK 6.3 million (NOK 7.4 million). The parent company did not record any revenue for 2021 or 2020.

The fima*VACC* programme received in 2017 a grant of up to NOK 13.8 million from the Research Council of Norway (BIA-programme). The grant was distributed over the course of four years, 2017-2021, and for 2021 a total of NOK 1.4 million (NOK 2.6 million) has been recorded as other income. The grant ended in June 2021, with an accumulated grant of NOK 13.4 million.

Expenditure on research activities is recognised as an expense in the period in which it was incurred. The Group had no development expenditure qualifying for recognition as an asset under IAS 38 in 2021 and as for previous years all research expenses are charged through the profit and loss statement. Total operating expenses were NOK 92.3 million in 2021 (NOK 89.5 million) and expenses are mainly driven by the research and development (R&D) activities. R&D expenses amounted to NOK 71.7 million in 2021 (NOK 75.6 million). Other operating (general and administrative) expenses were NOK 20.6 million (NOK 13.9 million). The change in general and administration costs is mainly driven by non-cash accounting elements for the groups share option scheme for employees, and increased number of employees. Operating result in 2021 ended at NOK -86.0 million (NOK -82.1 million) for the Group. Operating result for the parent company were NOK -5.0 million in 2021 (NOK -4.7 million).

Net financial results for the Group were NOK 2.4 million negative in 2021 (NOK 9.9 million positive). The net negative result in 2021 was mainly driven by negative effects of NOK 2.5 million from cash deposits placed in EUR at year-end, as a hedge of the foreign currency risk for the RELEASE study. The corresponding effect for 2020 was NOK 8.5 million positive. The parent company's financial income for 2021 consists mainly of interest on loans to the subsidiary PCI Biotech AS and the same kind of net accounting effect from cash deposits placed in EUR at year-end, as for the Group. Financial expenses consist of negative interest on cash deposits in EUR and an interest expense on right to use assets (IFRS 16 Leases). In 2021 the parent company made a partial write-down of its investment in the wholly-owned subsidiary PCI Biotech AS, based on the observable fair value of the Group at Oslo Børs per year-end 2021. The NOK 148.8 million write-down is disclosed as financial expenses for the parent company.

The Board of Directors proposes that the comprehensive loss of NOK 154.9 million in 2021 for the parent company, PCI Biotech Holding ASA, is covered by retained earnings.

**Balance sheet**
Property, plant and equipment of NOK 5.8 million mainly consist of devices used in the RELEASE trial. In January 2022 the company decided to stop recruitment into the trial, and the post-decision value of these devices are considered low. More details about the decision are described under the operational review for the fima*CHEM* programme. From a financial reporting perspective, the decision is a non-adjusting after the reporting date event, and more details are described under the subsequent event section of this report and in Note 25 Subsequent events.

Short term receivables per end of 2021 was NOK 12.2 million (NOK 13.2 million) and mainly consist of advance payments in connection with the RELEASE trial and recognised not received public grants.

Other long-term liabilities relate to potential future social security liabilities in connection with the company's share option program for employees, and the liability fluctuates with the share price and the number of outstanding 'in-the-money' share options per year-end. Social security liabilities for share options that are vested, or that may vest during the coming financial year, are disclosed as short-term liabilities. No share options were 'in-the-money' per year-end 2021. Current liabilities were

generally higher per the end of 2021 compared to the end of 2020, mainly due to increased enrolment into the RELEASE trial during fourth quarter of 2021.

Total equity for the Group were NOK 113.8 million per year-end 2021 (NOK 189.2 million). Total equity of the parent company amounts to NOK 544.6 million in 2021 (NOK 686.5 million) reflecting this year's result and equity settled share-based payment elements for the Group's share option scheme.

Equity in the wholly-owned subsidiary PCI Biotech AS was NOK 73.4 million at the end of 2021 (NOK 102.7 million). The equity in PCI Biotech AS were increased in 2021 by NOK 40 million, through a capital increase from the parent company PCI Biotech Holding ASA.

Total assets of the Group at the end of 2021 were NOK 136.0 million (NOK 209.1 million) and the decrease from last year is mainly due to net loss from operational activities. Total assets in the parent company amounted to NOK 545.7 million per year-end 2021 (NOK 687.7 million).

PCI Biotech does not recognise deferred tax assets in the balance sheet, due to uncertainty as to when the company will accrue a payable tax liability. Unrecognised deferred tax assets at the end of 2021 were NOK 142.9 million (NOK 125.3 million).

**Cash flow**

Net cash flow from operating activities amounted to NOK -68.3 million in 2021 (NOK -77.4 million) for the Group and for the parent company to NOK -3.5 million for 2021 (NOK -2.0 million). Net change in cash and cash equivalents for the Group was NOK -71.9 million in 2021 (NOK -73.1 million). Net change in cash and cash equivalents for the parent company were NOK -42.0 million in 2021 (NOK -54.3 million).

The Group held cash and cash equivalents of NOK 116.1 million at the end of 2021, compared to NOK 188.0 million per end of 2020, reflecting net negative changes in cash of NOK 69.3 million in 2021 (NOK 81.7 million) and NOK 2.5 million net negative (NOK 8.5 net positive) exchange rate effect on bank deposits in foreign currency. Cash flow from operations is mainly dependent on R&D activities. The Group employs a prudent cash management strategy for its cash and cash equivalents and assets are held as bank deposits or invested in low-risk short-term money market instruments. All cash and cash equivalents were held as bank deposits at the end of the year.

The Parent's cash and cash equivalents at the end of 2021 amounted to NOK 26.5 million (NOK 68.5 million).

**Related parties transactions**

All material transactions between the Group and shareholders, directors, management or close associates of such parties are valuated independently by a third party. No such transactions exist for 2021.

In 2021 the Group had regular business transactions with Helpyou2 Ltd. a UK based company wholly owned by Prof. Andrew Hughes, a Director in PCI Biotech Holding ASA. The services rendered concern Prof. Hughes position as member of the Scientific Advisory Committee ('SAC'), and related agreed scientific consultancies by Prof. Hughes during the year. The services rendered are pre-approved by the Board of Directors and regular fee overviews are presented for the Board of Directors. Helpyou2 Ltd. has for services related to the SAC received fees of NOK 21 thousand for 2021 (2020: NOK 0). For other agreed scientific consultancies, Helpyou2 Ltd. received NOK 24 thousand in fees for 2021 (2020: NOK 0). It is in management and the Board of Director's opinion that the service fee is based on 'arm's length' principles and the level of consultancy is not considered to constitute a threat to independence for the parties in 2021 or 2020. Please refer to Note 23 Related party transactions to the financial statements for 2021 where information regarding related party transactions are disclosed.

## RISK AND RISK MANAGEMENT

**Implications of the COVID-19 pandemic**
COVID-19's impact on the general biotech industry risks may in broad terms be summarised as the conduct and progress of clinical development, disruption of the supply chain, exchange rate fluctuations, access to resources through the capital market and other health economic aspects. PCI Biotech has closely monitored potential implications on its short- and long-term operations during the course of the COVID-19 pandemic. PCI Biotech's overriding priority has been the safety of its staff and patients participating in the clinical trial and its collaborators. Other key priorities during 2021 include identification and implementation of potential mitigating actions for the delays in progress of the fima*CHEM* RELEASE study in collaboration with our contract research organisation. Screening of patients was severely affected in 2020 and challenging in 2021. The Company did not experienced any major shortage in supplies of investigational products and devices during 2021.

PCI Biotech closed recruitment of patients into the RELEASE study in January 2022, and per date of this report the current implications of the COVID-19 pandemic are minimal and the pandemic has no material implications for balance sheet items per year-end 2021.

**Operational Risk and Risk Management**
There are great risks in the business of developing medical drugs, both related to regulatory affairs and market risk. The development may fail at any stage of the process, due to safety considerations or lack of clinical results. Changes in clinical development or patient management, or any other matters affecting patient's ability or willingness to participate in clinical trials may impede the recruitment of patients in the Company's studies. It is not possible to predict with certainty whether and when PCI Biotech will be able to submit applications to regulatory authorities in the relevant markets. Moreover, one cannot be sure that PCI Biotech will receive the marketing authorisations to commercialise the products. Regulatory approval and specific regulatory designations may be denied, suspended or limited. Poor clinical performance of PCI Biotech's potential products on the market and new technologies and innovative or generic products that are not yet launched may also limit the competitive edge of PCI Biotech's products and impact pricing and/or reimbursement. PCI Biotech's business strategy is to commercialise its technology partly through collaborative agreements and the Company cannot give any assurance that such agreements will be obtained on acceptable terms. There is no certainty that PCI Biotech or its licensees will achieve commercial success. The success, competitive position, and future revenues will depend in part on PCI Biotech's ability to protect intellectual property and know-how. Patent applications filed by others could also limit PCI Biotech's freedom to operate. Changes in the healthcare market and/or the market access environment could further preclude PCI Biotech from charging a premium price or obtaining coverage and/or reimbursement for the Company's products. The Company is highly dependent upon having a highly qualified senior management and scientific team. The loss of key employees might impede the achievement of the scientific development and commercialisation objectives. PCI Biotech cannot be certain that it will be able to enter into satisfactory agreements with third-party suppliers or manufacturers.

In parallel with the clinical development of PCI Biotech's lead programme, fima*CHEM* for inoperable extrahepatic bile duct cancer, the company has been building its knowledge base to enable the design of its commercialisation strategy for fima*CHEM*. Market research has guided management to understand the competitive environment, what potential future customers perceive as the areas of unmet needs and potential market access and reimbursement pathways.

PCI Biotech's potential product candidates could become a commercially successful therapeutic option provided certain prerequisites are met: (a) scientific engagement of the thought leaders in key institutions ahead of commercial launch, (b) well-designed clinical plan, (c) robust market access and reimbursement programme, (d) optimised referral pathway; and (e) streamlined distribution via centralised logistic services to customers. PCI Biotech is committed to leverage these insights to

develop strategies, when appropriate, that offer the best chance of commercial success for its potential product candidates.

PCI Biotech performed in 2018 and 2021 market opportunity assessments for the fima*VACC* technology platform, guiding management to understand the opportunity space based on the key attributes fima*VACC* may offer for peptide and protein based vaccines.

To handle the inherent risks in the industry, and to comply with national and international regulations, PCI Biotech has implemented a process to identify, analyse and manage the key risks for the Group, including the character of the relevant insurance policies.

The directors and officers of PCI Biotech Holding ASA and its subsidiary PCI Biotech AS are covered under a world-wide Group Director & Officer's Liability Insurance. The insurance covers personal legal liabilities including defence and legal costs. The cover also includes employees in managerial positions who become named in a claim or investigation.

The Group does not pollute the external environment.

**Financial Risk and Risk Management**

The Group's activities are exposed to certain financial risks including currency risk, interest rate risk and liquidity risk. The risk is of such character that the Group has chosen to put in place measures to mitigate the potential currency risk of the financial markets and a prudent strategy regarding interest rate risk.

PCI Biotech's most important future sources of financing are revenue related to any licensing and collaboration agreements, government grants and equity issues. The biotech industry is a resource demanding industry, and drug development can be both labour and cash intensive. PCI Biotech being a pre-commercial stage biotech, means that the Company mainly relies on the ability to raise funds via the equity market and government grants for its development plans, and no assurance of the availability of resources for current and future drug development plans can be made. The equity capital market is used as a source of liquidity when appropriate and conditions within this market are competitive. PCI Biotech has no external debt with financial covenants or any long-term debt.

Currency risk - The Group's expenses and revenues are incurred in multiple currencies. The Group is therefore exposed to fluctuations in exchange rates. The risks are assessed on a regular basis. PCI Biotech is currently not using any financial hedging instruments.

Interest rate risk - PCI Biotech has no interest-bearing debt and interest risks are mainly related to the Group's holdings of cash and cash equivalents. The Group employs a prudent cash management strategy for its cash and cash equivalents, and assets are placed as bank deposits or invested in low-risk short-term money market instruments. Per year-end 2021 all cash and cash-equivalents are placed as bank deposits.

Liquidity Risk - One of the main objectives of PCI Biotech's financial policy is to ensure that the Group has sufficient short- and long-term financial flexibility to achieve strategic and operational objectives. PCI Biotech's goal is to at least have sufficient cash to cover the expected capital need for the next 12 months, as well as a strategic reserve. The Group closely monitors cash flows based on short- and long-term forecasts. Cash burn rate depends mainly on the level of activity in the clinical and preclinical programmes. The programmes do not involve substantial long-term commitments for the Group, allowing flexibility for adjusting operational activities. The current cost base for the Company will be reduced over time in 2022, mainly due to the closure of the RELEASE trial and implemented cost reductions during first half of 2022, slimming down both the operational- and executive team. The cash position per year-end 2021 is on this basis estimated to enable a financial runway well into 2023.

## GOING CONCERN

In accordance with § 3-3a of the Norwegian Accounting Act (NAA) it is confirmed that the conditions for assuming that the Group will continue as a going concern are present and that the financial statements have been prepared on the basis of this assumption. The Board of Directors refers to the document on corporate governance in the annual report relating to corporate governance (NAA § 3-3b) and corporate social responsibility (NAA § 3-3c).

