



Unlocking the potential of innovative medicines

ANNUAL REPORT 2019
PCI Biotech Holding ASA

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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. PCI Biotech applies 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).

Chemotherapies and 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 around the world 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 target cells will not be killed, 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 blue led light may be used in vaccination, as deep light penetration is not needed to reach antigen presenting cells (APC’s) at the site of vaccination. fima*CHEM* and fima*VACC* are consequently very different products, although the same basic mechanism of targeted endosomal release is applied.

THREE DISTINCT BUSINESS AREAS

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 is now developing three parallel programmes.

INOPERABLE BILE DUCT CANCER AND **fimaCHEM**

The fimaCHEM programme aims to fulfil unmet medical needs by providing localised targeted enhancement approved chemotherapies for the benefit of the many patients currently left without effective treatment options. Based on findings from a successful Phase I study in bile duct cancer patients, a single pivotal clinical trial, named the RELEASE study, has been initiated in inoperable extrahepatic bile duct cancer, a rare, but fatal disease with no cure. The RELEASE study design is based on the outcome of meetings with the two leading regulatory authorities, the European Medicine Agency (EMA) and the U.S. Food and Drug Administration (FDA). The RELEASE study will provide the opportunity to generate robust comparative data of importance for market acceptance and has the potential of accelerated/conditional marketing approval as a first line treatment given the rare disease status and high unmet medical need for bile duct cancer patients.

Bile duct cancer (cholangiocarcinoma) affects the cell lining of the bile duct and represents a patient population with a high unmet medical need. It is a rare disease with an incidence rate of 1-2 per 100,000 in the western world, indicating a total patient population of close to 15,000 per year. The incidence rates are increasing worldwide. Overall survival at 5 years is dismal at less than 10%. Resection is today the only potential cure but only possible in 10-35% of the patients. Most patients die of local effects of the tumour and the cancer shows remarkable resistance to chemotherapy. Gemcitabine + cisplatin is the most effective chemotherapy combination and has become a standard treatment for bile duct cancer patients in most regions. Gemcitabine's anti-cancer effect is significantly enhanced by the fimaCHEM technology in preclinical studies.

The first line fimaCHEM treatment regimen consists of an intravenous injection of fimaporfin, followed four days later by an intravenous infusion of gemcitabine and a laser light application in the bile duct easily administered through endoscopic methods used routinely in these patients. The patients then follows the standard background treatment with up to 8 chemotherapy cycles of gemcitabine + cisplatin. The fimaCHEM treatment may be repeated during the background chemotherapy treatment cycles. Local tumour response in the bile duct is important to maintain biliary drainage and loco-regional control may therefore be more important for patient long term survival than would be the case for many other cancers. The fimaCHEM treatment boosts the chemotherapy effect locally in the bile duct, thereby directly targeting this area.

Bile duct cancer is an orphan indication with a range of development and market incentives. PCI Biotech has obtained orphan drug designation (ODD) for fimaporfin in this disease in both EU and the US, meaning that regulatory authorities may expedite a market approval process, and that a market exclusivity period can be secured under the orphan drug legislations in both regions. ODD is a significant regulatory milestone and it recognises the therapeutic benefits fimaCHEM seek to bring to the bile duct cancer patients in need of better local treatments.

The immediate target for PCI Biotech is inoperable patients with extrahepatic disease and metastatic disease limited to the liver. Across Europe and USA approximately 3,000 patients annually are assumed to be eligible for fimaCHEM treatment. The price potential is normally attractive for orphan drugs of this rarity. Possible upside to the targeted patient population are patients with more extensive metastatic spread. There may also be potential for restaging of patients from inoperable to operable disease by the fimaCHEM treatment.

There is a potential for obtaining a significant majority share of the identified eligible market due to the anticipated benefits, such as no competing marketable treatment alternatives, limited development pipeline, greater efficacy due to local chemotherapy boosts and fimaCHEM being an add-on to the current standard of care with easy light access through established standard procedures. The Asian market is also interesting, due to higher incidence of bile duct cancer than the western world.

IMMUNOTHERAPY AND **fimaVACC**

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 cancers 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). A 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 both therapeutic and prophylactic vaccination for several 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 **fimaVACC** 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.

In terms of type of vaccination, **fimaVACC** 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 **fimaVACC** technology: **fimaVACC** increases the number of T-cells induced by cancer vaccines while the CPIs prevent the tumour from evading the immune response. This potentially powerful combination could be summarised with a car analogy where the immune system is the engine, the vaccine is the fuel, the CPIs release the brakes, and **fimaVACC** is the turbocharger.

In addition to T-cell enhancement, the **fimaVACC** features also include antibody enhancement, suggesting that the technology has a clear potential to contribute to the development of new prophylactic vaccines for infectious diseases lacking effective vaccines. Prominent examples are malaria and tuberculosis, but there are also many other potential target diseases for **fimaVACC** based prophylactic vaccination.

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. **fimaVACC** 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. **fimaVACC** 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 **fimaVACC**'s key competitive differentiators.

The proprietary **fimaVACC** 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 **fimaVACC**'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. It is anticipated that a significant number of the cancer vaccines in development could use **fimaVACC** 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 fimaVACC has shown synergistic effects in the preclinical setting.

The number of clinical trials with peptide-based cancer vaccines is high, with close to ninety different indications targeted across the US and Europe, mostly by small biotech organisations (fimaVACC market assessment, 2018).

NUCLEIC ACID THERAPEUTICS AND THE **fimaNAC** DELIVERY TECHNOLOGY

PCI Biotech's nucleic acid therapeutics program (fimaNAC) aims at improving the efficacy of novel nucleic acid based therapies. The fimaNAC technology addresses a main hurdle in the development of nucleic acid based therapies: Sufficient release of the encapsulated 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 therapeutic effect that can be achieved. Thus, nucleic acids are very good candidates for enhancement by an endosomal release technology like fimaNAC, and preclinical experiments have shown that fimaNAC can give a substantial improvement in the effect of very 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 fimaNAC 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 more than eight nucleic acid based drugs on the market and more than one hundred in clinical trials.

fimaNAC is well positioned to capture a significant part of the nucleic acid therapeutics delivery market as demonstrated by the partnering activities of PCI Biotech in this field. PCI Biotech's fimaNAC strategy is to collaborate with biotech or pharmaceutical companies and develop long-term relationship with companies having early stage innovative nucleic acid based technology.

The fimaNAC programme, aiming at improving the efficacy of novel nucleic acid based therapies, is a preclinical stage collaborative programme with six research collaborations established with key players in this field.

KEY FIGURES

(In NOK 1,000)	2019	2018
Other income	9 392	9 585
Operating expenses	98 195	54 104
Operating results	-88 804	-44 519
Comprehensive income	-88 746	-34 780
Cash & cash equivalents	261 103	349 326
Total liabilities	27 204	17 102
Cash flow from operating activities	-83 471	-40 171

BOARD OF DIRECTORS REPORT

2019 IN REVIEW

2019 was an important and transformative year for PCI Biotech, with focus on execution of the pivotal RELEASE study. The encouraging overall survival data for the **fimaCHEM** Phase I bile duct cancer (cholangiocarcinoma) patients were presented during the year at key conferences in Asia-Pacific and US. Final confirmation of the safety milestone of up to two **fimaCHEM** treatments was reached in the Phase I extension study in Q2 2019 and focus since then has been on start-up activities for the pivotal RELEASE study with registration intent. The first RELEASE study patient was enrolled in Europe in Q2 2019. A delay in the opening of study sites pushed expected enrolment of the first US patient into 2020. Opening of sites is not yet back on track, and study recruitment and projections are currently behind the original plan. The company therefore activated several initiatives in 2019 to recoup long-term patient recruitment projections, with the aim to reach interim analysis by Q2 2022.

In May 2019 the translation of the **fimaVACC** vaccination technology into humans was successfully completed and the results were presented at ESMO Immuno-Oncology in December 2019. The results of the Phase I study provide proof-of-concept by demonstrating improved immunogenicity of vaccines in healthy volunteers. The focused patent work initiated in 2013-2014 has started to generate results, providing additional IP protection for the development programme. The development focus is two pronged; utilising the Phase I results in partnering efforts and planning for clinical proof-of-concept in a disease setting.

The collaborative **fimaNAC** programme continued its positive development in 2019, and the collaboration with AstraZeneca was extended and expanded during the year. The company received promising response on a patent application for mRNA delivery and a granted patent can provide valuable IP for **fimaNAC**.

On the corporate side, the Scientific Advisory Committee has been further strengthened to ensure adequate scientific support for continued progress of the **fimaVACC** programme. In March 2020, Dr Amir Snapir was appointed as Chief Medical Officer.

Implications of the COVID-19 outbreak

PCI Biotech is closely monitoring potential implications on its short- and long-term operations following the development of the COVID-19 pandemic in 2020 (after balance sheet date event). PCI Biotech's overriding priority has been the safety of its staff, patients participating in the clinical trial and its collaborators. PCI Biotech has per date of this report not a complete picture of the long-term consequences regarding timelines and costs for the **fimaCHEM** RELEASE study, but delays and increased costs are expected. The main priorities are now identification and implementation of potential mitigating actions for RELEASE study progress during the pandemic in collaboration with our contract research organisation, as well as removal of unnecessary recruitment hurdles in the study protocol. For the **fimaVACC** and **fimaNAC** programmes the main identified implications are transient downturn in business development activities. PCI Biotech has a solid cash position per year-end, placed in NOK and EUR, and the pandemic situation in 2020 has not impacted the 2019 figures.

HIGHLIGHTS

fimaCHEM – The RELEASE study was initiated with enrolment of the first European patient in May 2019 and full focus on successful execution of the pivotal study with registrational intent. The phase I study continued to deliver positive early signs of efficacy. Although the data sample is small, the results indicate a clear improvement over the best comparable published data for today's standard of care. Delays in the opening of study sites were experienced in 2019 and study recruitment and projections are behind plan. Several initiatives are activated with the aim to recoup long-term patient recruitment projections.

fimaVACC – Successful translation of the vaccination technology into humans through a Phase I study in healthy volunteers. The immune results provide Proof-of-Concept and clinical support for the technology's potential to enhance overall T-cell responses.

fimaNAC - Research collaborations with key players. The collaboration project with AstraZeneca was extended to the end of 2019 and the scope of the agreement was expanded to evaluate whether synergies established in oncology *in vivo* models are transferable to additional disease areas. The companies have agreed to use first half of 2020 to evaluate the potential for further collaboration.

The Scientific Advisory Committee has been reinforced. Professor Sjoerd van der Burg, was appointed as committee member from 2019. Prof. van der Burg is the Head of laboratory at the Department of Medical Oncology, Leiden University Medical Center (LUMC), The Netherlands and his research focus is on immunotherapy in oncology, including cancer vaccines.

BUSINESS AND LOCATION

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

The PCI Biotech group (The Group) comprises PCI Biotech Holding ASA, the wholly owned Norwegian subsidiary PCI Biotech AS. PCI Biotech is located at Ullernchausséen 64, Oslo, Norway. A former dormant Icelandic branch, PCI Biotech Utibu, was dissolved in 2019.

All operations of the Group are managed by PCI Biotech AS and the Group had 12 employees as of 31 December 2019 (2018: 13 employees).

OPERATIONS

Operational overview

PCI Biotech is a biopharmaceutical company focusing on development and commercialisation of novel therapies for the treatment of cancer through its innovative photochemical internalisation (PCI) technology platform, which induces triggered endosomal release that is used to unlock the true potential of a wide array of therapeutic modalities. PCI is applied to three distinct anticancer paradigms with the advantage of shared technological solutions in multiple business opportunities with different risk profiles: *fimaCHEM* (enhancement of chemotherapeutics for localised treatment of cancer), *fimaVACC* (T-cell induction technology for therapeutic vaccination), and *fimaNAC* (nucleic acid therapeutics delivery).

Development resources were in 2019 focused towards the lead programme *fimaCHEM* and the *fimaVACC* programme. In parallel PCI Biotech has made further progress with its collaborative strategy for the *fimaNAC* programme, where established preclinical data are utilised to pursue out-licensing opportunities.

fimaCHEM – pivotal RELEASE study for inoperable bile duct cancer

The *fimaCHEM* programme for local enhancement of cancer treatments is the most advanced of PCI Biotech's development programmes. The main focus is now to bring the lead candidate to the market through successful completion of the pivotal RELEASE trial for treatment of inoperable bile duct cancer. RELEASE is a single randomised pivotal study with registration intent, building on encouraging results from the Phase I study. The first of a total of 186 patients was enrolled in May 2019 after final confirmation of the safety of up to two *fimaCHEM* treatments in the Phase I extension study in April 2019. RELEASE will evaluate PCI Biotech's Amphinex® (the intravenous formulation of fimaporfin) in combination with the standard of care chemotherapy with gemcitabine and cisplatin. Bile duct cancer is a rare disease with high unmet medical need and the combination of Amphinex and chemotherapy will be evaluated as a first line treatment, with orphan drug designation granted in both EU and the US.

RELEASE start-up activities ongoing

Start-up activities are ongoing for the RELEASE study, with site contract negotiations, regulatory and ethics approvals, site activations and final protocol harmonisation based on feedback from the different national regulatory bodies.

By date of this report, the company had received regulatory and ethics approvals for USA and 10 out of 11 planned European countries; Norway, Germany, France, Spain, Italy, Belgium, Poland, Sweden, Denmark and Finland. The remaining country is UK. The study was initially planned to be executed in approximately 40 clinical sites, of which 34 sites had opened for recruitment at last update 25th March 2020. Two of these are in the US, with more sites lined up for activation during 1H 2020 and awaiting enrolment of the first US patient. In addition, regulatory approval for Taiwan has been achieved in March 2020.

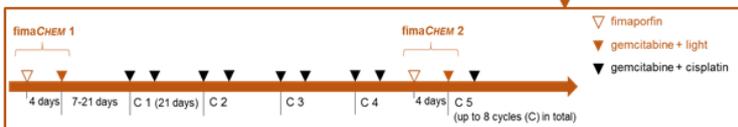
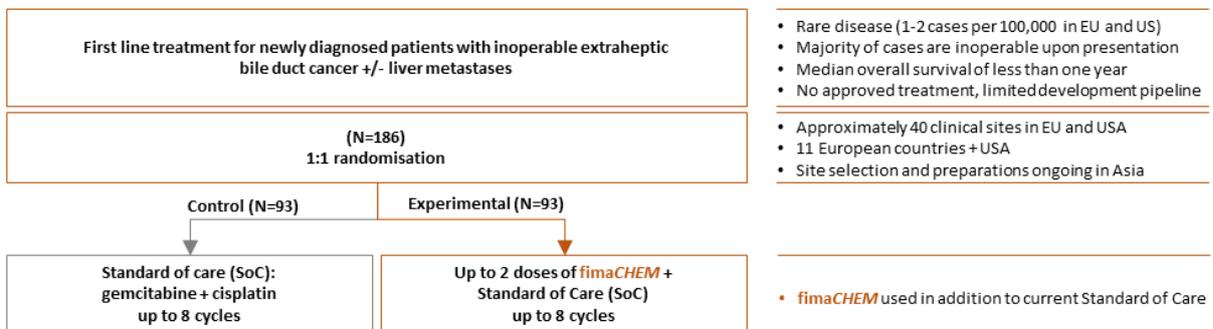
The RELEASE study has enthused investigators that are actively looking for patients, which is very important for clinical studies in rare patient groups such as cholangiocarcinoma. The opening of sites is however behind the original plan, which affects patient recruitment and study recruitment projections. PCI Biotech is therefore currently exploring and implementing several initiatives to recoup long-term patient recruitment projections, with the aim to reach interim analysis by Q2 2022. These initiatives include opening of more sites to increase capacity, deployment of field-based personnel to understand patient flow and facilitate enrolment, and close scrutiny of eligibility failures to clearly understand and remove unnecessary recruitment hurdles.

The design of the pivotal RELEASE study is based on regulatory interactions

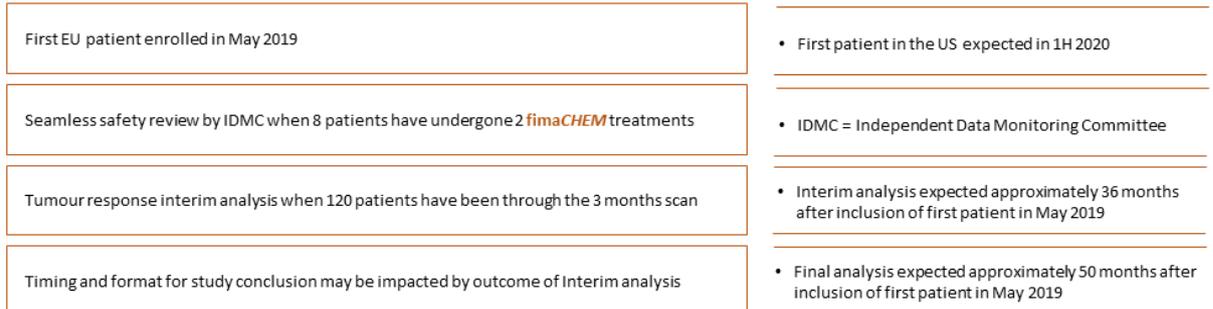
The RELEASE study design has been based on the outcome of meetings with the two leading regulatory authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). In the ongoing global protocol harmonisation process, the interim analysis primary endpoint has been changed from progression free survival (PFS) to objective response rate (ORR). The change is motivated by a post-investigational new drug (IND) recommendation by the FDA and the modification changes the interim read from an event driven analysis based on PFS to a recruitment driven analysis. The modification is not expected to have significant impact on the estimated timelines.

Bile Duct Cancer - RELEASE pivotal study with **fimaCHEM**

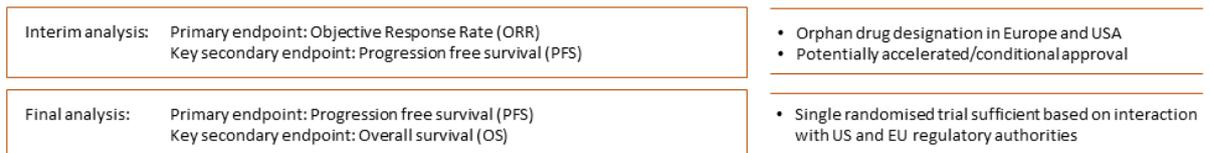
Study overview:



Milestones and timelines:



Endpoints:



Phase I results paved the way for the pivotal RELEASE trial with registration intent

The RELEASE study builds on the favourable safety results and encouraging early signs of efficacy in the Phase I study. The results database for this study is now closed, with all data quality checked and finally confirmed. Tumour response data from the full Phase I study (n=23) showed that more than

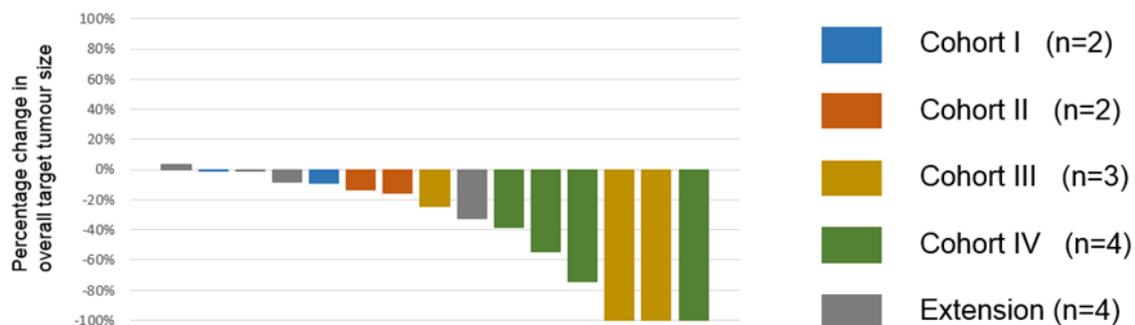
40% of the patients with radiologically evaluable tumours (n=15) had local target tumour response according to RECIST criteria.