## SUBSEQUENT EVENTS

The company decided in January 2022 to close recruitment to the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities within fima*VACC* and selected applications for the fima*NAC* asset. More details around the decision are described under the operational review for the fima*CHEM* 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 runway 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.

The war in Ukraine started after the company decided to close recruitment to the RELEASE trial and have therefore no material impact on the operations for PCI Biotech.

In March 2022 the CEO, Dr Per Walday, resigned to assume a new position. Dr Walday has a notice period of six months, and he will step down from his position by the end of September 2022, or earlier. The Board of Directors will initiate a succession process.

PCI Biotech is not aware of any other subsequent events since year-end 2021 which is of material significance to the financial statements as of 31 December 2021.

## 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 (**fima*VACC***) and nucleic acid therapeutics (**fima*NAC***).

An extensive Phase I study in healthy volunteers provided affirmative results on translation of the **fima*VACC*** 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 **fima*VACC*** product, aiming to demonstrate enhanced response to immunotherapy in patients with recurrent/metastatic head and neck cancer.

The **fima*NAC*** 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 **fima*CHEM*** 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 **fima*VACC***, 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

Oslo, 27 April 2022
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA

Hans Peter Bøhn
*Chairman*

Hilde Furberg
*Director*

Christina Herder
*Director*

Andrew Hughes
*Director*

Lars Viksmoen
*Director*

Per Walday
*CEO*

Enabling intracellular delivery

## RESPONSIBILITY STATEMENT FROM THE BOARD OF DIRECTORS AND CEO 2021

We confirm that the financial statements for the period 1 January to 31 December 2021, to the best of our knowledge, have been prepared in accordance with IFRS and that the accounts give a true and fair view of the assets, liabilities, financial position and results of operations, and that the information in the report includes a fair review of the development, performance and position of the Company and the Group, together with a description of the principal risks and uncertainties PCI Biotech faces.

Oslo, 27 April 2022
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA

Hans Peter Bøhn
*Chairman*

Hilde Furberg
*Director*

Christina Herder
*Director*

Andrew Hughes
*Director*

Lars Viksmoen
*Director*

Per Walday
*CEO*

# ANNUAL STATEMENT ON CORPORATE GOVERNANCE POLICY AND CORPORATE SOCIAL RESPONSIBILITY POLICY

**PCI Biotech Holding ASA emphasises good corporate governance**
The Norwegian Code of Practice for corporate governance is a guideline for listed companies to help regulate the division of roles between shareholders, the board of directors and executive management more comprehensively than is required by legislation.

PCI Biotech Holding ASA ("PCI Biotech" or "The Company") bases its policy for corporate governance on the Norwegian Code of Practice of 14 October 2021. Adherence to the code of practice is implemented on the basis of a "comply or explain principle".

The Board of Directors and management has resolved as a main principle to follow the recommendations of the Norwegian Corporate Governance Code ("the Code") to the extent not considered unreasonable due to the company size and stage of development. Explanations of non-conformance to the Code are provided if not fully implemented. PCI Biotech's compliance with the Code is described in this report and section numbers refer to the Code's chapters.

**1. Implementation and reporting on corporate governance**
PCI Biotech acknowledges the division of roles between shareholders, the Board of Directors, and the executive management team. PCI Biotech has implemented a sound corporate governance policy. Guidelines on corporate governance and statement of compliance with the Code is presented in the Company's annual report and website. The Company ensures that the policy is adopted by holding regular Board of Directors' meetings which the executive management team attends to present strategic, operational, and financial matters.

Corporate values are established with the purpose to establish a healthy corporate culture and preserve the Company's integrity by helping employees to comply with standards of good business conduct. Furthermore, the values are intended to be a tool for self-assessment and for further development of the Company's identity. Corporate values are important foundations for PCI Biotech's corporate governance. Ethical guidelines are also established and these guidelines are based on corporate values.

PCI Biotech adheres to the code of practice for corporate governance. The company has to date six deviations from the code and the reasons for the deviations and solutions selected are further explained under section 2.1, 6, 9 and 12.

**2. Business**
The objective and purpose of PCI Biotech's business are clearly defined and described in the articles of association. *"The Company's business activities shall include cancer treatment and drug delivery based on the PCI technology and other related activities, including participation in other companies with similar activities through equity, loan or by issue of guarantees."* The Company's articles of association are available at the Company's website and the Company's objectives and strategy are available in the annual report.

PCI Biotech has defined development programmes with clear objectives, strategies and risk, profiles for the company's business activities to enable PCI Biotech to create long-term value for its shareholders. The Board of Directors performs annual evaluations of the objectives, strategies, and risk profiles.

The company has implemented guidelines for how to integrate stakeholder considerations into its value creation in a sustainable manner, through corporate social responsibility and ethical guidelines.

**2.1 Corporate social responsibility (CSR)**
PCI Biotech is a Norwegian based company focusing on research and development within the field of cancer treatment. The PCI Biotech Group consists of 17 employees and the core competencies are possessed by these employees, while the group's other resources in research and development are mainly purchased from public and private research institutions and service providers across Europe and USA.

As of today, the Group has no sales or supply of services and a limited complexity in operations. The Group has established guidelines, policies, procedures, and standards in accordance with internal control policies for comparable businesses of similar size, complexity, and industry to fight corruption. This means that the group requires its directors and employees to demonstrate high ethical standards in business and interpersonal relationships. Other principles followed are prevention through awareness-raising, limitation of opportunities, high detection risk of, and zero tolerance for corruption.

The Group has established its own quality control system in line with authorities' requirements within the activities that the Group operates, both in terms of production and storage of pharmaceutical products and medical devices, and in connection with preclinical and clinical studies. The quality control procedures are based on the relevant activities in relation to the different phases of operation and the development of procedures is thus a continuous and systematic process. The Group is concerned that staff have appropriate training and experience in their business areas and staff are regularly updated within their business fields.

The Group is concerned with animal welfare, human- and labour rights, social issues and sustainable development. The Group's management conducts regular performance reviews and internal evaluations, and the Group adapts according to Norwegian law within the area. The Group's subcontractors are mainly public and private European and US research institutions and service providers. Preclinical and clinical research is subject to strict government regulation of animal welfare, human rights, and social conditions in all the countries where the research and development work is carried out, including South Korea and Taiwan where the RELEASE trial had open sites at selected hospitals in 2021. The Group therefore considers that animal welfare, human rights, labour rights, and social issues are well taken care of, both internally and among its subcontractors. Regarding sustainable development, please see section 2.2.

The Group has not identified any material issues based on the corporate social responsibility procedures (CSR) performed in 2021. The implementation of further detailed specific objectives, strategies or action plans related to CSR, beyond the ones described above, has not yet been prioritised, but will be developed along with the continuous development of PCI Biotech's operations.

Non-conformance with the recommendation: The Group's operations are of such character that it does not significantly affect the environment and the Group therefore believes it is not appropriate to establish specific guidelines, policies, procedures and standards in this area, but environmental issues are included in the ethical guidelines and please also see the separate reporting regarding sustainable development in section 2.2.

**2.2 Sustainable development**
PCI Biotech has not used any specific reporting standards or guidelines for sustainability reporting other than the Code and this section for sustainable development is considered an integrated part of the CSR reporting. In general PCI Biotech's strategy and operations are focused on human welfare through its vision of '*unlocking the potential of innovative medicines*'. PCI Biotech focuses its development on anti-cancer product- and technology candidates. This vision and focus may directly contribute to one of the UN's seventeen sustainable development goals, goal #3 'Good health and well-being'.

All international anti-cancer development is strictly regulated regarding animal welfare and high focus on safety and well-being for patients participating in clinical trials. PCI Biotech have internal routines securing that the Group and service providers comply with all relevant standard in these regards. The Group's operations are of such character that they do not significantly affect the environment beyond

normal course of business for a small biotech company. Travelling and the need for shipment of devices and materials for preclinical and clinical trials are identified as the activities with the most environmental impact. To keep the environmental impact to a minimum, devices that are no longer used are returned in bulk to the producer for recycling. Other shipments are optimised in collaboration with our service providers and collaborators to reduce the number of shipments. External meetings are evaluated for use of virtual meeting tools when appropriate, to limit travel to what is considered necessary from an operational perspective.

**2.3 Ethical guidelines**
The ethical guidelines encompass the following elements: core values, compliance with laws and regulations, working environment, interaction with different stakeholders, intragroup transactions, employees loyalty, conflicts of interest, confidentiality, environment, accounting, financial reporting, trading of Company shares, other employee activities and compliance with the ethical guidelines.

**3. Equity and dividends**
PCI Biotech's equity as of 31 December 2021 was NOK 113.8 million. The capital structure is regularly assessed in light of the Company's objectives, strategy and risk profile. The equity level is assessed as satisfactory per year-end 2021.

To date the Company has not distributed any dividends and this dividend policy will apply as long as PCI Biotech is in a research and development phase. The Board of Directors has no mandate to approve the distribution of dividend.

The Board of Directors has been authorised by the Company's General Assembly in May 2021 to increase the share capital by share issue of up to 2,790,000 shares in connection with the Company's employee incentive program and to issue shares in connection with private placements by an amount up to 10% of the share capital of the Company. The authorisations are valid to the next ordinary general assembly. Other than the above the Board of Directors has no general authorisation to issue shares.

**4. Equal treatment of shareholders**
PCI Biotech has only one class of shares and all shares have equal rights. Each share carries one vote.

The Board of Directors and management are committed to treat all shareholders equally. The Company had no transactions in own shares during 2021.

In the event of the Board of Directors resolving to issue new shares and waive the pre-emptive rights of existing shareholders, the Board of Directors intends to comply with the recommendation of the Norwegian Code of Practice for Corporate Governance that the justification for such waiver is noted in the Stock Exchange announcement relating to such a share issue.

**5. Shares and tradability**
The shares in PCI Biotech are freely tradable with no form of restriction. No restrictions regarding voting, ownership or tradability are placed on the shares in the Company's articles of association.

**6. General Meetings**
The Board of Director's facilitate that as many shareholders as possible may exercise their rights by participating at the General Meeting and that the General Meeting is an effective forum for both the views of shareholders and the Board of Director's.

The Chairman, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) are present at the Annual General Meeting, along with representatives from the Nomination Committee and the group auditor.

Shareholders who are unable to participate themselves may vote by proxy and a person can also be appointed to vote for the shareholders as a proxy. The Board of Directors may decide that

shareholders may submit their votes in writing, including by use of electronic communication, in a period prior to the general meeting.

Notice of the meeting and relevant documents, including the proposal of the nomination committee, are made available on the company website three weeks in advance of the meeting. Notice of the meeting is sent to all shareholders individually, or to their depository banks, three weeks in advance of the meeting. The meeting notice include information regarding shareholders' rights, guidelines for registering and voting at the meeting. The company provides information on the procedure for representation at the meeting through proxy, nominations of a person to vote on behalf of the shareholders and to the extent possible prepare a form which allows separate voting instructions for each matter, hereunder for individual candidates for appointment to the Group's governing bodies. The deadline for notice of attendance is set as close to the meeting as practically possible and in accordance with the provisions in the Articles of Association.

Non-conformance with the recommendation: PCI Biotech is a small company and has encouraged directors to attend the General Meeting. The entire Board has not usually attended the General Meeting as, thus far, the items on the agenda of the General Meeting have not required all directors to attend. The Chair of the Board is present, and other Board members participate on an ad hoc basis. From the Group's perspective, this is considered to be sufficient. The recommendation to implement routines to ensure an independent chairing of the meeting has not been applied, both for cost and convenience reasons based on the size of the company. From the Group's perspective, this is considered to be sufficient.

**7. Nomination Committee**

The requirement for a Nomination Committee and its guidelines follows from article 6 of the articles of association. The Nomination Committee's duties are to propose candidates for election to the Board of Directors and to propose remuneration. The Nomination Committee is required to justify its recommendations and encouraged to interact with shareholders, the Board of Directors and the Chief Executive Officer (CEO) in its work. The Nomination Committee's members, including the chairperson, are elected by the General Meeting for two years at a time, unless otherwise resolved by the General Meeting and the General Meeting may adopt instructions for the Nomination Committee. The Nomination Committee shall consist of minimum two members who shall be shareholders or representatives for the shareholders. The remuneration to the members of the Nomination Committee is determined by the General Meeting.

The Nomination Committee ensures that shareholders' views are taken into account when qualified members are nominated to the governing bodies of PCI Biotech. Shareholders are encouraged to submit proposals to the Nomination Committee for candidates for election to the board of directors. Such proposals must be in writing and justified and be submitted minimum 2 months before the general meeting if they are to be considered by the nomination committee.

None of the Committee's members represents PCI Biotech's management or Board and they are all considered to be independent of daily management and the Board. The Nomination Committee is considered to have a composition that reflects the common interests of the community of shareholders.

The nomination committee currently consists of the following three members: Jónas Einarsson (chairperson), Erik Must and Trond Johansen. The current members have been elected by the general meeting with a term until the Company's ordinary general meeting in 2023. The Nomination Committee's contact details are available at PCI Biotech's website.