The **fimaCHEM** treatment boosts the chemotherapy effect locally in the bile duct. Local tumour response in the bile duct is important to maintain biliary drainage, and the primary tumour response may therefore be more important for survival outcome than would be the case for many other cancers.

The dose-escalation part (Cohort I to IV) of the study showed increasing tumour response rates with increasing dose levels of fimaporfin, and the encouraging radiological results from the highest dose levels (Cohorts III & IV) were sent for independent centralised expert read. This confirmed the encouraging results, reporting that more than 20% tumour reduction was observed in 17 out of 19 identified target lesions and that 12 of these lesions became undetectable. The Cohort IV dose was taken forward into the RELEASE study. The extension part with two **fimaCHEM** treatments provided less tumour response, but the average tumour burden was higher in this group.

Overview best overall response – patients with measurable disease in all cohorts (n=15)

(Cohort I, II & Extension: data from local read, Cohort III & IV: data from centralised read)



Tumour response translates into encouraging survival data

All patients have been followed-up for survival post-study and the finally confirmed median overall survival (mOS) for the full study ended on 16.1 months at final censoring, with two patients still being alive.

The group in the dose escalation study that received the RELEASE study dose (n=6, cohort IV) had a mOS of 22.8 months. Three of these patients exceeded 30 months survival, including one patient still alive more than four years after inclusion in the study. The mOS in the extension group (n=7), where patients received up to two treatments of the RELEASE dose, was 16.6 months and one patient is still alive. Five of the seven extension patients received two **fimaCHEM** treatments.

Although these are small patient groups with considerable heterogeneity, PCI Biotech is pleased to see that the positive signs of tumour response seem to translate into encouraging survival data.

During 2019 the Phase I results and the pivotal study design and plans were presented at two key conferences to increase awareness about **fimaCHEM** among both clinicians and patients: the US Cholangiocarcinoma Foundation Annual Conference in Salt Lake City, USA and the 3rd Asia-Pacific Cholangiocarcinoma conference in Taipei, Taiwan.

Regular communication milestones for the RELEASE study

The planned communication milestones for the pivotal RELEASE study will be quarterly updates on the number of countries and clinical sites open for recruitment, as well as updates on expected timelines for major milestones. Other milestones and updates will be communicated as appropriate, including outcome of the IDMC reviews, as well as further details regarding timing and plan for interim analysis.

fimaVACC - Vaccination program

The **fimaVACC** programme aims to enhance the cellular immune responses that are important for the therapeutic effect of vaccines, and the **fimaVACC** technology has proven excellent preclinical efficacy with protein- and peptide-based vaccines. The technology has shown particularly strong CD8 T-cell immune responses, which are important for therapeutic vaccination, as well as enhanced helper (CD4) T-cell and antibody responses.

Successful clinical proof-of-concept in healthy volunteers

PCI Biotech successfully translated the vaccination technology into humans through a Phase I study in healthy volunteers that was completed in May 2019. The immune results provided 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.

The Phase I results showed 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.

The important CD8 responses were more robust with **fimaVACC** and also exhibited increased functionality compared to control.

fimaVACC provides highly desired features for therapeutic vaccination technologies:

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

More than 90 subjects were included, and tolerability of intradermal treatment with **fimaVACC** is established across a wide range of doses. The study results were presented at the ESMO Immunology Congress in December 2019 and PCI Biotech aims for a publication in a relevant scientific journal in 2020. A general presentation of the technology and its capabilities was given at the World Vaccine Congress Europe, Spain, in October 2019.

Study design

The study was designed as an open-label, antigen-adjuvant controlled study with the objectives to determine immune responses, safety and tolerability of **fimaVACC** in healthy volunteers. Two model vaccines were used; a large immunogenic protein called keyhole limpet hemocyanin (KLH) and two less immunogenic peptides from human papillomavirus (HPV). The control group was treated with the two model vaccines and a state-of-the-art adjuvant technology (Hiltonol). The T-cell response to vaccination was most strongly enhanced by **fimaVACC** with the HPV peptides, which are much less immunogenic than the KLH protein. The two HPV peptide antigens chosen for the Phase I study were derived from the E7 protein of the human papillomavirus (HPV). A very high CD8 T-cell response hurdle was set by this choice, as it is notoriously difficult to induce CD8 T-cell responses in man with peptides from the HPV E7 protein.

Collaboration with international immunotherapy experts

The analysis of overall T-cell responses was done in collaboration with Oslo University Hospital, The Radium Hospital, and the analysis of CD8 T-cell responses were performed at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg.

New US patents granted

In January 2020, a US patent was granted providing a broad coverage for the combination of various cytokines with the **fimaVACC** technology. In April 2020, a further US patent was granted providing a broad coverage for the combination of the **fimaVACC** technology with a new important class of adjuvants, called toll like receptor agonists. These US patents secure protection until 2035, while patent applications are still pending in Europe and key Asian markets. These patents are important for

PCI Biotech's development strategy, as it supplements the company's ability to potentially generate an internal future vaccine pipeline, in addition to bringing value for the **fimaVacc** technology in partnering efforts.

Research and development supported by a grant

The **fimaVacc** programme is supported by a government grant from the Research Council of Norway (BIA-programme) of up to NOK 13.8 million distributed over the course of four and a half years, 2017-2021.

fimaNAc - delivery of nucleic acid therapeutics

The **fimaNAc** programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage collaborative programme, with six research collaborations established with key players in the field. All the collaborators have the same purpose of exploring synergies between their proprietary nucleic acid technologies and the **fimaNAc** technology. Thereafter, if successful, the intention is to explore the potential for further partnerships. The current collaboration partners include AstraZeneca and the five biotechnology companies Bavarian Nordic, BioNTech, eTheRNA immunotherapies, IMV and Phio Pharmaceuticals.

The collaboration agreement with AstraZeneca has been extended several times and most recently until the end of December 2019. The scope of the agreement was in 2019 expanded to evaluate whether synergies established in oncology *in vivo* models are transferrable to additional disease areas. The research collaboration ran to the end of 2019 and the companies have agreed to use the following 6 months until end of June 2020 to evaluate the potential for further collaboration.

In 2019 PCI Biotech received initial positive feedback on an important patent application for intracellular delivery of mRNA. The patent application may provide an important competitive advantage and generate valuable intellectual property (IP) for the **fimaNAc** programme, as several of the current research collaborations are within the field of mRNA delivery.

Corporate

Further strengthened the Scientific Advisory Committee (SAC)

The SAC has been reinforced by the appointment of Professor Sjoerd van der Burg as committee member from 2019. Professor van der Burg is the Head of laboratory at the Department of Clinical Oncology, Leiden University Medical Center (LUMC), The Netherlands. Professor van der Burg's research focus is on immunotherapy in oncology, including cancer vaccines, aiming at developing new treatments of solid tumours. With a translational approach, Professor van der Burg's research spans from preclinical studies and methodological development to clinical trials and collaborative initiatives with special focus on human T-cell response against cancer associated antigens. Professor van der Burg is a member of numerous international advisory committees and societies including American and European societies for immunology or cancer (AACR, C-IMT, ESCII), the Cancer Vaccine Consortium and the International Papillomavirus Society. He is an Associate Editor for Cancer Therapy.

Update on the Board of Directors

Board Member Dr. Hilde H. Steiniger notified PCI Biotech Holding ASA's nomination committee that she was not a candidate for re-election and ended her term at the Annual General Meeting in May 2019. Dr. Steiniger has made strong contributions to the company with her solid industry and scientific knowledge and experience during her service as a Board Member since May 2014.

Hilde Furberg was appointed as Board Member in May 2019. Hilde Furberg holds a Master of Science from the University of Oslo, Norway. She is an independent consultant and a professional board member. She has broad senior leadership experience, coming from her 35 years in sales, marketing, strategy and general management in Pharma/Biotech. Her experience is in different areas of specialty care and from small to large global companies. Hilde Furberg has worked in companies like Baxter

and Genzyme, she was most recently European Head of Rare Diseases for Sanofi Genzyme. In addition to working for Genzyme/Sanofi Genzyme, she has served as a non-executive director of BerGenBio, Probi, Pronova, Clavis, Algeta and chair of the board for Blueprint Genetics. She is currently an industrial advisor to Investinor and board member of Calliditas, CombiGene and Tappin.

Management changes

Dr. Hans Olivecrona was appointed Chief Medical Officers (CMO) in August 2017 and has provided instrumental drive and competence to PCI Biotech's clinical projects, including design and start-up of the pivotal RELEASE study. From July 2019 Dr. Olivecrona has functioned as a CMO via a consultancy agreement. In March 2020, PCI Biotech announced the appointment of Dr Amir Snapir, MD, PhD as Chief Medical Officer (CMO). Dr Snapir will also serve as a member of PCI Biotech's executive management team. He will lead the execution of all clinical development programmes, and be a key contributor to the identification and implementation of new opportunities and pipeline expansions. Dr Snapir brings extensive experience in global clinical development of novel therapeutics, from early clinical translation to marketing authorisation, combined with extensive international regulatory experience. Dr Snapir also brings years of experience in business collaborations, alliances and product co-developments. Since 2007 Dr Snapir has held various positions at Orion Pharma, Espoo, Finland, spanning from leader of clinical pharmacogenomics to clinical development leader in Oncology. In his most recent role, Dr Snapir held the position as Director, Rare Disease Development. Dr Snapir has a PhD from the University of Turku, Finland and an MD from the University of Tel Aviv, Israel. Dr. Snapir is the author of numerous scientific publications. Dr Snapir will commence as CMO no later than 1 May 2020.

The company is also actively working on recruitment to the vacant chief business development officer (CBDO) position after Mr L'Heveder resigned from his position end March 2019. The business development responsibilities are shared between the management members in the interim.

Business development

PCI Biotech's strategy is to create value by effectively progressing development of the three distinct 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, and the signed **fimaNAC** research collaborations indicates that external companies share this view. PCI Biotech will continue the business development activities, to build on the proven ability to initiate new research collaborations and explore the business opportunities present in the active collaborations.

The Company's lead programme, **fimaCHEM** for bile duct cancer, has initiated the pivotal clinical RELEASE trial with the potential of accelerated / conditional marketing approval as a first-line treatment given the rare disease status and unmet medical need in this condition.

An important value-creating step for the **fimaVACC** programme was the successful clinical translation of the promising preclinical data, through a Phase I study in healthy volunteers. The successful clinical validation provides substantial risk reduction for the **fimaVACC** asset, as well as significant value enhancement and opening up for new partnering opportunities enabling PCI Biotech to enter into the immunotherapy field. PCI Biotech pursues two development strategies in parallel for **fimaVACC**, utilising the Phase I results both in direct partnering efforts and planning for clinical Proof-of-Concept in a disease setting.

The **fimaNAC** programme will continue to follow a collaborative approach, pursuing out-licensing opportunities based on established preclinical data and entering into early collaborations with the aim to transform the collaborations into commercial agreements.

Organisation

The Board of Directors –The Board of Directors consist of Hans Peter Bøhn (Chairman), Hilde Furberg, Christina Herder, Lars Viksmoen and Andrew Hughes. Dr. Hilde Steineger notified PCI Biotech Holding ASA's Nomination Committee and Board of Directors that she was not able to be a candidate for re-election as Director of PCI Biotech Holding ASA's Board of Directors and ended his term at the ordinary general meeting, in May 2019. Hilde Furberg was elected as new Director at the same meeting.

Employees - The Group had 12 employees at the end of 2019 (13 at year end 2018). 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 and Hans Olivecrona, Chief Medical Officer.

The parent company has no employees. The Group mainly uses external service providers for manufacturing, research and development and regulatory work.

The working environment is considered good. No accidents or injuries were reported in 2019 or 2018. Absence due to illness was 148 days, approximately 7.36% in 2019 (2018: 42 days, approximately 1.65%). The majority of the absence in 2019 was related to long term sick leaves of two employees.

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. 7 out of 12 employees as of year-end 2019 were women. Working time and remuneration of the Group employees are not related to gender.

FINANCIAL REVIEW

Profit and loss

(All amounts in brackets are comparative figures for 2018 unless otherwise specifically stated)

The Group did not record revenues in 2019 nor 2018. Grants received from various public sources such as the Research Council of Norway and "SkatteFUNN" were recorded as other operating income amounting to NOK 9.4 million (NOK 9.6 million). The parent company did not record any revenue for 2019 or 2018.

The fimaVACC programme received in 2017 a grant of up to NOK 13.8 million from the Research Council of Norway (BIA-programme). The grant will be distributed over the course of four years, 2017-2020, and for 2019 a total of NOK 3.6 million (NOK 3.9 million) has been recorded as other income.

Total operating expenses were NOK 98.2 million in 2019 (NOK 54.1 million) and expenses are mainly driven by the research and development (R&D) activities. In 2019 the initiation of the RELEASE study has increased expenses compared to previous years. 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 2019 and as for previous years all research expenses are charged through the profit and loss statement. R&D expenses amounted to NOK 83.3 million in 2019 (NOK 40.3 million). In addition to the RELEASE trial expenses, the production of a new batch of product under development (fimaporfin) has increased the R&D expenses in 2019. Other operating (general and administrative) expenses were NOK 14.9 million (NOK 13.8 million). The increase by around NOK 1 million compared to 2018 is mainly driven by none-cash elements from the groups share option programme. Operating result in 2019 ended at NOK -88.8 million (NOK -44.5 million) for the Group. Operating result for the parent company were NOK -4.6 million in 2019 (NOK -4.7 million).

Net financial results for the Group were NOK 0.1 million in 2019 (NOK 9.7 million). The net positive result in 2018 was mainly driven by positive effects from cash deposits placed in Euro at year-end, as a hedge of the foreign currency risk for the RELEASE study. In 2019 this effect has been negative with NOK 1.6 million. The parent company's financial income for 2019 consists mainly of interest on loans

to the subsidiary PCI Biotech AS. Financial expenses consist of negative interest on cash deposits in Euro and the negative effect on cash deposits placed in Euro of NOK 1.5 million.

The Board of Directors proposes that the comprehensive income of NOK 0.1 million for the parent company in 2019 is transferred to retained earnings.

Balance sheet

During 2019 PCI Biotech acquired the first lots of lasers to be used in the pivotal RELEASE study, increasing non-current assets compared to last year. In addition, PCI Biotech adopted IFRS 16 Leases for the first time in 2019, applying the modified retrospective method. The implementation effects for 2019 are disclosed under note 24 Right of use assets and lease liabilities.

Short term receivables per end of 2019 was NOK 14.6 million (NOK 7.7 million) and increased by NOK 6.9 million compared to end of 2018, mainly due to advance payments in connection with initiation of the RELEASE study and timing effects.

Current liabilities were generally higher per the end of 2019 compared to the end of 2018, due to the increased R&D activities. Other long-term liabilities relate to potential future social security liabilities in connection with the company's share option program, and the liability fluctuates with the share price and number of outstanding 'in-the-money' share options per year end. Social security liabilities for share options that are vested, or may be vested during 2020, are disclosed as short-term liabilities.

Total equity for the Group were NOK 254.9 million per year-end 2019 (NOK 340.0 million). Total equity of the parent company amounts to NOK 673.5 million in 2019 (NOK 669.7 million) reflecting this year's result and share based payments elements charged through equity for the Group's share option programme.

Equity in the wholly owned subsidiary PCI Biotech AS was NOK 105.1 million at the end of 2019 (NOK 56.6 million). The equity in PCI Biotech AS were increased in 2019 by NOK 135 million, through a capital increase from the parent company PCI Biotech Holding ASA.

Total assets of the Group at the end of 2019 were NOK 282.0 million (NOK 357.1 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 674.6 million per year-end 2019 (NOK 671.8 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 2019 were NOK 109.7 million (NOK 89.5 million).

Cash flow

Net cash flow from operating activities amounted to NOK -83.5 million in 2019 (NOK -40.2 million) for the Group and for the parent company to NOK 1.4 million for 2019 (NOK -3.9 million). Net change in cash and cash equivalents for the Group was NOK -88.2 million in 2019 (NOK 298.6 million). 2019 figures are impacted by increased R&D activities regarding the RELEASE trial, while 2018 figures were impacted by net proceeds of NOK 328.9 million from share issues during the year. Net change in cash and cash equivalents for the parent company were NOK -69.6 million in 2019 (NOK 191.6 million).

Investment activities during the year include NOK 5.4 million (NOK 0 million) in acquisition cost of devices (lasers) to be used in the RELEASE trial. Financing activities are impacted by first time adoption of IFRS Leases and payment of principal portion of the lease liability in 2019 of NOK 0.7 million.

The Group held cash and cash equivalents of NOK 261.1 million at the end of 2019, compared to NOK 349.3 million per end of 2018, reflecting net negative cash flow of NOK 86.6 million (NOK 40.1 million) in 2019 and NOK 1.6 million net negative (NOK 9.1 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 2019 amounted to NOK 122.8 million (NOK 192.4 million).

Share capital - capital increases following share option exercises

Net proceeds from the share issue of NOK 360 million in the parent company in 2018 are partly transferred to the operating company, PCI Biotech AS, as capital increases and loan. During 2019 the Group received net proceeds of NOK 1.2 million from capital increases following exercise of share options in PCI Biotech's share option programme for employees.

Participants in the Company's share option programme exercised on 20 February 2019 a total number of 61,000 share options. Out of these share options 30,000 were exercised at a strike price of NOK 19.24, 15,000 share options were exercised at a strike price of NOK 7.84, 11,000 share options were exercised at a strike price of NOK 3.26 and 5,000 share options were exercised at a strike price of NOK 21.48. Following the exercise of share options on 20 February 2019, the Company's Board of Directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 29 May 2018, decided to increase the Company's share capital with NOK 183,000 by issuing 61,000 new shares, each share of par value NOK 3.00. The transaction was completed 25 February 2019. The capital increase resulted in net proceeds of NOK 0.8 million.