**8. Board of Directors, composition and independence**

The Board of Directors is composed to ensure that the Board of Directors can operate independently, attend the common interest for all shareholders and the Company's need for expertise, capacity and diversity. The shareholders elect between three and seven members to the Board of Directors, including the Chair and they are elected for one-year terms by the General Meeting. The Board of Directors is presented on the company website. All board members are considered to be independent

from the Company's day-to-day management, main shareholders and material business connections. All board members are encouraged to be shareholders and their shareholdings are disclosed in the Annual Report.

**9. Work of the Board of Directors**

It is the responsibility of the Board of Directors to ensure that the Company has a well-functioning internal control environment in accordance with the regulations that apply to its activities and to supervise daily management and activities of the company in general. In addition, the Board of Directors is responsible for appointment of Chief Executive Officer (CEO) and convening and preparing for general meetings. The Board of Directors has implemented instructions for the Board and the executive management, with focus on allocation of internal responsibilities and duties. These instructions incudes handling of agreements with related parties, including whether an independent valuation must be obtained, and disclosure of such agreements in the annual directors' report. The objectives, responsibilities and functions of the Board of Directors and the CEO are in compliance with rules and standards applicable for the company.

The Board of Directors should ensure that members of the Board and executive personnel make the company aware of any material interests that they may have in items to be considered by the Board of Directors. The Board of Directors' consideration of material matters in which the Chairman of the Board is, or has been, personally involved, shall be chaired by another member of the Board.

The Board of Directors adopts an annual plan for its work, which includes objectives, strategy and implementation. The CEO is responsible for keeping the Board of Directors informed about the company's activities, position and financial and operational developments. The Board of Directors evaluates its performance and expertise annually and the evaluation is made available to the Nomination Committee. The Company has not established a separate Audit Committee in accordance with the exemption in the Norwegian Public Limited Liability Companies Act. The Company has not established a separate Remuneration Committee. The Board of Directors in its entirety serves as an Audit and Remuneration Committee.

The Board conducted nine meetings in 2021. Board members had the following attendance at these meetings:

Hans Peter Bøhn, 9/9
Hilde Furberg, 9/9
Christina Herder 8/9
Lars Viksmoen, 8/9
Andrew Hughes 9/9

Non-conformance with the recommendation: PCI Biotech has not established separate Audit and Remuneration Committees. The Board of Directors believes that this is most appropriate given the Company's current size and complexity. The Board of Directors will, depending on the Company's performance, consider appointing a separate Audit and Remuneration Committee.

**10. Risk management and internal control**

It is the responsibility of the Board of Directors to ensure that the Company has sound internal controls and systems for risk management that are appropriate in relation to the extent and nature of the Company's activities. Significant risks include strategic risks, market risks, financial risks, liquidity risks and operational risks including risks related to development of products. The internal control systems also include company values, code of ethics and corporate social responsibility. The Company's significant risk areas and internal control systems are assessed on an on-going basis and at least once a year by the Board of Directors.

Please also refer to The Board of Directors report, for a description of relevant risk factors.

**11. Remuneration of the Board of Directors**

The General Meeting determines the remuneration to the Board of Directors based on a proposal from the Nomination Committee. Remuneration reflects the Board of Directors responsibility, expertise, time commitment and the business complexity. The remuneration is not linked to the Company's

performance, and no share options are granted to Directors. Detailed information on the remuneration of the Board of Directors can be found in the Annual Report.

Board members or companies to which they are connected should not undertake separate assignments for the Group in addition to the Board appointment. If they nevertheless do, the whole Board is to be informed. Fees for such assignments are to be approved by the Board. If remuneration has been paid above the normal Board fee, this is to be specified in the annual report.

**12. Remuneration of executive personnel**

The Board has established guidelines on the determination of salaries and other remuneration of executive management in accordance with § 6–16a of the Norwegian Public Companies Act. The remuneration guidelines shall be communicated to and approved by the Annual General Meeting. The remuneration guidelines seek to contribute to the alignment of interests between the shareholders and executive management and sets out the main principles in determining the salary and other remuneration for the executive management. Performance-related remuneration is linked to long-term value creation for shareholders and is based on quantifiable factors that can be influenced by the executive management. A share option scheme is part of the remuneration policy, and the scheme is approved by the general meeting.

Non-conformance with the recommendation: The established guidelines for other performance-based remuneration of executive management do not set an absolute limit in terms of potential future value per awarded share option. The remuneration guidelines do on the other hand have other measures that are set to limit potential undesirable future value. The BoD will seek to award share options with a total fair value, calculated according to the Black-Scholes model at allotment, that is partly linked to the annual base salary for each individual. Other elements to be considered at the allotment, to limit potential undesirable future value, are reflected in terms of the current value of share options held, a service-based vesting schedule spaced over time, a fixed annual allotment period, vested share options can only be exercised during four specified periods in a year, and shares acquired through the exercise of options are subject to a minimum ownership period ('lock-up') of one year. The BoD expects members of the executive team to build up and maintain share ownership with a market value equal to at least one-year of gross base salary, before any shares may be sold. Great care is taken by the BoD when awarding share options to executive management and based on all elements of the guidelines for performance-based remuneration the current guidelines are considered to be appropriate.

**13. Information and communication**

The Company presents its financial statements in accordance with IFRS, and procedures have been established to ensure compliance with IFRS interim and annual reporting requirements. The Company's management, the Chief Executive Officer (CEO) and Chief Financial Officer (CFO) are responsible for preparing the financial statements, and financial reports are approved by the Board of Directors prior to publication. PCI Biotech reports in accordance with the rules in the Norwegian Securities Trading Act, as well as with the requirements specified by the Oslo Børs for companies with listed shares.

The Group's report on corporate social responsibility is integrated into the annual report. The Board has set an IR policy for PCI Biotech's reporting of financial and other information. The Board has approved guidelines and procedures relating to the handling of insider information and trading in the company's shares.

The Company's guidelines for reporting of financial and other information are based on transparency and take into account the requirement for equal treatment of all participants in the securities market. The Company is committed to report financial results and other relevant information on an accurate and timely basis. The Company publishes a financial calendar on an annual basis, including dates for release of interim and annual reports and dates for general meetings. PCI Biotech considers it important to inform shareholders about the Group's development and economic and financial status. Management members are available for discussions with shareholders, other than through general meetings, to develop a balanced understanding of such shareholders' situation and focus, subject

however to the provisions in legislation and regulations. The Chair of the Board ensures that shareholders' viewpoints are communicated to the whole Board.

**14. Take-overs**
The Board of Directors endorses the principles concerning equal treatment of all shareholders. In the event of a take-over bid, it is obliged to act in accordance with the requirements of Norwegian law and in accordance with the applicable principles for good corporate governance.

The Board of Directors will not hinder or obstruct takeover bids for PCI Biotech's activities or shares. The Board will ensure that shareholders are given sufficient information and time to form an opinion on an offer. If a takeover offer is received, the Board will issue a statement with a recommendation as to whether shareholders should or should not accept the offer.

A transaction that in fact is a business disposal shall be approved by a General Meeting.

**15. Auditor**
Ernst & Young AS (EY) is the appointed auditor of PCI Biotech.

The auditor shall annually in writing confirm to the Board of Directors that he/she satisfies established requirements for independence and objectivity. The auditor participates at least one Board of Directors meeting per year, where he/she present auditors plan for the audit, the assessment of the Company's internal control and participate during the approval of the annual accounts. The auditor has a minimum of one meeting per year with the Board of Directors without the presence of the Executive Management. The Board of Directors has established separate guidelines for use of non-audit services. Fees paid to the external auditor for audit and non-audit services are reported in the Company's Annual Report, which are, in turn, approved by the annual general meeting. The auditor is requested to participate at the annual general meeting for consideration of the annual financial statement.

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# PCI Biotech Holding ASA – financial statement

## STATEMENT OF COMPREHENSIVE INCOME
## For the year ended 31 December 2021
(1.1 - 31.12)

| Parent | | | | Group | |
|---|---|---|---|---|---|
| **2021** | **2020** | *(figures in NOK 1.000)* | **Note** | **2021** | **2020** |
| - | - | Other income | *5,6* | 6 273 | 7 368 |
| **-** | **-** | **Total income** | | **6 273** | **7 368** |
| - | - | Research and development | *7,8* | 71 707 | 75 571 |
| 4 969 | 4 664 | General and administrative | *7,8,9,10,14,23,24* | 20 595 | 13 917 |
| **4 969** | **4 664** | **Total operating expenses** | | **92 302** | **89 488** |
| **-4 969** | **-4 664** | **Operating results** | | **-86 029** | **-82 121** |
| 1 593 | 11 400 | Financial income | *11* | 789 | 10 796 |
| 151 539 | 307 | Financial expenses | *11,24* | 3 151 | 915 |
| **-149 946** | **11 092** | **Net financial results** | | **-2 362** | **9 881** |
| **-154 915** | **6 429** | **Profit/Loss before income tax** | | **-88 391** | **-72 239** |
| - | - | Income tax | *12* | - | - |
| **-154 915** | **6 429** | **Net profit/loss for the year** | | **-88 391** | **-72 239** |
| | | **Other comprehensive income, net of tax** | | | |
| - | - | Items that will not be reclassified to income statement | | - | - |
| - | - | Items that subsequently may be reclassified to income statement | | - | - |
| **-154 915** | **6 429** | **Total comprehensive income for the year** | | **-88 391** | **-72 239** |
| | | Loss per share basic and diluted (figures in NOK) | *13* | 2.37 | 1.94 |

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# PCI Biotech Holding ASA

## BALANCE SHEET
## for the year ended 31 December 2021

| Parent | | | | Group | |
|---|---|---|---|---|---|
| **2021** | **2020** | **ASSETS** | | **2021** | **2020** |
| | | *(figures in NOK 1.000)* | **Note** | | |
| | | **Non-current assets** | | | |
| - | - | Property, plant and equipment | *14* | 5 806 | 7 388 |
| - | - | Right to use assets | *24* | 1 854 | 605 |
| 504 191 | 600 070 | Shares in subsidiary | *15* | - | - |
| **504 191** | **600 070** | **Total non-current assets** | | **7 660** | **7 994** |
| | | **Current assets** | | | |
| 15 019 | 19 021 | Receivables from group companies | *18* | - | - |
| 33 | 86 | Other short-term receivables | *18* | 12 200 | 13 162 |
| **15 052** | **19 107** | **Total receivables** | *17* | **12 200** | **13 162** |
| 26 476 | 68 474 | Cash and cash equivalents | *16,17,19* | 116 118 | 187 967 |
| **41 528** | **87 581** | **Total current assets** | | **128 318** | **201 129** |
| **545 719** | **687 651** | **Total assets** | | **135 978** | **209 123** |

# PCI Biotech Holding ASA
## BALANCE SHEET for the year ended 31 December 2021

| Parent 2021 | Parent 2020 | EQUITY AND LIABILITIES *(figures in NOK 1.000)* | Note | Group 2021 | Group 2020 |
|---|---|---|---|---|---|
| | | **Equity** | | | |
| 111 979 | 111 979 | Share capital | *20* | 111 979 | 111 979 |
| 361 148 | 361 148 | Share premium | | 450 464 | 450 464 |
| 31 626 | 18 687 | Other paid-in capital | | - | - |
| 39 818 | 194 732 | Retained earnings | | -448 650 | -373 199 |
| **544 570** | **686 546** | **Total equity** | *8* | **113 792** | **189 244** |
| | | **Liabilities** | | | |
| | | **Non-current liabilities** | | | |
| | | Other long-term liabilities | *16* | - | 32 |
| | | Long-term lease liabilities | *24* | 1 277 | - |
| **-** | **-** | **Total non-current liabilities** | | **1 277** | **32** |
| | | **Current liabilities** | | | |
| 19 | 60 | Trade account payables | | 3 745 | 5 191 |
| - | - | Current lease liabilities | *24* | 629 | 673 |
| 140 | 129 | Public duties payables | | 1 713 | 2 107 |
| 990 | 915 | Other current liabilities | *22* | 14 823 | 11 877 |
| **1 149** | **1 104** | **Total current liabilities** | *16,21* | **20 909** | **19 847** |
| **1 149** | **1 104** | **Total liabilities** | *17* | **22 186** | **19 879** |
| **545 719** | **687 651** | **Total equity and liabilities** | | **135 978** | **209 123** |

Oslo, 27 April 2022
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA

Hans Peter Bøhn
*Chairman*

Christina Herder
*Director*

Hilde Furberg
*Director*

Andrew Hughes
*Director*

Lars Viksmoen
*Director*

Per Walday
*CEO*

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# PCI Biotech Holding ASA - GROUP

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

## for the year ended 31 December 2021

### (attributable to the equity holders of the parent)

| *(figures in NOK 1.000)* | Note | Share capital | Share premium | Other paid-in capital | Retained earnings | Total equity |
|---|---|---|---|---|---|---|
| **Equity 31 December 2019** | *20* | **111 797** | **450 329** | **0** | **-307 297** | **254 828** |
| Loss for the period | | - | - | - | -72 239 | -72 239 |
| Other comprehensive income, net of tax | | - | - | - | - | 0 |
| **Total comprehensive income for the period** | | **-** | **-** | **-** | **-72 239** | **-72 239** |
| Capital increase | | 182 | 135 | - | - | 316 |
| Capital increase expenses | | - | - | - | - | 0 |
| Share based payments | | - | - | 6 339 | - | 6 339 |
| Allocation | | - | - | -6 339 | 6 339 | 0 |
| **Equity 31 December 2020** | *20* | **111 979** | **450 464** | **0** | **-373 199** | **189 244** |
| Loss for the period | | - | - | - | -88 391 | -88 391 |
| Other comprehensive income, net of tax | | - | - | - | - | 0 |
| **Total comprehensive income for the period** | | **-** | **-** | **-** | **-88 391** | **-88 391** |
| Capital increase | | - | - | - | - | 0 |
| Capital increase expenses | | - | - | - | - | 0 |
| Share based payments | | - | - | 12 939 | - | 12 939 |
| Allocation | | - | - | -12 939 | 12 939 | 0 |
| **Equity 31 December 2021** | *20* | **111 979** | **450 464** | **0** | **-448 650** | **113 792** |