In September 2019 participants of the company's share option programme for employees exercised a total number of 40,000 share options at a strike price of NOK 8.63. 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 29 May 2019, decided to increase the company's share capital with NOK 120,000 by issuing 40,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the company's general meeting. The transaction was completed 9 September 2019. The capital increase resulted in net proceeds of NOK 0.3 million.

Subsequent to completion of the two capital increases following exercise of share options during 2019 the Company's share capital per 31 December 2019 is NOK 111,797,670 divided into 37,265,890 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

RISK AND RISK MANAGEMENT

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 patients 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 employee 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, *fimaCHEM* for inoperable extrahepatic bile duct cancer, the company has been building its knowledge base to enable the design of its commercialisation strategy for *fimaCHEM*. 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 lead programme, *fimaCHEM*, could become a commercially successful therapeutic option, for inoperable extrahepatic bile duct cancer, 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 logistics service to customers. PCI Biotech is committed to leverage these insights to develop strategies that offer the best chance of commercial success for *fimaCHEM*.

PCI Biotech has also performed a market opportunity assessment for the *fimaVACC* technology platform, guiding management to understand the opportunity space based on the key attributes *fimaVACC* 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 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 is revenue related to any licensing and collaboration agreements, government grants and equity issues. 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, but in October 2018 parts of the net NOK proceeds from the fully underwritten rights issue were converted into EURO as a hedge of the foreign exchange rate risk for the *fimaCHEM* programme.

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 2019 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.

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

PCI Biotech has closely monitored potential implications on its short- and long-term operations following the development of the COVID-19 pandemic in 2020. PCI Biotech's overriding priority has been the safety of its staff, patients participating in the clinical trial and its collaborators. PCI Biotech has per date of this report not a complete picture of the long-term consequences regarding timelines and costs for the RELEASE study, but delays and increased costs are expected.

The main identified near-term implications concern the RELEASE study in bile duct cancer. The COVID-19 pandemic has negatively impacted both the opening of new sites and new patient enrolment into the trial, by postponement of site activation dates, and by the changing priorities and physical constraints that are being implemented at the hospitals as a consequence of the pandemic. By date of this report a total number of 34 out of the originally planned 40 sites in Europe and US are activated. In addition, PCI Biotech has made regulatory progress in the process of adding Asian sites into the RELEASE study, having secured regulatory approval in Taiwan in 2020. PCI Biotech has not identified any major short-term shortage in supplies of investigational products and devices for the trial. The main priorities are now identification and implementation of potential mitigating actions for RELEASE study progress during the pandemic, as well as removal of unnecessary recruitment hurdles in the study protocol. For the fimaVACC and the fimaNAC programmes the main identified implications are transient downturn in business development activities. PCI Biotech has a solid cash position per year-end, placed in NOK and EUR, and the pandemic situation in 2020 has not impacted the 2019 figures.

In January 2020, a US patent were granted providing a broad coverage for the combination of various cytokines with the fimaVACC technology. In April 2020, a further US patent were granted providing a broad coverage for the combination of the fimaVACC technology with a new important class of adjuvants, called toll like receptor agonists. These US patents secure protection until 2035, while patent applications are still pending in Europe and key Asian markets.

In March 2020, PCI Biotech announced the appointment of Dr Amir Snapir, MD, PhD as Chief Medical Officer (CMO). Dr Snapir will also serve as a member of PCI Biotech's executive management team. He will lead the execution of all clinical development programmes, and be a key contributor to the identification and implementation of new opportunities and pipeline expansions. Dr Snapir brings extensive experience in global clinical development of novel therapeutics, from early clinical translation to marketing authorisation, combined with extensive international regulatory experience. Dr Snapir also brings years of experience in business collaborations, alliances and product co-developments. Since 2007 Dr Snapir has held various positions at Orion Pharma, Espoo, Finland, spanning from leader of clinical pharmacogenomics to clinical development leader in Oncology. In his most recent role, Dr Snapir held the position as Director, Rare Disease Development. Dr Snapir has a PhD from the University of Turku, Finland and an MD from the University of Tel Aviv, Israel. Dr. Snapir is the author of numerous scientific publications. Dr Snapir will commence as CMO no later than 1 May 2020.

PCI Biotech is not aware of any other subsequent events since year-end 2019 which is of material significance to the financial statements as of 31 December 2019.

OUTLOOK

PCI Biotech believes that the proprietary PCI technology has the possibility to unlock the true potential of certain classes of innovative medicines. Supported also by external collaboration partners' opinion, the PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (fimaVACC) and nucleic acid therapeutics (fimaNAC).

Although the company's focus is divided over the three programmes, most resources are currently spent on progressing the lead project of fimaCHEM, which is clinical development of fimaporfin with gemcitabine for the treatment of inoperable extrahepatic bile duct cancer; a rare disease with high unmet medical need. Based on the encouraging early signs of efficacy in Phase I, the company worked with regulators in Europe and the U.S. receiving important guidance for the design of a pivotal phase study.

The final pivotal study design has thus been determined and funding expected to finance the study to interim read-out is in place. The first patient was enrolled in May 2019. The company is fully committed to advance the programme with the ambition of helping patients currently left without effective treatment options to achieve a good quality of life.

In parallel, the two other programmes, fimaVACC and fimaNAC, are proceeding in accordance with the established development strategy. The clinical validation of the fimaVACC technology is essential for PCI Biotech's role within the immunotherapy space. The Phase I study in healthy volunteers provided affirmative results on translation of the technology into humans and key data to support the programme's further development. The fimaNAC programme continues to follow a collaborative approach, by pursuing out-licensing opportunities.

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

- Effectively drive the fimaCHEM development programme in inoperable extrahepatic bile duct cancer towards the market
- Implement the strategy for the next phase of development for fimaVACC
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

Oslo, 21 April 2020
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA



Hans Peter Bøhn
Chairman



Christina Herder
Director



Lars Viksmoen
Director



Hilde Furberg
Director



Andrew Hughes
Director



Per Walday
CEO

RESPONSIBILITY STATEMENT FROM THE BOARD OF DIRECTORS AND CEO 2019

We confirm that the financial statements for the period 1 January to 31 December 2019, 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, 21 April 2020
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA



Hans Peter Bøhn
Chairman



Christina Herder
Director



Lars Viksmoen
Director



Hilde Furberg
Director



Andrew Hughes
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 17 October 2018. 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 are provided of non-conformance to the code 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. The corporate values are important foundations for PCI Biotech's corporate governance. Ethical guidelines are also established and these guidelines are based on the corporate values.

PCI Biotech adhere to the code of practice for corporate governance. The company has to date four deviations from the code and reasons for the deviation and what solutions that are selected are further explained under section 2.1, 6 and 9.

2. Business

The objective and purpose for 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 three distinct 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 perform annual evaluations of the objectives, strategies and risk profiles.

The company has implemented guidelines for how to integrate considerations related to its stakeholders into its value creation, 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 12 employees and the core competencies are possessed by these employees, while the group's other resources in research and development are 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 activities, 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 are 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 rights, labour rights, social issues and sustainable development. The Group's management conducts regular performance reviews and internal evaluations. 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. 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 separate reporting.

The Group has not identified any material issues based on the corporate social responsibility procedures (CSR) performed in 2019. 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 2.3.

2.3. 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 as 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 focus its development on anti-cancer product- and technology candidates. All international anti-cancer development is strictly regulated regarding animal welfare and high focus on safety and wellbeing 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 it does not significantly affect the environment beyond normal course of business for a small biotech company. Travelling and the needs for shipment of devices and materials for preclinical and clinical trials are identified as the activities with most environmental impact. To keep the environmental impact to a minimum, devices that are no longer used are returned in bulks to the producer for recycling. Other shipments are optimised in collaboration with our service providers and

collaborators to reduce number of shipments. External meetings are evaluated for use of virtual meeting tools when appropriate, to keep travels at a low level.

2.4. 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 2019 was NOK 255 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 2019.

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 have no mandate to approve the distribution of dividend.

The Board of Directors has been authorised by the Company's General Assembly in May 2019 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 and transactions with close associates

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 2019.

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.

The Group had regular business transactions with one related party in 2019 and 2018. The PCI technology originates from the Norwegian Radium Hospital and the Norwegian Radium Hospital Research Foundation owns 3.44% of PCI Biotech at year end 2019. PCI Biotech has extensive cooperation with the Norwegian Radium Hospital mainly regarding pre-clinical activities. The cooperation is regulated through signed agreements and it is the Board of Director's and management's opinion that the contracts are based on "arm's length" principles.

Please refer to Note 23 Related party transactions to the financial statements for 2019 where information regarding related party transactions are disclosed.

All material transactions between the Group and shareholders, directors, management or close associates of such parties are valued independently by a third party. No such transactions exist for 2019. Directors and members of the executive management are obliged to notify the Board of Director's of any direct or indirect material interest in any transaction entered into by the Group.

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.

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 implemented, 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 chairman, 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 2021. See PCI Biotech's website for the Nomination Committee's contact details.

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 shareholder-elected 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), convening and preparing for general meeting. The Board of Directors has implemented instructions for the Board and the executive management, with focus on allocation of internal responsibilities and duties. 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 ten meetings in 2019. Board members had the following attendance at these meetings:

Hans Peter Bøhn, 10/10
Hilde Furberg, 4/5
Christina Herder 9/10

Lars Viksmoen, 10/10
Hilde H. Steineger, 4/5
Andrew Hughes 9/10

Hilde H. Steineger ended her term as member of the Board of Directors in May 2019. Hilde Furberg was elected as new member of the Board of Directors at the Annual General Meeting in May 2019.