# PCI Biotech Holding ASA - PARENT
## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
## for the year ended 31 December 2021

| *(figures in NOK 1.000)* | Note | Share capital | Share premium | Other paid-in capital | Retained earnings | Total equity |
|---|---|---|---|---|---|---|
| **Equity 31 December 2019** | *20* | **111 797** | **361 013** | **12 348** | **188 303** | **673 462** |
| Profit for the period | | - | - | - | 6 429 | 6 429 |
| Other comprehensive income, net of tax | | - | - | - | - | 0 |
| **Total comprehensive income for the period** | | **-** | **-** | **-** | **6 429** | **6 429** |
| Capital increase | | 182 | 135 | - | - | 316 |
| Capital increase expenses | | - | - | - | - | 0 |
| Share based payments in subsidiary | | - | - | 6 339 | - | 6 339 |
| **Equity 31 December 2020** | *20* | **111 979** | **361 148** | **18 687** | **194 732** | **686 546** |
| Profit for the period | | - | - | - | -154 915 | -154 915 |
| Other comprehensive income, net of tax | | - | - | - | - | - |
| **Total comprehensive income for the period** | | **-** | **-** | **-** | **-154 915** | **-154 915** |
| Capital increase | | - | - | - | - | 0 |
| Capital increase expenses | | - | - | - | - | 0 |
| Share based payments in subsidiary | | - | - | 12 939 | - | 12 939 |
| **Equity 31 December 2021** | *20* | **111 979** | **361 148** | **31 626** | **39 818** | **544 570** |

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# PCI Biotech Holding ASA
## CASH FLOW STATEMENT
## for the year ended 31 December 2021

| Parent 2021 | Parent 2020 | *(figures in NOK 1,000)* | Note | Group 2021 | Group 2020 |
|---|---|---|---|---|---|
| -154 915 | 6 429 | Profit/Loss before income tax | | -88 391 | -72 239 |
| - | - | Depreciation and amortization | 7,14 | 2 541 | 2 208 |
| - | - | Leasing interest cost | 24 | 38 | 75 |
| 148 817 | - | Write down investment in subsidiary | | - | - |
| - | - | Share-based payments | 8 | 12 939 | 6 339 |
| 2 513 | -8 411 | Currency gain (-) / loss (+) not related to operations | 19 | 2 529 | -8 526 |
| 53 | -17 | Changes in accounts receivables | | 962 | 1 484 |
| -41 | -90 | Changes in account payables | | -1 445 | -3 410 |
| 86 | 52 | Changes in other net operating assets and liabilities | | 2 520 | -3 322 |
| **-3 487** | **-2 037** | **Cash flow from operating activities** | | **-68 307** | **-77 391** |
| -41 598 | -65 194 | Disbursement intragroup interest-bearing loan | | - | - |
| 5 600 | 4 184 | Proceeds intragroup interest-bearing loan | | - | - |
| - | - | Investment in subsidiary | 15 | - | - |
| - | - | Acquisition of non-current assets | 14 | -341 | -3 919 |
| **-35 998** | **-61 010** | **Net cash flow from investing activities** | | **-341** | **-3 919** |
| - | - | Payment principal portion of lease liability | 24 | -673 | -668 |
| - | 317 | Proceeds from issue of new equity | 8,20 | - | 316 |
| - | - | Expenses in relation to issues of new equity | 20 | - | - |
| **0** | **317** | **Net cash flow from financing activities** | | **-673** | **-352** |
| **-39 485** | **-62 730** | **Net changes in cash and cash equivalents** | | **-69 321** | **-81 662** |
| -2 513 | 8 411 | Exchange rate effect bank deposits in foreign currency | 19 | -2 529 | 8 526 |
| 68 474 | 122 794 | Cash and cash equivalents 1 January | | 187 967 | 261 103 |
| **26 476** | **68 474** | **Cash and cash equivalents 31 December** | 19 | **116 118** | **187 967** |

# PCI BIOTECH HOLDING ASA – ACCOUNTING PRINCIPLES 2021

## 1. Corporate information

The annual accounts for 2021 for PCI Biotech Holding ASA (the Company) and the consolidated financial statement (the Group or PCI Biotech) was approved for publication by the Board of Directors on 27th April 2022.

PCI Biotech Holding ASA is a public listed company domiciled in Norway. The business of the Group is associated with research and development of pharmaceutical products and related technical equipment. The Company is listed on the Oslo Børs and the registered office address is Ullernchausséen, N-0379 Oslo.

## 2. Significant accounting policies

### 2.1 Basis of preparation

The Group and the Company's annual accounts are prepared in accordance with International Financial Reporting Standards (IFRS) as specified by the International Accounting Standards Board and implemented by the EU as per 31 December 2021.

The annual accounts for the Group and the Company have been prepared on the basis of historical cost. The financial income statement is presented by function of expense.

NOK (Norwegian kroner) is the functional currency for all companies within the Group. 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 financial statements may not add up to the totals. The Group's consolidated financial statements are presented in NOK, which is also the parent company's functional currency.

### 2.2 Basis of consolidation

The consolidated accounts include the overall financial results and overall financial position when the parent company PCI Biotech Holding ASA and the fully owned subsidiary PCI Biotech AS. The subsidiary is fully consolidated. The consolidated financial statements are prepared using uniform accounting policies for similar transactions and events under similar circumstances. Intercompany transactions and balances, including internal profits and unrealised gains and losses, are eliminated. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

### 2.3 Summary of significant accounting policies

a) Current versus non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realised or intended to be sold or consumed in the normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realised within twelve months after the reporting period

Or

- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:
- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period

Or
- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current. Deferred tax assets and liabilities are classified as non-current assets and liabilities.

b) Government grants

Government grants are presented as other income, see Note 5 for further information. Government grants are recognised where there is reasonable assurance that the grant will be received, and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognised as income in equal amounts over the expected useful life of the related asset.

c) Taxes

*Current income tax*
Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognised directly in equity is recognised in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

*Deferred tax*
Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognised for all taxable temporary differences.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognised outside profit or loss is recognised outside profit or loss. Deferred tax items are recognised in correlation to the underlying transaction either in OCI or directly

in equity. Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

d) Foreign currencies

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

e) Cash dividend distribution to equity holders of the parent

The Company recognises a liability to make cash distributions to equity holders of the parent when the distribution is authorised and the distribution is no longer at the discretion of the Company. As per the corporate laws in Norway, a distribution is authorised when it is approved by the shareholders. A corresponding amount is recognised directly in equity.

f) Property, plant and equipment

Tangible fixed assets are recognised at cost less deductions for accumulated depreciation and write-downs (carrying amount). It is assessed at each reporting date whether there is an indication that an asset may be impaired. If any indication exists, the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of an asset's fair value, less costs of disposal, and its value in use. For assets where the carrying amount exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. Tangible fixed assets are depreciated over the expected useful life of the assets taking any residual value into consideration. Costs accrued for major replacements and upgrades of tangible fixed assets are added to cost if it is probable that the costs will generate future economic benefits for the Group and if the costs can be reliably measured. Ordinary maintenance is expensed as incurred.

Tangible fixed assets are depreciated on a straight-line basis over the estimated useful life of the asset as follows:
- Production and test equipment 3-5 years
- Furniture and equipment 3–5 years

g) Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets. If ownership of the leased asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset. The right-of-use assets are also subject to impairment.

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating the lease, if the lease term reflects the Group exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognised as expenses (unless they are incurred to produce inventories) in the period in which the event or condition that triggers the payment occurs.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, PCI Biotech' incremental borrowing rate. The incremental borrowing rate is used as the discount rate. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be of low value. Lease payments on short-term leases and leases of low-value assets are recognised as expense on a straight-line basis over the lease term.

h) Intangible assets - *Research and development costs*

Research costs are expensed as incurred. Development costs will be capitalized once the asset being developed has met requirements of technical and commercial feasibility to signal that the intangible investment is likely to either be brought to market or sold.

The Group has currently no development expenditure that qualifies for recognition as an asset under IAS 38. Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortisation and accumulated impairment losses. Amortisation of the asset begins when development is complete, and the asset is available for use. It is amortised over the period of expected future benefit. Amortisation is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

i) Impairment of non-financial assets

The Group assesses at each reporting date, whether there is an indication that an asset may be impaired. If any indication exists, or when annual impairment testing for an asset is required, the Group estimates the asset's recoverable amount. An asset's recoverable amount is the higher of an asset's fair value less costs of disposal and its value in use. When the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount. Right-of-use assets are also subject to impairment.

j) Financial instruments

Financial assets

The Group´s financial assets are governmental grant receivables and cash and cash equivalents. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. The Group initially measures

a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

The Group measures financial assets at amortised cost if both of the following conditions are met
• The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows and,
• The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortised cost is the most relevant category for the Group. Financial assets at amortised cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired. A receivable represents the Group's right to an amount of consideration that is unconditional.

The Groups financial assets at amortised cost includes governmental grant receivables and cash and cash equivalents (short-term deposits). The Group does not have financial assets at fair value through profit and loss.

Derecognition
A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group's consolidated statement of financial position) when:
• The rights to receive cash flows from the asset have expired
or
• The Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

Impairment of financial assets
Further disclosures relating to impairment of financial assets are also provided in the following notes:
• Note 16 Financial risk
• Note 18 Receivables by year-end
• Note 19 Cash and cash equivalents

A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial liabilities

Initial recognition and measurement
Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss and other comprehensive income, loans and borrowings, or payables. All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs. The Group's financial liabilities include trade and other payables. The Group does not have financial liabilities at fair value through profit and loss.

Subsequent measurement
The measurement of financial liabilities depends on their classification. After initial recognition, payables are measured at their nominal amount when the effect of discounting when using the amortised cost measurement is not material. Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

Derecognition
A financial liability is derecognised when the obligation under the liability is discharged or cancelled or expires.

k) Cash and short-term deposits

Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment of other purposes. Cash and short-term deposits in the statement of financial position comprise cash at banks and short-term deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value.

l) Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

m) Pensions and other post-employment benefits

PCI Biotech AS has an agreement with a life assurance company concerning contribution-based pensions for employees. Contributions, ranging from 7% to 21% of the employee's ordinary salary up to 12 times the basic amount (G) of the Norwegian National Insurance scheme, are paid into the employee's contribution account with the life assurance company. The Company's payment of contributions is expensed in the period it is accrued. Any prepayments made to the contribution fund are recognised in the balance sheet.

n) Share-based payments

Employees (including executive management) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions).
*Equity-settled transactions*
The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using the Black-Scholes valuation model. That cost is recognised, together with a corresponding increase in other capital reserves in equity, over the period in which the service conditions are fulfilled in employee benefits expense. The cumulative expense recognised for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period and is recognised in employee benefits expense. See Note 8 Salary expenses and other remuneration for further information.

No expense is recognised for awards that do not ultimately vest, except for equity-settled transactions for which vesting are conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied. When the terms of an equity-settled award are modified, the minimum expense recognised is the expense had the terms not been modified, if the original terms of the award are met. An additional expense is recognised for any modification that increases the total fair value of the share-based payment transaction, or is otherwise beneficial to the employee as measured at the date of modification. The dilutive effect of outstanding options is reflected as additional share dilution in the computation of diluted earnings per share, further details are given in Note 13 Earnings per share.

o) License costs

Agreements with external parties concerning access to technology in the form of license agreements and agreements that allow the use of patented technology are expensed when they occur according to the agreement and are disclosed as “Research and development expenses” in the income statement.

p) Segment reporting

Segments are reported similarly as the internal reporting to the Group’s Chief Operating Decision Maker. Chief Operating Decision Makers are defined as the Group’s management group. The Group has only one segment and see Note 6 for further information.

q) Cash-flow statement

The statement of cash flows distinguishes between cash flows from operating, investing, and financing activities and the statement has been prepared in accordance with the indirect method. For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash at banks and short-term deposits with a maturity of three months or less. Cash and cash equivalents denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising from the translation of these monetary items are not considered to be related to operations and are presented as part of net changes in cash and cash equivalents. Interest paid and interest received are included under cash flow from operating activities. Cash flows from share issues are recognised as cash flows from financing activities.

r) Events after the balance sheet date

New information regarding the Group’s financial position on the balance sheet date has been considered in the annual accounts. Events after the balance sheet date that do not affect the Group’s financial position on the balance sheet date, but which will affect the Group’s financial position in the future, are reported if they are significant.

s) Contingent liabilities and assets

Contingent liabilities are defined as:

- Possible liabilities as a result of earlier events where their existence depends on future events;
- Liabilities that are not included because it is not probable that they will lead to an outflow of resources from the Group;
- Liabilities that cannot be measured with sufficient reliability.

Contingent liabilities are not included in the annual accounts. Notes on significant contingent liabilities are provided, with the exception of contingent liabilities with little probability of occurring. Contingent assets are not included in the annual accounts, but are reported in cases in which there is a certain likelihood of their resulting in a benefit to the Group.

**Accounting policies only relevant for the Parent:**

t) Investment in subsidiaries

Shares and investments intended for long-term ownership are reported in the Company’s statement of financial position as non-current assets and valued at cost. The Company determines at each reporting date whether there is any objective indication that the investment in the subsidiary is impaired. If this is the case, the amount of impairment is calculated as the difference between the recoverable amount of the subsidiary and its carrying value and recognizes the amount in the statement of profit and loss. Any realised and unrealised losses and any write-downs relating to these investments will be included in the Company’s statement of comprehensive income as financial items.

### 2.4 Changes in accounting policies and disclosures

**New and amended standards and interpretations**
The Group applied for the first-time certain standards and amendments, which are effective for annual periods beginning on or after 1 January 2021, but they do not have an impact on the consolidated financial statements of the Group. The Group has not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective.

The following standards and amendments are applied for the first time in the 2021 consolidated accounts,
* Interest Rate Benchmark Reform – Phase 2: Amendments to IFRS 9, IFRS 39, IFRS 7, IFRS 4 and IFRS 16.

These amendments had no impact on the consolidated financial statements of the Group for 2021.

### 3. Significant accounting estimates and assumptions

The preparation of the Group's consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Other disclosures relating to the Group's exposure to risks and uncertainties include:

- Financial risk management and policies, Note 16 Financial risk.

In the process of applying the Group's accounting policies, management has made the following estimates and assumption, which have the most significant effect on the amounts recognised in the consolidated financial statements:

- The fair value of employee options is calculated according to the Black-Scholes method. This method involves the use of estimates and discretionary assessments, as described in more detail in Note 8. The allocation of options to employees of subsidiary is made directly from the parent company and the financial presentation is correspondingly reported in the subsidiary.

- The Group has not recognised a deferred tax asset related to carry forward losses, as described in more detail in Note 12 Tax.

**Significant accounting estimates and assumptions only relevant for the Parent**
In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognised in the separate financial statements for the Parent:

- PCI Biotech Holding ASA has in its separate financial statement performed an assessment of the carrying amount of the subsidiary PCI Biotech AS, see Note 11 Financial income and Note 15 Shares in subsidiaries for further information.

### 4. Standards issued, but not yet effective

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2021 reporting periods and have not been early adopted by the Group. These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

# PCI BIOTECH HOLDING ASA - NOTES FINANCIAL STATEMENT 2021

## 5 OTHER INCOME

**OTHER INCOME**

*(figures in NOK 1,000)*

| | Group | |
|---|---|---|
| | **2021** | **2020** |
| SkatteFUNN | 4 750 | 4 750 |
| Grants from the Research Council of Norway | 1 422 | 2 573 |
| Other | 101 | 45 |
| **Total other income** | **6 273** | **7 368** |

Government grants are recognised where there is reasonable assurance that the grant will be received, and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. Grants are disclosed as other income. R&D projects have been approved for SkatteFUNN for the period 2020 through 2022. The Group was awarded a grant from The Research Council of Norway (user-driven research-based innovation programme (BIA)) of up to NOK 13.8 million in total for the period June 2017 through June 2021 and per end of 2021 a total of NOK 13.4 million were received and recognised. Grant receivables as of year-end are disclosed in Note 18 Receivables.

## 6 OPERATING SEGMENTS

The Group has only one operating segment, which is research and development, and had no revenues for the reporting periods.

## 7 STATEMENT OF COMPREHENSIVE INCOME ACCORDING TO CLASSIFICATION AND R&D EXPENSES BY CATEGORY

Operating costs according to classification.

*(figures in NOK 1,000)*

| | | Group | | Parent | |
|---|---|---|---|---|---|
| | Note | **2021** | **2020** | **2021** | **2020** |
| Salary expenses | 8 | 26 428 | 22 125 | 1 482 | 1 450 |
| Share option scheme, accounting effect | 8 | 12 549 | 1 291 | 0 | 0 |
| R&D exclusive salary and other operating expenses | | 43 595 | 55 389 | 0 | 0 |
| Depreciation and amortisation | 14,24 | 1 923 | 2 208 | 0 | 0 |
| Legal, audit, accounting, patents, and other fees* | | 4 722 | 4 879 | 2 380 | 2 159 |
| Other operating expenses | | 3 084 | 3 596 | 1 107 | 1 055 |
| **Total operating expenses** | | **92 302** | **89 488** | **4 969** | **4 664** |

*Other fees relate to the Parent company which pays for management services performed by employees formally employed by the wholly-owned subsidiary, PCI Biotech AS.

Of the total salary expenses NOK 17 369 relates to R&D activities (2020: NOK 15 379).

**R&D expenses by category:**

| | **2021** | **2020** |
|---|---|---|
| Clinical studies | 57 204 | 57 761 |
| Pre-clinical studies | 6 966 | 6 607 |
| CMC and equipment | 3 332 | 6 637 |
| Patents | 4 205 | 4 566 |
| Other expenses | 0 | 0 |
| **Total R&D expenses** | **71 707** | **75 571** |

The Group has no development expenditure that qualifies for recognition of an asset under IAS 38 and intangible assets and all research expenditures are charged through the income statement, in line with previous years. A new batch of the product under development (fimaporfin) was produced in 2019 and an estimated cost value of fimaporfin in stock per year-end is NOK 2.7 million (2020: NOK 3.8 million).

## 8 SALARY EXPENSES AND OTHER REMUNERATION

| *(figures in NOK 1,000)* | Note | Group | | Parent | |
|---|---|---|---|---|---|
| | | **2021** | **2020** | **2021** | **2020** |
| Wages and Board of Directors remuneration | | 21 255 | 17 277 | 1 340 | 1 278 |
| Social security contributions | | 2 805 | 2 801 | 142 | 172 |
| Share-based payments, incl social security | | 12 549 | 1 291 | 0 | 0 |
| Pension costs | 9 | 1 702 | 1 627 | 0 | 0 |
| Other expenses | | 666 | 419 | 0 | 0 |
| **Total salary expenses** | | **38 977** | **23 416** | **1 482** | **1 450** |
| No. of full-time equivalent positions | | 14.3 | 14.2 | 0.0 | 0.0 |

**Share option programme for employees**
Employees (including executive management) of the Group receive remuneration partly in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions). The employees are employed in the subsidiary, PCI Biotech AS, and the share-based payment is thus accounted for as a P&L effect in the Group accounts and an investment in subsidiary in the parent company accounts. The general vesting term in the employee share option scheme is three years, with one third vested each year. The share options expire five years from grant date. All share options will lapse immediately upon the event that the employee's employment with the company are terminated. Each share option gives the right to subscribe for or acquire one share upon PCI Biotech Holding ASA's choice. The strike price is set at market terms and no premium for the share options are paid. The Black-Scholes method is used for fair value assessment of the share options at grant date. Further details about the share option program can be found in the Group remuneration policy.

**Valuation method for fair value assessment of share options granted**
The Black-Scholes method is used for fair value assessment of the share options at grant date. Volatility is calculated based on PCI Biotech's own stock market price. The exercise price is set at market terms, equal to the average volume weighted share price last five days of trade prior to grant date (5 days VWAP), and no premium for the share options are paid. The risk-free interest rate is based on Norwegian 3-5 years government bond yield. Each option program is calculated separately with actual exercise price and lifetime for the program. The table below shows the input values used in the fair value assessment model at grant date.

Fair value for share options granted in 2021 were NOK 7.5 million (2020: NOK 20.7 million). The fair value estimated at grant date is amortised over the vesting period of three years.

| **Share options granted in 2021 and 2020** | **September 2021** | **October 2020** |
|---|---|---|
| Number of share options | 485 000 | 540 000 |
| Dividend | 0 | 0 |
| Historical volatility (%) | 132 % | 107 % |
| Risk free interest rate (%) | 1,11% | 0.37 % |
| Expected lifetime (years) | 5 | 5 |

**Authorisation from the annual general meeting**
The general meeting held 28 May 2021 authorised the Board of Directors to grant the employees with a total of 2,790,000 share options and the authorisation applies for one year. 1,615,000 share options of the current authorisation have been granted by the Board of Directors at year-end 2021. The Board of Directors has not been granted any share options. See note 23 Related party transactions for further information.

**Share option transactions during the year**
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 the 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 the following primary insiders: 70,000 share options were allotted to Per Walday, CEO. 60,000 share options were allotted to Amir Snapir, CMO. 50,000 share options were allotted to Ronny Skuggedal, CFO. 40,000 share options were allotted to Ludovic Robin, CBO. 40,000 share options were allotted to Anders Høgset, CSO. 40,000 share options were allotted to Lucy Wabakken, CDO (acting). 40,000 share options were allotted to Kristin Eivindvik, CDO.

**Share option transactions during 2020**
Participants in the Company's share option program exercised on 2 September 2020 a total number of 60,500 share options, out of these 26,000 share options were exercised at a strike price of NOK 7.84 and 34,500 share options were exercised at a strike price of NOK 3.26. The average market value for the shares were NOK 45.60. All of the exercised share options were about to expire unless exercised.

Out of the total number of exercised share options, 54,500 share options are exercised by the following primary insiders:

Primary insider Per Walday (CEO) has on 2 September 2020 exercised a total number of 9,000 share options at a strike price of NOK 3.26. The share options were granted to Walday in November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 4,600 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.

Primary insider Ronny Skuggedal (CFO) has on 2 September 2020 exercised a total number of 20,000 share options at a strike price of NOK 7.84 and a total number of 6,000 share options at a strike price of NOK 3.26. The share options were granted to Skuggedal in April 2015 and November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 14,000 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.

Primary insider Kristin Eivindvik (PD) has on 2 September 2020 exercised a total number of 6,000 share options at a strike price of NOK 7.84 and a total number of 7,500 share options at a strike price of NOK 3.26. The share options were granted to Eivindvik in April 2015 and November 2015 and now about to expire unless exercised. Subsequent to the exercise she has sold 7,100 shares in the market at an average price of NOK 45.6 per share in order to finance the cash and tax impact of the transaction.

Primary insider Anders Høgset (CSO) has on 2 September 2020, as a participant in the Company's share option program, exercised a total number of 6,000 share options at a strike price of NOK 3.26. The share options were granted to Høgset in November 2015 and now about to expire unless exercised. Subsequent to the exercise he has sold 4,500 shares in the market at an average price of NOK 45.6 per share.

In accordance with the authorisation granted by the Annual General Meeting 27 May 2020, the Board of Directors of PCI Biotech Holding ASA awarded a total of 540,000 share options to key employees on 6th October 2020. 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 50.36, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date.

The share options vest over approximately three years and can be exercised with 1/3 of the options after approximately one year, further 1/3 after approximately two years and the last third after approximately three years. To ensure long term ownership by executive management, shares shall be held for at least three years after exercise, except shares to be sold immediately to cover transaction costs and tax under a so called cash less exercise.

The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value is assessed to NOK 20.7 million which will be charged to the profit and loss statement over the vesting period for the share options. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2025.

Of the 540,000 share options, 400,000 share options were allotted to the following primary insiders: 90,000 share options were allotted to Amir Snapir, CMO. 90,000 share options were allotted to Ludovic Robin, CBO. 70,000 share options were allotted to Per Walday, CEO. 50,000 share options were allotted to Anders Høgset, CSO. 50,000 share options were allotted to Ronny Skuggedal, CFO. 50,000 share options were allotted to Lucy Wabakken, CDO (acting).

**P&L and balance sheet accounting effects of the share option programme**
The net P&L accounting effect for share-based payments and corresponding social security liability following potential future share option exercises were a net cost of NOK 12.6 million (2020: NOK 1.3 million). The potential social security liability for future exercises are calculated based upon share options that are in-the-money per reporting date and recognised as a short- or long-term liability in the balance sheet depending on vesting date of the underlying share options. No share options are in-the-money per year-end 2021.

For the parent company, PCI Biotech Holding ASA, a net amount of NOK 12.9 million for share based payments (2020: NOK 6.3 million) is recognised as an investment in subsidiary.