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, which are all integrated into the Company's value creating activities. 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 the executive management

The Board prepares a statement on the determination of salaries and other remuneration of executive management in accordance with § 6–16a of the Norwegian Public Companies Act. The statement is presented to the general meeting. The statement sets out the main principles for executive management's salary policy and seeks to contribute to the alignment of interests between the shareholders and executive management. The Board assesses the CEO's terms and conditions of employment once a year. The CEO consult the Board of Directors in connection with the annual adjustment of the remuneration of 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. It is established a limit for the performance related remuneration. A share option scheme is part of the remuneration policy and the scheme is approved by the general meeting.

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 Stock Exchange for companies with listed shares.

The Group's report on corporate social responsibility is integrated in 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 is based on transparency and takes 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, in order 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 making 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.

PCI Biotech Holding ASA – financial statement

STATEMENT OF COMPREHENSIVE INCOME For the year ended 31 December 2019 (1.1 - 31.12)

Parent				Group	
2019	2018	(figures in NOK 1.000)	Note	2019	2018
		Other income	5,6	9 392	9 585
-	-	Total income		9 392	9 585
		Research and development	7,8	83 312	40 337
4 582	4 711	General and administrative	7,8,14	14 883	13 767
4 582	4 711	Total operating expenses	7,8,9,10,23,24	98 195	54 104
-4 582	-4 711	Operating results		-88 804	-44 519
6 750	12 278	Financial income	11	2 737	9 890
1 989	117	Financial expenses	11,24	2 680	151
4 761	12 161	Net financial results		58	9 739
179	7 450	Profit/Loss before income tax		-88 746	-34 780
-	-	Income tax	12	-	-
179	7 450	Net profit/loss for the year		-88 746	-34 780
		Other comprehensive income, net of tax			
-	-	Items that will not be reclassified to income statement		-	-
-	-	Items that subsequently may be reclassified to income statement		-	-
179	7 450	Total comprehensive income for the year		-88 746	-34 780
		Loss per share basic and diluted (figures in NOK)	13	2.38	1.25

PCI Biotech Holding ASA

BALANCE SHEET for the year ended 31 December 2019

Parent 2018	2019	ASSETS <i>(figures in NOK 1.000)</i>	Note	Group 2019	2018
		Non-current assets			
		Property, plant and equipment	14	5 072	17
		Right to use assets	24	1 211	
386 294	523 731	Shares in subsidiary	15	-	-
386 294	523 731	Total non-current assets		6 283	17
		Current assets			
92 840	28 011	Receivables from group companies	18	-	-
252	69	Other short term receivables	18	14 646	7 713
93 092	28 080	Total receivables	17	14 646	7 713
192 373	122 794	Cash and cash equivalents	16,17,19	261 103	349 326
285 465	150 874	Total current assets		275 749	357 039
671 760	674 604	Total assets		282 032	357 056

PCI Biotech Holding ASA

BALANCE SHEET for the year ended 31 December 2019

Parent 2018	2019	EQUITY AND LIABILITIES <i>(figures in NOK 1.000)</i>	Note	Group 2019	2018
		Equity			
111 494	111 797	Share capital	20	111 797	111 494
360 133	361 013	Share premium		450 329	449 448
9 912	12 348	Other paid-in capital		-	-
188 124	188 303	Retained earnings		-307 297	-220 988
669 663	673 462	Total equity	8	254 828	339 954
		Liabilities			
		Non-current liabilities			
		Other long term liabilities	16	2 037	107
		Long term lease liabilities	24	539	-
-	-	Total non-current liabilities		2 576	107
		Current liabilities			
1 196	150	Trade account payables		8 601	1 889
-	-	Current lease liabilities	24	657	
110	119	Public duties payables		4 684	1 980
790	872	Other current liabilities	22	10 685	13 126
2 096	1 141	Total current liabilities	16,21	24 628	16 995
2 096	1 141	Total liabilities	17	27 204	17 102
671 760	674 604	Total equity and liabilities		282 032	357 056

Oslo, 21 April 2020
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

PCI Biotech Holding ASA - GROUP

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 December 2019
(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 at 1 January 2018	20	74 961	157 148	0	-190 266	41 842
Loss for the period		-	-	-	-34 780	-34 780
Other comprehensive income, net of tax		-	-	-	-	-
Total comprehensive income for the period		-	-	-	-34 780	-34 780
Capital increase		36 534	324 686	-	-	361 220
Capital increase expenses		-	-32 387	-	-	-32 387
Share based payments		-	-	4 059	-	4 059
Allocation		-	-	-4 059	4 059	0
Equity at 31 December 2018	20	111 494	449 448	0	-220 987	339 954
Loss for the period		-	-	-	-88 746	-88 746
Other comprehensive income, net of tax		-	-	-	-	-
Total comprehensive income for the period		-	-	-	-88 746	-88 746
Capital increase		303	880	-	-	1 183
Capital increase expenses		-	-	-	-	0
Share based payments		-	-	2 436	-	2 436
Allocation		-	-	-2 436	2 436	0
Equity at 31 December 2019	20	111 797	450 329	0	-307 297	254 828

PCI Biotech Holding ASA - PARENT

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 December 2019

(figures in NOK 1.000)

	Note	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
Equity at 1 January 2018	20	74 961	67 833	5 853	180 673	329 320
Profit for the period		-	-	-	7 450	7 450
Other comprehensive income, net of tax		-	-	-	-	-
Total comprehensive income for the period		-	-	-	7 450	7 450
Capital increase		36 534	324 686	-	-	361 220
Capital increase expenses		-	-32 387	-	-	-32 387
Share based payments in subsidiary		-	-	4 059	-	4 059
Equity at 31 December 2018	20	111 494	360 133	9 912	188 124	669 663
Profit for the period		-	-	-	179	179
Other comprehensive income, net of tax		-	-	-	-	-
Total comprehensive income for the period		-	-	-	179	179
Capital increase		303	880	-	-	1 183
Capital increase expenses		-	-	-	-	-
Share based payments in subsidiary		-	-	2 436	-	2 436
Equity at 31 December 2019	20	111 797	361 013	12 348	188 303	673 462

PCI Biotech Holding ASA CASH FLOW STATEMENT for the year ended 31 December 2019

Parent 2018	2019		Note	Group 2019	2018
7 450	179	Profit/Loss before income tax		-88 746	-34 780
-	-	- Depreciation and amortisation	7,14	955	5
-	-	- Leasing interest cost	24	37	-
-	-	- Share-based payments	8	2 436	4 059
-9 108	1 529	Currency gain (-) / loss (+) not related to operations	19	1 649	-9 092
-3 054	445	Net interest paid/received	11	-1 776	-782
-209	184	Changes in accounts receivables		-6 934	-87
1 099	-1 046	Changes in account payables		6 713	392
-65	93	Changes in other net operating assets and liabilities		2 194	115
-3 887	1 383	Cash flow from operating activities		-83 471	-40 171
-73 163	-73 925	Disbursements from intragroup interest bearing loan		-	-
7 669	3 753	Proceeds from intragroup interest bearing loan		-	-
-80 000	-	- Investment in subsidiary	15	-	-
-	-	- Acquisition of non-current assets	14	-5 405	-
3 054	-445	Net interest paid/received	11	1 776	782
-142 440	-70 616	Net cash flow from investing activities		-3 629	782
-	-	- Payment principal portion of lease liability	24	-657	
361 220	1 183	Proceeds from issue of new equity	20	1 183	361 220
-32 387	-	- Expenses in relation to issues of new equity	20	-	-32 387
328 834	1 183	Net cash flow from financing activities		526	328 834
182 507	-68 050	Net changes in cash and cash equivalents		-86 574	289 445
9 108	-1 529	Exchange rate effect on bank deposits in foreign currency	19	-1 649	9 092
759	192 373	Cash and cash equivalents at 1 January		349 326	50 789
192 373	122 794	Cash and cash equivalents at 31 December	19	261 103	349 326

PCI BIOTECH HOLDING ASA – ACCOUNTING PRINCIPLES 2019

1. Corporate information

The annual accounts for 2019 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 21st April 2020.

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 2019.

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.

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 dormant Icelandic branch PCI Biotech Utibu were dissolved in 2019. 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 statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realised or intended to sold or consumed in 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 disclosed under revenue 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

The Group's consolidated financial statements are presented in NOK, which is also the parent company's functional currency.

Transactions and balances

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. 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 adopted IFRS 16 Leases for the first time in 2019, please see section 2.4 and Note 24 for further details regarding accounting policy and first time adoption effects.

h) Intangible assets - Research and development costs

Research costs are expensed as incurred. Internal development costs related to development of products are recognised in the income statement in the year incurred unless it meets the asset recognition criteria of IAS 38 "Intangible Assets". Development expenditures on an individual project are recognised as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that the asset will be available for use or sale
- Its intention to complete and its ability and intention to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development

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. The Group has currently no development expenditure that qualifies for recognition as an asset under IAS 38.

i) Impairment of non-financial assets

Further disclosures relating to impairment of non-financial assets are also provided in the following notes:

- Property, plant and equipment (note 14)

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. When the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

j) Financial instruments

Financial assets

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income (OCI), and fair value through profit or loss.

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. In order for a financial asset to be classified and measured at amortised cost or fair value through OCI, it needs to give rise to cash flows that are 'solely payments of principal and interest (SPPI)' on the principal amount outstanding.