Share options outstanding at the end of the period have the following expiry date and exercise prices:

| Expiry date | Exercise price in NOK per share | Number of share options | |
|---|---|---|---|
| | | 2021 | 2020 |
| 2022 - Q3 | 21.48 | 310 000 | 325 000 |
| 2024 - Q3 | 25.78 | 300 000 | 320 000 |
| 2025 - Q3 | 50.36 | 520 000 | 540 000 |
| 2026 - Q3 | 19.41 | 485 000 | - |
| **Total** | | **1 615 000** | **1 185 000** |

Options granted to employees, average exercise price and transactions during the year is listed below:

| | 2021 | | 2020 | |
|---|---|---|---|---|
| | Number | Average exercise price in NOK per share | Number | Average exercise price in NOK per share |
| Outstanding at the beginning of the year | 1 185 000 | 35.80 | 705 500 | 17.70 |
| Granted during the year | 485 000 | 19.41 | 540 000 | 50.36 |
| Lapsed during the year | 55 000 | 33.55 | 0 | - |
| Exercised during the year | 0 | - | 60 500 | 5.23 |
| Expired during the year | 0 | - | 0 | - |
| Outstanding at year-end | 1 615 000 | 30.96 | 1 185 000 | 35.80 |
| Exercisable options at year-end | 683 333 | 30.06 | 431 667 | 22.54 |

Exercise price and average remaining lifetime for outstanding options per year-end:

| Number of options 2021 / 2020 | Exercise price in NOK per share | Average remaining lifetime (years) | |
|---|---|---|---|
| | | 2021 | 2020 |
| 310 000 / 325 000 | 21.48 | 0.7 | 1.7 |
| 300 000 / 320 000 | 25.78 | 2.7 | 3.7 |
| 520 000 / 540 000 | 50.36 | 3.7 | 4.7 |
| 485 000 / 0 | 19.41 | 4.7 | - |

## 9 PENSION EXPENSES

| *(figures in NOK 1,000)* | Group | |
|---|---|---|
| | 2021 | 2020 |
| Total pension cost from contribution schemes | 1 702 | 1 627 |

The contribution pension scheme is in compliance with Norwegian public requirements and a total of 13 employees are included in the scheme at year-end 2021 (2020: 14 employees), in addition to one employee in a Finnish pension scheme and two employees in a Swedish pension scheme.

## 10 AUDITORS FEE

| AUDITOR FEES | Group | | Parent | |
|---|---|---|---|---|
| *(figures in NOK 1,000)* | 2021 | 2020 | 2021 | 2020 |
| Statutory audit | 210 | 198 | 131 | 135 |
| Other assurance services | 52 | 60 | 8 | 17 |
| **Total** | **262** | **259** | **139** | **152** |

## 11 FINANCIAL INCOME AND EXPENSES

| *(figures in NOK 1,000)* | Group | | Parent | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Interest income | 640 | 1 849 | 2 | 84 |
| Interest income group company | - | - | 1 591 | 2 905 |
| Other financial income | 149 | 8 947 | 0 | 8 411 |
| **Total financial income** | **789** | **10 796** | **1 593** | **11 400** |
| | | | | |
| Interest expense | 51 | 322 | 187 | 307 |
| Interest expense leasing | 38 | 75 | 0 | 0 |
| Other financial expense | 3 062 | 518 | 151 351 | 0 |
| **Total financial expense** | **3 151** | **915** | **151 539** | **307** |

For 2021 NOK 2.5 million in other financial expense (2020: NOK 8.4 million other financial income) in Parent and NOK 2.5 million in other financial expense (2020: NOK 8.5 million other financial income) in Group are related to accounting effects of cash deposits in Euro per year-end, resulting from converting these Euro cash positions into NOK as functional currency for the annual accounts.

In 2021 the parent company made a partial write-down of its investment in the wholly-owned subsidiary PCI Biotech AS, based on the observable fair value of the Group at Oslo Børs per year-end 2021. The NOK 148.8 million write-down is disclosed as financial expenses for the parent company.

## 12 TAX

| *(figures in NOK 1,000)* | Group | | Parent | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **Comprehensive income before tax** | **-88 391** | **-72 239** | **-154 915** | **6 429** |
| Expected nominal rate of tax (2021: 22% / 2020: 22%) | -19 446 | -15 893 | -34 081 | 1 414 |
| Permanent differences charged through P&L | 1 803 | 343 | 32 741 | 2 |
| Deferred tax asset not recognised in the balance sheet | 17 643 | 15 549 | 1 340 | -1 416 |
| Total tax expense for the year | 0 | 0 | 0 | 0 |

**Specification of basis for deferred tax asset / liability**

| **Tax effect of temporary differences:** | Group | | Parent | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Fixed assets | 64 | 184 | 0 | 0 |
| Receivables | -11 | 0 | 0 | 0 |
| Carry forward loss | -142 957 | -125 484 | -11 215 | -9 914 |
| **Total tax asset** (22% for 2021 / 22% for 2020) | **-142 904** | **-125 300** | **-11 215** | **-9 914** |
| Deferred tax asset not recognised | 142 904 | 125 300 | 11 215 | 9 914 |
| **Deferred tax asset recognised in the balance sheet** | 0 | 0 | 0 | 0 |

The Group and Parent have no history of taxable profits and due to uncertainty of future utilisation, deferred tax assets have not been recognised in the balance sheets. Deferred tax asset not recognised in the balance sheet amounts to NOK 142.9 million (2020: NOK 125.3 million) at group level. The carry forward loss has no time limit according to current tax legislations.

## 13 EARNINGS PER SHARE

Earnings per share for the Group (diluted earnings per share) are calculated on the basis of the financial result after tax for the year (financial result after tax for the year adjusted for dilutive effects) divided by a weighted average number of shares outstanding for the year (weighted average number

of outstanding shares for the year adjusted for dilutive effects). Dilution effect is weighted number of outstanding share options which are in-the-money during the year. Accretive effects are not taken into consideration. Earnings per share are not affected by the dilution effect if negative results in the period.

| **Earnings per share** | **2021** | **2020** |
|---|---|---|
| Weighted average number of shares (in '000) | 37 326 | 37 285 |
| Net loss for the year | -88 391 | -72 239 |
| Earnings per share (NOK per share) | -2.37 | -1.94 |

Dilution effect of in-the-money outstanding share options are not relevant as the result for the year is negative for 2021 and 2020.

## 14 FIXED AND INTANGIBLE ASSETS

*(figures in NOK 1,000)*

| | **Group** | | |
|---|---|---|---|
| | **Device (laser)** | **Office equipment** | **Total** |
| **Acquisition cost per 31 December 2019** | **5 349** | **392** | **5 742** |
| Additions in 2020 | 3 919 | 0 | 3 919 |
| Disposals and scrapping during 2020 | 0 | 0 | 0 |
| **Acquisition cost per 31 December 2020** | **9 268** | **392** | **9 661** |
| Additions in 2021 | 341 | 0 | 341 |
| Disposals and scrapping during 2021 | 0 | 0 | 0 |
| **Acquisition cost per 31 December 2021** | **9 609** | **392** | **10 001** |
| | | | |
| **Accumulated depreciation per 31 December 2019** | **339** | **330** | **669** |
| Ordinary depreciation 2020 | 1 589 | 13 | 1 603 |
| Disposals in 2020 | 0 | 0 | 0 |
| **Accumulated depreciation per 31 December 2020** | **1 928** | **343** | **2 272** |
| Ordinary depreciation 2021 | 1 908 | 16 | 1 923 |
| Disposals in 2021 | 0 | 0 | 0 |
| **Accumulated depreciation per 31 December 2021** | **3 836** | **359** | **4 195** |
| | | | |
| Book value per 31 December 2020 | 7 340 | 48 | 7 388 |
| **Book value per 31 December 2021** | **5 773** | **33** | **5 806** |

The laser device is for the fima*CHEM* programme. The COVID-19 pandemic has not impacted the valuation of fixed assets per year-end 2021 or 2020. A non-adjusting event after the reporting period has made the device (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 25 Subsequent events for more details.

## 15 SHARES IN SUBSIDIARIES – only relevant for the Parent company

| Company | Year of acquisition | Share capital of company | Equity participation and share of voting rights | Carrying amount (NOK thousand) | Equity (NOK thousand) | Financial result (NOK thousand) |
|---|---|---|---|---|---|---|
| PCI Biotech AS, Oslo - Norway | 2008 | | | | | |
| Figures for 2021 | | 5 818 680 | 100 % | 504 191 | 73 393 | -82 293 |
| Figures for 2020 | | 5 495 420 | 100 % | 600 070 | 102 748 | -78 668 |

In 2021 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 39 676 740, totalling to NOK 40 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 40 million by PCI Biotech Holding ASA.

In 2020 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 69 676 740, totalling to NOK 70 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 70 million by PCI Biotech Holding ASA.

The carrying amount is assessed at the lowest of historic cost value and the observable market value of PCI Biotech at Oslo Børs. Per year-end the carrying amount is at fair value based on the observable market value of PCI Biotech at Oslo Børs (2020: at historic cost). In 2021 the parent company made a partial write-down of its investment in the wholly-owned subsidiary PCI Biotech AS, based on the observable fair value of the Group at Oslo Børs per year-end 2021. The NOK 148.8 million write-down is disclosed as financial expenses for the parent company.

## 16 FINANCIAL RISK

This note describes the Group's various financial risks and the management of these. In addition, numerical tables for risk associated with financial risks are also presented.

**(I) Organisation of financial risk management**
PCI Biotech has an international business operation and is exposed to currency risk, interest risk, liquidity risk and credit risk. The Group has not utilised any derivatives or other financial instruments to reduce these risks during the accounting period. The responsibility for managing financial risk is at group level. The risk associated with centralised activities such as financing, interest rate and currency management is managed at group level. In addition, the group manages the risks associated with the business processes. The financial risk management is monitored by the Board of Directors.

**Centralised risk management**
PCI Biotech has a centralised risk management policy. The most important tasks within risk management are to ensure the Group's financial freedom to act both in a short- and long term perspective, and to monitor and manage financial risk in cooperation with the individual units in the group. A hedging-oriented view forms the basis for risk management of the finance department's positions so that all transactions with financial instruments have a counter item in an underlying commercial hedging requirement. Any permits required for borrowing and entering into derivative framework agreements are given on an annual basis by the Board of Directors.

**Financial risk**
This section describes the most important risk factors within each business area and the management of these. In this context, financial risk is understood as risk associated with financial instruments. These can either be hedging instruments for underlying risk or be considered themselves as a source of risk. Market risk is not hedged with financial instruments.

**Research and development activities**
PCI Biotech carries out research and development for new innovative medical products based on the company's patented technology. The currency risk in research and development is limited to the purchase of services, primarily related to clinical and pre-clinical studies. Foreign currency risk associated with purchase of goods and services are foremost related to transactions in EUR and GBP. Foreign currency exposure associated with research and development is not normally hedged, but at year-end 2021 the Group has placed cash deposits in EURO to hedge the foreign currency risk for the RELEASE study.

**(II) Classes of financial risk**

**Interest rate risk**
Except for interest-bearing leasing liabilities, PCI Biotech does not have any interest-bearing debt, and the group's interest rate risk is primarily associated with the Group's cash positions and cash equivalents. This risk is managed at group level. The main strategy is to diversify the risk and invest in cash deposits with fixed or spot interest rates or money market funds with low risk, high liquidity and short duration. All funds are placed as cash deposits per year-end 2021.

**Liquidity risk**
One of the most important objectives of PCI Biotech's finance policy is to ensure that the Group has financial freedom to act in the short and long-term in order to attain strategic and operational goals. PCI Biotech shall have sufficient funds to cover expected capital requirements during the forthcoming 12 month period in addition to a strategic reserve. Cash flow in research and development depends mainly on the activity level of the clinical programmes and the activity levels are adjustable without substantial long term commitments. The finance department monitors the cash flows in a short- and long term perspective. PCI Biotech's most important source of finance are future royalty and milestone payments associated with licence agreements, government grants and the capital market. The biotech industry is a resource demanding industry, and drug development can be both labour and cash intensive. PCI Biotech being a pre-commercial stage biotech, means that the Company mainly relies on the ability to raise funds via the equity market and government grants for its development plans, and no assurance of the availability of resources for current and future drug development plans can be made. The capital market is used as a source of liquidity when this is appropriate and the conditions in these markets are competitive. The finance department continually evaluate other sources of financing. PCI Biotech does not have any debt agreements with key business ratio requirements (covenants).