Subsequent measurement

For purposes of subsequent measurement, financial assets are classified in four categories:

- Financial assets at amortised cost (debt instruments)
- Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instruments)
- Financial assets designated at fair value through OCI with no recycling of cumulative gains and losses upon derecognition (equity instruments)
- Financial assets at fair value through profit or loss

Financial assets at amortised cost

This category is the most relevant to the Group. 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 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.

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 by year end

The Group recognises an allowance for expected credit losses (ECLs) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date, meaning that a loss allowance is made for losses expected over the remaining life of the exposure.

For debt instruments at fair value through OCI, the Group applies the low credit risk simplification. At every reporting date, the Group evaluates whether the debt instrument is considered to have low credit risk using all reasonable and supportable information that is available without undue cost or effort. In making that evaluation, the Group reassesses the internal credit rating of the debt instrument. In addition, the Group considers that there has been a significant increase in credit risk when contractual payments are more than 30 days past due.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. 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, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. All financial liabilities are recognised 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.

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 and short-term deposits in the statement of financial position comprise cash at banks and short-term deposits with a maturity of twelve 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 17% 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 performance and/or 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 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.

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 senior decision makers. Senior 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 cash flow 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 and short-term deposits with a maturity of twelve months or less.

r) Events after the balance sheet date

New information regarding the Group's financial position on the balance sheet date has been taken into account 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 is 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 IFRS 16 Leases for the first time in 2019. The nature and effect of the changes as a result of adoption of this new accounting standard is described below and in Note 24.

Several other standards, amendments and interpretations apply for the first time in 2019, but do not have an impact on the consolidated financial statements of the Group. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

IFRS 16 Leases

IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17. The standard includes two recognition exemptions for lessees – leases of 'low-value' assets (e.g., personal computers) and short-term leases (i.e., leases with a lease term of 12 months or less). At the commencement date of a lease, a lessee will recognise a liability to make lease payments (i.e., the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e., the right-of-use asset). Lessees are required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees are also required to re-measure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognise the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset.

Lessor accounting under IFRS 16 is substantially unchanged from today's accounting under IAS 17. Lessors will continue to classify all leases using the same classification principle as in IAS 17 and distinguish between two types of leases: operating and finance leases. IFRS 16, which is effective for annual periods beginning on or after 1 January 2019, requires lessees and lessors to make more extensive disclosures than under IAS 17.

Transition to IFRS 16

The Group adopted IFRS 16 retrospectively to each prior reporting period presented, applying the modified retrospective method. The Group elected to apply the standard to contracts that were previously identified as leases applying IAS 17 and IFRIC 4. The Group therefore do not apply the standard to contracts that were not previously identified as containing a lease applying IAS 17 and IFRIC 4.

The Group elected to use the exemptions proposed by the standard on lease contracts for which the lease terms ends within 12 months as of the date of initial application, and lease contracts for which the underlying asset is of low value.

3. Significant accounting judgments, 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 includes:

- Financial risk management and policies Note 16

Judgments

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 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 judgment, 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.
- Regarding development of pharmaceuticals and medical equipment the Group cannot render probable future earnings large enough to justify recognising development costs in the balance sheet before marketing approval has been obtained, in accordance with IAS 38 Intangible assets. Own development costs are therefore recognised as an expense as incurred until national market approval for the product and indication has been obtained. Any further development of the product after marketing approval has been obtained and market launch completed will be recognised in the balance sheet to the extent that this involves significant changes to the product, which is considered likely to generate future financial benefits.

Significant accounting judgments, 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 and Note 15 for further information.

4. Standards issued, but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

IFRS 17 Insurance contracts. This standard is currently not applicable to the Group.

Amendments to IFRS 3: Definition of a Business. Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Group will not be affected by these amendments on the date of transition.

Amendments to IAS 1 and IAS 8: Definition of Material. The amendments to the definition of material is not expected to have a significant impact on the Group's consolidated financial statements.

PCI BIOTECH HOLDING ASA - NOTES FINANCIAL STATEMENT 2019

5 OTHER INCOME

OTHER INCOME

(figures in NOK 1,000)

	Group	
	2019	2018
Tax incentive scheme - SkatteFUNN	5 777	5 695
Grants from the Research Council of Norway	3 615	3 890
Total other income	9 392	9 585

Government grants are recognised at the value of the contributions at the transaction date. Grants are not recognised until it is probable that the conditions attached to the contribution will be achieved. The grant is recognised in the statement of profit and loss in the same period as the related costs, and are disclosed as other income. R&D projects have been approved for SkatteFUNN for the period 2017 through 2019. The Group is 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 December 2021. Grant receivables as of 31 December 2019 are disclosed in Note 18.

6 OPERATING SEGMENTS

The Group has only one operating segment, which is research and development, and had no revenues for the reporting periods. The Group received Norwegian grants and tax incentive scheme (SkatteFUNN) in the reporting periods and these are disclosed as other income, see Note 5.

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

Operating costs according to classification.

(figures in NOK 1,000)

	Note	Group		Parent	
		2019	2018	2019	2018
Salary expenses	8	24 669	20 509	1 378	1 240
R&D exclusive salary and other operating expenses		64 341	25 662	0	0
Depreciation and amortisation	14	955	5	0	0
Other operating expenses		8 229	7 928	3 204	3 471
Total operating expenses		98 195	54 104	4 582	4 711

Of the total salary expenses NOK 16 021 relates to R&D activities (2018: NOK 14 356).

Specification of other operating expenses

	2019	2018	2019	2018
Travel expenses	964	1 086	53	48
Patent, legal and other fees	4 075	3 654	2 257	2 375
Other expenses	3 190	3 188	894	1 049
Total other operating expenses	8 229	7 928	3 204	3 471

R&D expenses by category:

	2019	2018
Clinical studies	62 971	27 499
Pre-clinical studies	6 198	5 943
CMC and equipment	10 716	3 846
Patents	3 427	3 049
Other expenses	0	0
Total R&D expenses	83 312	40 337

The Group has no development expenditure that qualifies for recognition of an asset under IAS 38. Per year end 2019 there is stock of the product under development (fimaporfin) at a cost value of NOK 4.3 million not recognised in the balance sheet (2018: NOK 0.4 million). The increase compared to last year is due to the production of a new batch during 2019. Intangible assets and all research expenditures are charged through the income statement, in line with previous years.

8 SALARY EXPENSES AND OTHER REMUNERATION

(figures in NOK 1,000)

	<u>Group</u>		<u>Parent</u>	
	2019	2018	2019	2018
Wages and Board of Directors remuneration	13 796	14 568	1 198	1 080
Social security contributions	2 257	2 186	181	159
Share-based payments, incl social security	7 199	2 166	0	0
Pension costs 9	1 224	1 326	0	0
Other expenses	194	264	0	1
Total salary expenses	24 669	20 509	1 378	1 240
No. of full-time equivalent positions	8,7	11,0	0,0	0,0

Share option programme for employees

Employees (including senior 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). 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.

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 2019 were NOK 6.8 million. The fair value estimated at grant date is amortised over the vesting period of three years. No share options were granted in 2018.

Options granted in 2019	June 2019
Number of options	320 000
Dividend	0
Historical volatility (%)	110 %
Risk free interest rate (%)	1.21 %
Expected lifetime (years)	5

Authorisation from the annual general meeting

The general meeting held 29 May 2019 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. 745,500 share options of the current authorization have been granted by the Board of Directors, including the 40,000 share options exercised in September 2019. The Board of Directors have not been granted any share options. See note 23 Related party transactions for further information.

Share option transactions during the year

Participants in the Company's share option program exercised on 20 February 2019 a total number of 61,000 share options. Out of these share options 30,000 were exercised at a strike price of NOK 19.24, 15,000 share options were exercised at a strike price of NOK 7.84, 11,000 share options were exercised at a strike price of NOK 3.26 and 5,000 share options were exercised at a strike price of NOK 21.48.

Out of the total number of exercised share options, 5,000 share options at a strike price of NOK 21.48 and 6,000 share options at a strike price of NOK 3.26 were exercised by the primary insider Gaël L'Hévéder (CBDO at that time), who sold 5,300 shares in the market at an average price of NOK 25.75 per share in order to finance the cash and tax impact of the share option exercise.

Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 were exercised by the primary insider Hans Olivecrona (CMO), who has sold 30,000 shares in the market at an average price of NOK 25.75 per share.

The Board of Directors awarded in June 2019 a total of 320,000 share options under the employee share option program. 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 25.78, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The share options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after 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 share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2024.

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 6.8 million which will be charged to the profit and loss statement over the vesting period for the share options. During 2019 a total number of 70,000 non-vested share options were terminated due to cease of employment. Expenses for these share options charged through profit and loss in previous periods have been reversed in 2019, with a net positive effect of NOK 1.0 million.

In September 2019 participants of the company's share option program for employees exercised a total number of 40,000 share options. All share options were exercised by the primary insider Ronny Skuggedal (CFO), at a strike price of NOK 8.63. Mr Skuggedal sold at the same time 25,300 shares in the market at an average price of NOK 27.08 per share in order to finance the cash and tax impact of the share option exercise.

Share option transactions during 2018

In October 2018 a share issue was completed and the strike price for outstanding share options were adjusted in accordance with the standard terms for dilution effects for the employee incentive program agreements. The fair value assessments, based on calculation using the Black- Scholes valuation model, resulted in a share based payment expense of NOK 0.6 million, of which NOK 0.3 million is charged to the profit and loss (P&L) statement in 2018. The residual value will be charged over the remaining lifetime of the outstanding share options.