The current cost base for the Company will be reduced over time in 2022, mainly due to the closure of the RELEASE trial and implemented cost reduction matters during first half of 2022 slimming down both the operational- and executive team. The cash position per year-end 2021 is on this basis estimated to enable a financial runway well into 2023.

| **Group** *(figures in NOK 1,000)* | **Remaining period** | | | | |
|---|---|---|---|---|---|
| | **Less than 1 month** | **1-3 months** | **3-12 months** | **1-5 years** | **Total** |
| **31.12.2021** | | | | | |
| Other long-term liabilities | 0 | 0 | 0 | 0 | **0** |
| Long term-lease liabilities | 0 | 0 | 0 | 1 277 | **1 277** |
| Trade accounts payables | 3 745 | 0 | 0 | 0 | **3 745** |
| Current lease liabilities | 0 | 0 | 629 | 0 | **629** |
| Public duties payables | 1 171 | 542 | 0 | 0 | **1 713** |
| Other current liabilities | 760 | 3 398 | 10 665 | 0 | **14 823** |
| **Total liabilities** | **5 676** | **3 940** | **11 294** | **1 277** | **22 186** |
| **31.12.2020** | | | | | |
| Other long-term liabilities | 0 | 0 | 0 | 32 | **32** |
| Long term lease liabilities | 0 | 0 | 0 | 0 | **0** |
| Trade accounts payables | 5 191 | 0 | 0 | 0 | **5 191** |
| Current lease liabilities | 168 | 168 | 336 | | **673** |
| Public duties payables | 950 | 165 | 992 | 0 | **2 107** |
| Other current liabilities | 175 | 4 516 | 7 186 | 0 | **11 877** |
| **Total liabilities** | **6 484** | **4 849** | **8 514** | **32** | **19 879** |

Other long-term liabilities relates to estimated social securities for potential future share option exercises in the Group's remuneration incentive program.

| **Parent** *(figures in NOK 1,000)* | **Remaining period** | | | | |
|---|---|---|---|---|---|
| | **Less than 1 month** | **1-3 months** | **3-12 months** | **1-5 years** | **Total** |
| **31.12.2021** | | | | | |
| Trade accounts payables | 19 | 0 | 0 | 0 | **19** |
| Public duties payables | 0 | 0 | 140 | 0 | **140** |
| Other current liabilities | 0 | 0 | 990 | 0 | **990** |
| **Total liabilities** | **19** | **0** | **1 130** | **0** | **1 149** |
| **31.12.2020** | | | | | |
| Trade accounts payables | 60 | 0 | 0 | 0 | **60** |
| Public duties payables | 0 | 0 | 129 | 0 | **129** |
| Other current liabilities | 0 | 0 | 915 | 0 | **915** |
| **Total liabilities** | **60** | **0** | **1 044** | **0** | **1 104** |

**Credit risk**

PCI Biotech has no sales or receivable balances based on sales for 2020 and 2019 and faces therefore no credit risk. PCI Biotech has no need for monitoring of receivable balances based on sales and no bad debt provision has been recognised during 2021 or 2020. The majority of the Group's financial assets are cash and cash equivalents and these funds are placed in cash deposits in different banks with satisfactory credit ratings. The credit risk for these funds is assessed to be low and no impairment test are performed for 2021 or 2020.

The following table shows an overview of the maturity structure of the group's financial obligations, based on non-discounted contractual payments.

**Foreign currency risk**
As NOK is the Group's functional currency, PCI Biotech is exposed to foreign currency risk associated with the Group's foreign net exchange rate exposure. The Group's expenses accrue in various currencies, primarily EUR, GBP, USD, SEK and NOK. PCI Biotech is therefore exposed to fluctuations in foreign exchange rates. The Group evaluates whether measures should be taken to reduce the foreign currency risk through hedging for significant transactions and projects.

The following table details the Group's and Parent company's sensitivity to potential changes in the foreign currency exchange rate, with all other factors constant. The changes in exchange rates of +/10% is considered to be a reasonably possibly change. The calculation assumes an equal change in exchange rates against all relevant foreign currencies. The estimated effect on operating result is due to changes in value of monetary items in the balance sheet per year end, with no effect on Other Comprehensive Income

| | Changes in exchange rates | Effect on operating result | |
|---|---|---|---|
| | | Parent | Group |
| **2021** | +/- 10 % | +/- 2 647 | +/- 1 811 |
| **2020** | +/- 10 % | +/- 6 790 | +/- 6 432 |

## 17 CLASSIFICATION OF FINANCIAL ASSETS AND LIABILITIES

The Group´s financial assets are governmental grant receivables, and the Group's financial liabilities are accounts payables and other current liabilities. The Parent's financial assets also include receivables from group companies. All these financial assets and liabilities are classified as financial instruments at amortised costs, and no financial assets or liabilities are classified at fair value through profit and loss.

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.

## 18 RECEIVABLES

Receivables are measured by the amortised cost method, but due to the assets being short-term receivables the non-discounted contractual payments are disclosed. No credit losses allowance is recognised at year-end 2021 or 2020.

**Other current receivables - specification**
*(Figures in NOK 1,000)*

| | Group | | Parent | |
|---|---|---|---|---|
| | **31.12.2021** | **31.12.2020** | **31.12.2021** | **31.12.2020** |
| Recognised not received government grants | 4 750 | 5 373 | 0 | 0 |
| Prepaid payables | 7 096 | 7 176 | 5 | 54 |
| VAT receivables | 354 | 613 | 28 | 32 |
| **Total other receivables** | **12 200** | **13 162** | **33** | **86** |

The parent company has supported its wholly owned subsidiary, PCI Biotech AS, with loans and capital increases during the year. The capital increase during 2021 was NOK 40 million (2020: NOK 70 million) and per year-end the loan balance is NOK 15.0 million (2020: NOK 19.0 million).

## 19 CASH AND CASH EQUIVALENTS

| *(Figures in NOK 1,000)* | Group | | Parent | |
|---|---|---|---|---|
| | 31.12.2021 | 31.12.2020 | 31.12.2021 | 31.12.2020 |
| Cash and cash equivalents, restricted (1) | 938 | 799 | 0 | 0 |
| Cash and cash equivalents, non-restricted | 115 180 | 187 168 | 26 476 | 68 474 |
| **Total** | **116 118** | **187 967** | **26 476** | **68 474** |

(1) Restricted cash and cash equivalents are security for the employees' withholding tax and bank deposits.

The carrying amount of cash and cash equivalents is approximately equal to fair value since these instruments have a short term to maturity. The cash and cash equivalents are placed in cash deposits in NOK and EUR in different banks with satisfactory credit ratings. The credit risk for these funds is assessed to be low and no impairment test are performed for 2021 or 2020.

Conversion effects for bank deposits in foreign currency (Euro) versus NOK as functional currency for the Group accounts was NOK -2.5 million (2020: NOK 8.5 million) and for the parent accounts NOK -2.5 million in 2021 (2020: NOK 8.4 million).

## 20 SHARE CAPITAL

| | No. of shares | Nominal value per share in NOK | Share capital in NOK |
|---|---|---|---|
| **Share capital as per 31.12.2019** | **37 265 890** | **3,00** | **111 797 670** |
| Share issues in 2020 | 60 500 | 3,00 | 181 500 |
| **Share capital as per 31.12.2020** | **37 326 390** | **3,00** | **111 979 170** |
| Share issues in 2021 | - | - | - |
| **Share capital as per 31.12.2021** | **37 326 390** | **3,00** | **111 979 170** |

All shares have equal voting rights and otherwise have equal rights in the company and one share represents one voting right.

Ordinary shares are classified as equity and only one class of shares exists. Expenses that are directly attributable to the issue of ordinary shares are disclosed as reduction of equity.

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 was 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.

Share issues in 2020

In September 2020 participants in the Company's share option program exercised a total number of 60,500 share options. Following the exercise of share options, the Company's Board of Directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 27 May 2020, decided to increase the Company's share capital with NOK 181,500 by issuing 60,500 new shares, each share of par value NOK 3.00. The transaction was registered in the Norwegian Register of Business Enterprises on 8 September 2020, and the capital increase has thus been completed. The capital increase resulted in net proceeds of NOK 0.3 million.

Subsequent to the transaction the Company's new 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.

Ownership structure 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% |
| ODD R. GRESSLIEN | 852 000 | 2.28% |
| NORDNET BANK AB | 728 409 | 1.95% |
| JANDERSEN KAPITAL AS | 470 000 | 1.26% |
| ALEXANDER BERG-LARSEN | 461 148 | 1.24% |
| FORENEDE FORVALTNING AS | 380 467 | 1.02% |
| **Total 10 largest shareholders** | **12 474 445** | **33.42%** |
| **Others** | **24 851 945** | **66.58%** |
| **Total** | **37 326 390** | **100.00%** |

Shares owned, directly or indirectly, by members of the board and executive management, and their personally related parties per 31.12.2021 and per 31.12.2020:

| | | Number of shares | |
|---|---|---|---|
| **Name** | **Position** | **31.12.2021** | **31.12.2020** |
| 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 | - | - |
| 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 | - | - |
| Amir Snapir | CMO | - | - |
| **Total** | | **378 336** | **378 336** |

* Hilde Furberg's shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.

## 21 FINANCING STRUCTURE

Except for interest-bearing leasing debt the Group had no external interest-bearing debt as of year-end 2021 or 2020.

## 22 OTHER CURRENT LIABILITIES BY YEAR END

| *(Figures in NOK 1,000)* | Group | | Parent | |
|---|---|---|---|---|
| | **31.12.2021** | **31.12.2020** | **31.12.2021** | **31.12.2020** |
| Accruals for incurred external R&D expenses | 8 721 | 6 440 | 0 | 0 |
| Accruals for employee bonus, holiday payments, board remuneration etc. | 5 495 | 5 437 | 990 | 915 |
| Other accruals | 0 | 0 | 0 | 0 |
| **Total other current liabilities** | **14 217** | **11 877** | **990** | **915** |

Other current liabilities are measured by the amortised cost method, but due to the liabilities being short term liabilities the non-discounted contractual payments are disclosed.

## 23 RELATED PARTIES TRANSACTIONS

Figures for remuneration are expensed amounts in the financial year. All board remunerations are accounted for in the parent company.

| *(Figures in NOK 1,000)* | **Board remuneration** | **Salary** | **Bonus** | **Other benefits** | **Pension benefits** | **Total** |
|---|---|---|---|---|---|---|
| **Senior executives 2021** | | | | | | |
| Per Walday, CEO | 0 | 2 260 | 487 | 20 | 161 | **2 928** |
| Ronny Skuggedal, CFO | 0 | 1 666 | 287 | 20 | 154 | **2 128** |
| Anders Høgset, CSO | 0 | 1 399 | 152 | 20 | 138 | **1 710** |
| Kristin Eivindvik, PD | 0 | 498 | 15 | 16 | 78 | **607** |
| Lucy Wabakken, CDO (acting) | 0 | 1 139 | 104 | 20 | 145 | **1 408** |
| Ludovic Robin, CBO | 0 | 1 793 | 222 | 63 | 0 | **2 078** |
| Amir Snapir, CMO | 0 | 2 163 | 318 | 44 | 406 | **2 932** |
| **Total senior executives remuneration** | **0** | **10 919** | **1 585** | **205** | **1 082** | **13 790** |
| | | | | | | |
| **Senior executives 2020** | | | | | | |
| Per Walday, CEO* | 0 | 2 031 | 317 | 400 | 154 | **2 902** |
| Ronny Skuggedal, CFO* | 0 | 1 434 | 258 | 1 027 | 153 | **2 873** |
| Anders Høgset, CSO* | 0 | 1 124 | 106 | 273 | 131 | **1 633** |
| Kristin Eivindvik, PD* | 0 | 1 017 | 54 | 558 | 130 | **1 759** |
| Lucy Wabakken, CDO (acting) | 0 | 1 094 | 92 | 19 | 127 | **1 331** |
| Ludovic Robin, CBO** | 0 | 1 110 | 0 | 65 | 0 | **1 175** |
| Amir Snapir, CMO** | 0 | 1 271 | 0 | 44 | 183 | **1 497** |
| **Total senior executives remuneration** | **0** | **9 080** | **827** | **2 386** | **878** | **13 171** |

* "Other benefits" include salary benefits in relation to exercise of share options during 2020.
** Ludovic Robin and Amir Snapir joined the Company in May 2020.

| | Board remuneration | Salary | Bonus | Other benefits | Pension benefits | Total |
|---|---|---|---|---|---|---|
| **Board of Directors 2021** | | | | | | |
| Hans Peter Bøhn, Chairman | 355 | 0 | 0 | 0 | 0 | 355 |
| Hilde Furberg | 220 | 0 | 0 | 0 | 0 | 220 |
| Christina Herder | 220 | 0 | 0 | 0 | 0 | 220 |
| Lars Viksmoen | 220 | 0 | 0 | 0 | 0 | 220 |
| Andrew Hughes | 220 | 0 | 0 | 0 | 0 | 220 |
| **Total remuneration** | **1 235** | **0** | **0** | **0** | **0** | **1 235** |

| | Board remuneration | Salary | Bonus | Other benefits | Pension benefits | Total |
|---|---|---|---|---|---|---|
| **Board of Directors 2020** | | | | | | |
| Hans Peter Bøhn, Chairman | 345 | 0 | 0 | 0 | 0 | 345 |
| Hilde Furberg | 210 | 0 | 0 | 0 | 0 | 210 |
| Christina Herder | 210 | 0 | 0 | 0 | 0 | 210 |
| Lars Viksmoen | 210 | 0 | 0 | 0 | 0 | 210 |
| Andrew Hughes | 210 | 0 | 0 | 0 | 0 | 210 |
| **Total remuneration** | **1 185** | **0** | **0** | **0** | **0** | **1 185** |

The senior executives participate in the Group's pension plan that is a defined contribution plan which entails payment of 7% to 21% of the employee's annual salary up to 12 times the basic National Insurance amount (G). The pension scheme also covers in the event of disability.

The CEO is entitled to six months' notice and has an agreement of additional 6 months' salary on certain terms. There are no agreements beyond the statutory requirements for other senior executives.

Senior executives have not received any remuneration or financial benefits from other companies in the Group other than those disclosed above. It is not given additional remuneration for special services outside the normal functions of a senior executive.

There are no loans or pledges to senior executives, board of directors, employees or other persons in elected corporate bodies. For more details about PCI Biotech's remuneration policy, please see the established guidelines on the determination of salaries and other remuneration of executive management in accordance with § 6–16a of the Norwegian Public Companies Act.

Senior executive's shareholdings in PCI Biotech Holding ASA are disclosed in note 20 Share capital.

Allocation, exercise and holdings of share options in the Company for senior executives are presented in the table below:

| Overview share options, Senior executives | Total holdings 31.12.2020 | Allocated | Lapsed | Exercised | Expired | Total holdings 31.12.2021 | Average exercise price in NOK |
|---|---|---|---|---|---|---|---|
| Per Walday, CEO | 225 000 | 70 000 | 0 | 0 | 0 | 295 000 | 28.72 |
| Ronny Skuggedal, CFO | 140 000 | 50 000 | 0 | 0 | 0 | 190 000 | 29.44 |
| Anders Høgset, CSO | 150 000 | 40 000 | 0 | 0 | 0 | 190 000 | 29.55 |
| Kristin Eivindvik, CDO | 70 000 | 40 000 | 0 | 0 | 0 | 110 000 | 24.92 |
| Lucy Wabakken, CDO (acting) | 120 000 | 40 000 | 0 | 0 | 0 | 160 000 | 30.79 |
| Ludovic Robin, CBO | 90 000 | 40 000 | 0 | 0 | 0 | 130 000 | 40.84 |
| Amir Snapir, CMO | 90 000 | 60 000 | 0 | 0 | 0 | 150 000 | 37.98 |
| **Total** | **885 000** | **340 000** | **0** | **0** | **0** | **1 225 000** | |

**Related parties:**

Helpyou2 Ltd.
Helpyou2 Ltd. is a UK based company wholly owned by Prof. Andrew Hughes, a Director in PCI Biotech Holding ASA. The services rendered concern Prof. Hughes position as member of the Scientific Advisory Committee ('SAC'), and other related agreed scientific consultancies by Prof. Hughes during the year. The services rendered are pre-approved by the Board of Directors and regular fee overviews are presented for the Board of Directors. Helpyou2 Ltd. has for services related to the SAC received fees of NOK 21 thousand for 2021 (2020: NOK 0.). For other related agreed scientific consultancies, Helpyou2 Ltd. received NOK 24 thousand in fees for 2021 (2020: NOK 0). It is in management and the Board of Director's opinion that the service fee is based on 'arm's length' principles and the level of consultancy is not considered to constitute a threat to independence for the parties in 2021 or 2020.

PCI Biotech AS:
The parent company, PCI Biotech Holding ASA, has no employees. The Group operations are managed through the wholly-owned subsidiary PCI Biotech AS that has a management service agreement with the parent company, including services like management, offices, finance and investor relation functions for the Group. All transactions are performed at market terms.

The parent company has been charged for operations according to the service agreement of NOK 2.2 million in 2021 (2020: NOK 1.9 million). The parent company has charged PCI Biotech AS interest expenses for intercompany loans of NOK 1.6 million during 2021 (2020: NOK 2.9 million). Net current receivables from PCI Biotech AS at year-end 2021 were NOK 15.0 million (2020: NOK 19.0 million). In 2021 an intercompany loan to PCI Biotech AS of NOK 40 million was utilised as contribution in kind from PCI Biotech Holding ASA for a capital increase in PCI Biotech AS.

## 24 RIGHT TO USE ASSETS AND LEASE LIABILITIES

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway. The lease originally runs to 31 December 2021, with an option for three more years. PCI Biotech exercised the lease option in 2021 and the lease now runs to 31 December 2024. The lease agreement is subject to annual adjustment according to changes in the consumer price index. Amounts of minimum lease payment for the non-cancellable operating lease is NOK 1.9 million (discounted contractual payments) per year-end 2021, applying an incremental borrowing rate of 6%.

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

| **Right to use asset - office lease** | |
|---|---|
| Initial recognition 01.01.2019 | 1 815 |
| **Acquisition costs 31.12.2019** | **1 815** |
| Acquisitions FY 2020 | 0 |
| Acquisitions FY 2021 | 1 867 |
| **Accumulated acquisition costs 31.12.2021** | **3 682** |
| Depreciation FY 2020 | 605 |
| **Accumulated depreciation and impairment as of 31.12.2020** | **1 209** |
| Depreciation FY 2021 | 620 |
| **Accumulated depreciation and impairment as of 31.12.2021** | **1 828** |
| **Total right to use assets – office lease as of 31.12.2020** | **605** |
| **Total right to use assets – office lease as of 31.12.2021** | **1 854** |
| Lower of remaining lease term or economic life - 2020 | 1.0 years |
| Lower of remaining lease term or economic life - 2021 | 3.0 years |
| Depreciation method | Linear |

| **Lease liabilities - office** | |
|---|---|
| Accumulated recognition 31.12.19 | 1 196 |
| Recognition during 2020 | 0 |
| Recognition during 2021 | 1 867 |
| **Accumulated recognition 31.12.21** | **3 086** |
| Payments principal portion of the lease liability FY 2020 | -668 |
| Payments principal portion of the lease liability FY 2021 | -672 |
| Interest expenses on the lease liability FY 2020 | 144 |
| Interest expenses on the lease liability FY 2021 | 40 |
| **Total lease liabilities for office as of 31.12.2020** | **673** |
| **Total lease liabilities for office as of 31.12.2021** | **1 906** |
| Whereof: | |
| Short term lease liabilities < 1 year 2020 / 2021 | 673 / 629 |
| Long term lease liabilities > 1 year 2020 / 2021 | 0 / 1 277 |

The Group 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.

| **Income statement effects leasing** | **2021** | **2020** |
|---|---|---|
| Depreciation of right to use asset | -620 | -606 |
| Operating expenses for short-term leases | 0 | -170 |
| **Effect on Operating results net of tax** | **-620** | **-777** |
| Interest expenses on the lease liabilities | -40 | -144 |
| **Effect on Net financial result net of tax** | **-660** | **-921** |
| **Comprehensive income effect net of tax** | **-660** | **-921** |

The Group had total cash outflows related to leases of NOK 1.0 million in 2021 (2020: NOK 0.8 million). Minimum payments for non-cancellable payments for all leases are NOK 0.7 million per year-end 2021 (2020: NOK 0.9 million).

## 25 SUBSEQUENT EVENTS

The company decided in January 2022 to close recruitment to the RELEASE study and focus the drug development efforts on the promising immunotherapy opportunities within fima*VACC* and selected applications for the fima*NAC* asset.

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 runway 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.

The war in Ukraine started after the company decided to close recruitment to the RELEASE trial and have therefore no material impact on the operations for PCI Biotech.

In March 2022 the CEO, Dr Per Walday, resigned to assume a new position. Dr Walday has a notice period of six months, and he will step down from his position by the end of September 2022, or earlier. The Board of Directors will initiate a succession process.

PCI Biotech is not aware of any other subsequent events since year-end 2021 which is of material significance to the financial statements as of 31 December 2021.

Building a better working world

Statsautoriserte revisorer
Ernst & Young AS

Dronning Eufemias gate 6a, 0191 Oslo
Postboks 1156 Sentrum, 0107 Oslo

Foretaksregisteret: NO 976 389 387 MVA
Tlf: +47 24 00 24 00

www.ey.no
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**INDEPENDENT AUDITOR'S REPORT**

To the Annual Shareholders' Meeting of PCI Biotech Holding ASA

# Report on the audit of the financial statements

## Opinion

We have audited the financial statements of PCI Biotech Holding ASA (the Company), which comprise the financial statements of the Company and the consolidated financial statements of the Company and its subsidiaries (the Group). The financial statements of the Company and the Group comprise the balance sheet as at 31 December 2021 and the statement of comprehensive income, statement of cash flows and statement of changes in equity for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements comply with applicable legal requirements and give a true and fair view of the financial position of the Company and the Group as at 31 December 2021 and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

Our opinion is consistent with our additional report to the audit committee.

## Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial statements* section of our report. We are independent of the Company and the Group in accordance with the requirements of the relevant laws and regulations in Norway and the International Ethics Standards Board for Accountants' *International Code of Ethics for Professional Accountants (including International Independence Standards)* (IESBA Code), and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

To the best of our knowledge and belief, no prohibited non-audit services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided.

We have been the auditor of the Company for 15 years from the election by the general meeting of the shareholders on 17 December 2007 for the accounting year 2007.

## Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements for 2021. We have determined that there are no key audit matters to communicate in our report.

## Other information

Other information consists of the information included in the annual report other than the financial statements and our auditor's report thereon. Management (the board of directors and Chief Executive Officer) is responsible for the other information. Our opinion on the financial statements does not cover the other information, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information, and, in doing so, consider whether the board of directors' report, the statement on corporate governance

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and the statement on corporate social responsibility contain the information required by applicable legal requirements and whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information or that the information required by applicable legal requirements is not included, we are required to report that fact.

We have nothing to report in this regard, and in our opinion, the board of directors' report, the statement on corporate governance and the statement on corporate social responsibility are consistent with the financial statements and contain the information required by applicable legal requirements.

## Responsibilities of management for the financial statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards as adopted by the EU, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's and the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or the Group, or to cease operations, or has no realistic alternative but to do so.

## Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's and the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's and the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit

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evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company and the Group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the board of directors, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

# Report on other legal and regulatory requirement

## Report on compliance with regulation on European Single Electronic Format (ESEF)

*Opinion*

As part of our audit of the financial statements of PCI Biotech Holding ASA we have performed an assurance engagement to obtain reasonable assurance whether the financial statements included in the annual report, with the file name pcibiotechholdingasa-2021-12-31-en, has been prepared, in all material respects, in compliance with the requirements of the Commission Delegated Regulation (EU) 2019/815 on the European Single Electronic Format (ESEF Regulation) and regulation given with legal basis in Section 5-5 of the Norwegian Securities Trading Act, which includes requirements related to the preparation of the annual report in XHTML format and iXBRL tagging of the consolidated financial statements.

In our opinion, the financial statements included in the annual report have been prepared, in all material respects, in compliance with the ESEF Regulation.

*Management's responsibilities*

Management is responsible for the preparation of an annual report and iXBRL tagging of the consolidated financial statements that complies with the ESEF Regulation. This responsibility comprises an adequate process and such internal control as management determines is necessary to enable the preparation of an annual report and iXBRL tagging of the consolidated financial statements that is compliant with the ESEF Regulation.

*Auditor's responsibilities*

Our responsibility is to express an opinion on whether, in all material respects, the financial statements included in the annual report have been prepared in accordance with the ESEF Regulation based on the evidence we have obtained. We conducted our engagement in accordance with the International

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Standard for Assurance Engagements (ISAE) 3000 – “Assurance engagements other than audits or reviews of historical financial information”. The standard requires us to plan and perform procedures to obtain reasonable assurance that the financial statements included in the annual report have been prepared in accordance with the ESEF Regulation.

As part of our work, we performed procedures to obtain an understanding of the company’s processes for preparing its annual report in XHTML format. We evaluated the completeness and accuracy of the iXBRL tagging and assessed management’s use of judgement. Our work comprised reconciliation of the iXBRL tagged data with the audited financial statements in human-readable format. We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Oslo, 27 April 2022
ERNST & YOUNG AS

*The auditor's report is signed electronically*

Tommy Romskaug
State Authorised Public Accountant (Norway)

# OTHER INFORMATION

## DEFINITIONS AND GLOSSARY

| | |
|---|---|
| Amphinex: | Trade name of the clinical intravenous formulation of fimaporfin |
| APC: | Antigen Presenting Cell |
| BIA: | User-driven research-based innovation program by the Research Council of Norway |
| CCA: | Cholangiocarcinoma – Bile duct cancer |
| CPI: | Checkpoint Inhibitor |
| CRC: | Cohort Review Committee |
| CSR: | Corporate Social Responsibility |
| FDA: | US Food and Drug Administration |
| Fimaporfin: | Generic name of the photosensitiser active ingredient TPCS2a |
| fima*CHEM*: | PCI Biotech's development program for enhancement of generic chemotherapies |
| fima*NAC*: | PCI Biotech's development program for delivery of nucleic acids |
| fima*VACC*: | PCI Biotech's development program for a vaccination technology |
| HPV: | Human papillomavirus |
| IDMC: | Independent Data Monitoring Committee |
| IFRS: | International Financial Report Standards |
| IND | Investigational New Drug |
| *In vitro*: | Studies performed with cells or biological molecules studied outside their normal biological context; for example proteins are examined in solution, or cells in artificial culture medium. |
| *In vivo*: | Studies in which the effects of various biological entities are tested on whole, living organisms usually animals. |
| KLH | Keyhole limpet hemocyanin |
| NAA: | Norwegian Accounting Act |
| 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 |
| SAC: | Scientific Advisory Committee |
| SoC: | Standard of Care |

## FINANCIAL CALENDAR

| | |
|---|---|
| First quarter 2022 report | 11 May 2022 |
| Ordinary general meeting 2022 | 25 May 2022 |
| Second quarter 2022 report | 31 August 2022 |
| Third quarter 2022 report | 23 November 2022 |

## INVESTOR CONTACT

Contact person: Ronny Skuggedal, email: rs@pcibiotech.no mob: +47 9400 5757

Web: www.pcibiotech.com

## 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.

**PCI BIOTECH HOLDING ASA**
Ullernchausséen 64
N-0379 Oslo, Norway

Phone: +47 67 11 54 00
email: post@pcibiotech.com
web: www.pcibiotech.com

**PCI BIOTECH AS, subsidiary**
Ullernchausséen 64
N-0379 Oslo, Norway