One participant in the Group's share option program exercised 12 April 2018 a total number of 5,000 share options at a strike price of NOK 9.11 and a total number of 3,000 share options at a strike price of NOK 3.79, corresponding to a total number of 8,000 shares. At the same time another 4,000 share options lapsed. The total share based payment effect from the transactions were an expense of NOK 0.1 million.

Participants of the Group's share option program for employees exercised a total number of 170,000 share options on 17 October 2018. Out of these share options 85,000 were exercised at a strike price of NOK 9.08, 60,000 share options were exercised at a strike price of NOK 3.26 and 25,000 share options were exercised at a strike price of NOK 7.84.

The lifetime of 125,000 share options originally expiring in Q3 2018, during the rights issue process, were extended with one year in August 2018 and are now expiring in Q3 2019. The total share based payment effect of the change, based on calculation using the Black- Scholes valuation method, was an expense of NOK 0.1 million which was charged to the P&L in 2018.

P&L and balance sheet effects of the share option programme

The net P&L effect for share-based payments for 2019 were a net cost of NOK 2.4 million (2018: NOK 4.1 million) in addition to NOK 4.8 million (2018: NOK -1.9 million) for a potential social security liability following future exercises. 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 expiry date of the underlying share options.

For the parent company, PCI Biotech Holding ASA, the Group's net cost of NOK 2.4 million for share based payments (2018: NOK 4.1 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 shares	
		2019	2018
2019 - Q3	8,63	-	40 000
2020 - Q3	7,84	26 000	41 000
2020 - Q3	3,26	34 500	45 500
2022 - Q3	21,48	325 000	340 000
2022 - Q3	19,24	-	90 000
2024 - Q3	25,78	320 000	-
Sum		705 500	556 500

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

	2019		2018	
	Number	Average exercise price in NOK per share	Number	Average exercise price in NOK per share
Outstanding at the beginning of the year	556 500	17,70	738 500	17,44
Granted during the year	320 000	25,78	0	0
Lapsed during the year	0	7,12	4 000	7,12
Exercised during the year	101 000	11,72	178 000	6,86
Expired during the year	70 000	25,14	0	0
Outstanding at year end	705 500	22,04	556 500	17,70
Exercisable options at year end	277 167	17,93	269 833	14,18

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

Number of options 2019 / 2018	Exercise price in NOK per share	Average remaining lifetime (years)	
		2019	2018
0 / 40 000*	8,63	-	0,7
26 000 / 41 000	7,84	0,7	1,7
34 500 / 45 500	3,26	0,7	1,7
325 000 / 340 000	21,48	2,7	3,7
0 / 90 000	19,24	-	3,7
320 000 / 0	25,78	3,7	-

*The lifetime of the share options was extended in 2018 with one year.

9 PENSION EXPENSES

(figures in NOK 1,000)

	Group	
	2019	2018
Total pension cost from contribution schemes	1 224	1 326

The contribution pension scheme is in compliance with Norwegian public requirements and a total of twelve employees are included in the scheme at year end (2018: eleven employees).

10 AUDITORS FEE

AUDITOR FEES

(figures in NOK 1,000)

	Group		Parent	
	2019	2018	2019	2018
Statutory audit	203	157	139	100
Other assurance services	43	100	16	53
Total	246	257	155	153

11 FINANCIAL INCOME AND EXPENSES

(figures in NOK 1,000)

	Group		Parent	
	2019	2018	2019	2018
Interest income	2 398	740	16	13
Interest income group company	-	0	6 734	3 157
Other financial income	339	9 150	0	9 108
Total financial income	2 737	9 890	6 750	12 278
Interest expense	469	117	461	117
Interest expense leasing	37	0	0	0
Other financial expense	2 174	34	1 528	0
Total financial expense	2 680	151	1 989	117

For 2019 the other financial expense of NOK 1.5 million in Parent and NOK 1.6 million in Group are related to loss on cash deposits in Euro per year end, resulting from converting these Euro cash positions into NOK as functional currency for the annual accounts. The Euro-NOK conversion effect for 2018 were a financial income of NOK 9.1 million for both Parent and Group.

12 TAX

(figures in NOK 1,000)

	Group		Parent	
	2019	2018	2019	2018
Comprehensive income before tax	-88 746	-34 780	179	7 450
Expected nominal rate of tax (2019: 22% / 2018: 23%)	-19 524	-7 999	39	1 714
Permanent differences charged through P&L	-737	-379	0	0
Deferred tax asset not recognised in the balance sheet	20 261	8 379	-39	-1 714
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	
	2019	2018	2019	2018
Fixed assets	423	-7	0	0
Receivables	0	0	0	0
Carry forward loss	-110 134	-89 445	-11 292	-11 331
Total tax asset (22% for 2019 / 22% for 2018)	-109 712	-89 452	-11 292	-11 331
Deferred tax asset not recognised	109 712	89 452	11 292	11 331
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 109.7 million (2018: NOK 89.5 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 is not affected by the dilution effect if negative results in the period.

Earnings per share	2019	2018
Weighted average number of shares (in '000)	37 229	27 797
Dilution effect (in '000)	706	556
Weighted average number of shares fully diluted (in '000)	37 935	28 353
Net loss for the year	-88 746	-34 780
Earnings per share (NOK per share)	-2.38	-1.25
Diluted earnings per share (NOK per share)	-2.38	-1.25

14 FIXED AND INTANGIBLE ASSETS

(figures in NOK 1,000)

	Group		
	Device (laser)	Office equipment	Total
Acquisition cost per 31 December 2017	0	337	337
Additions in 2018	0	0	0
Disposals and scrapping during 2018	0	0	0
Acquisition cost per 31 December 2018	0	337	337
Additions in 2019	5 349	55	5 405
Disposals and scrapping during 2019	0	0	0
Acquisition cost per 31 December 2019	5 349	392	5 742
Accumulated depreciation per 31 December 2017	0	315	315
Ordinary depreciation 2018		5	5
Disposals in 2018		0	0
Accumulated depreciation per 31 December 2018	0	320	320
Ordinary depreciation 2019	339	10	349
Disposals in 2019	0	0	0
Accumulated depreciation per 31 December 2019	339	330	669
Book value per 31 December 2018	0	17	17
Book value per 31 December 2019	5 010	62	5 072

The laser device is for the fimaCHEM programme.

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 2019 (NOK thousand)
PCI Biotech AS, Oslo - Norway	2008	5 172 160	100 %	523 731	105 077	-88 925

In 2019 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 134 676 740, totalling to NOK 135 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 135 million by PCI Biotech Holding ASA.

In 2018 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 79 676 740, totalling to NOK 80 000 000. The share capital was increased by a cash contribution 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 Stock Exchange. Per year end 2019 the carrying amount is at historic cost.

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 2019 the Group has placed cash deposits in EURO to hedge the foreign currency risk for the fimaCHEM pivotal study.

(II) Classes of financial risk

Interest rate risk

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 2019.

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 milestones associated with licence agreements, government grants and the capital market. 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).

Credit risk

PCI Biotech has no sales or receivable balances based on sales for 2019 and 2018 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 2019 or 2018. 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 2019 or 2018.

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

Group (figures in NOK 1,000)	Remaining period				
	Less than 1 month	1-3 months	3-12 months	1-5 years	Total
31.12.2019					
Other long term liabilities	0	0	0	2 037	2 037
Long term lease liabilities	0	0	0	539	539
Trade accounts payables	8 601	0	0	0	8 601
Current lease liabilities	164	164	329		657
Public duties payables	915	0	3 770	0	4 684
Other current liabilities	85	3 986	6 615	0	10 685
31.12.2018					
Other long term liabilities	0	0	0	107	107
Trade accounts payables	1 889	0	0	0	1 889
Public duties payables	943	0	1 037	0	1 980
Other current liabilities	489	2 842	9 795	0	13 126

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
31.12.2019					
Trade accounts payables	150	0	0	0	150
Public duties payables	0	0	119	0	119
Other current liabilities	25	0	847	0	872
31.12.2018					
Trade accounts payables	1 196	0	0	0	1 196
Public duties payables	0	0	110	0	110
Other current liabilities	10	0	780	0	790

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 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.

	Changes in exchange rates	Effect on operating result	
		Parent	Group
2019	+/- 10 %	+/- 12 516	+/- 11 144
2018	+/- 10 %	+/- 19 047	+/- 20 557

17 CLASSIFICATION OF FINANCIAL ASSETS AND LIABILITIES

(Figures in NOK 1,000)

31.12.2019

	Group		
	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Other current receivables	14 646	0	14 646
Cash and cash equivalents	0	261 103	261 103
TOTAL FINANCIAL ASSETS	14 646	261 103	275 749
Liabilities - other financial liabilities			
Other long term liabilities	2 037	0	2 037
Long term lease liabilities	539	0	539
Trade accounts payables	8 601	0	8 601
Current lease liabilities	657	0	657
Public duties payables	4 684	0	4 684
Other current liabilities	10 685	0	10 685
TOTAL FINANCIAL LIABILITIES	27 204	0	27 204

31.12.2018

	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Other current receivables	7 713	0	7 713
Cash and cash equivalents	0	349 326	349 326
TOTAL FINANCIAL ASSETS	7 713	349 326	357 039
Liabilities			
Other long term liabilities	107	0	107
Trade accounts payables	1 889	0	1 889
Public duties payables	1 980	0	1 980
Other current liabilities	13 126	0	13 126
TOTAL FINANCIAL LIABILITIES	17 102	0	17 102

Parent			
31.12.2019	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Receivables from group company	28 011	0	28 011
Other current receivables	69	0	69
Cash and cash equivalents	0	122 794	122 794
TOTAL FINANCIAL ASSETS	28 080	122 794	150 874
Liabilities			
Trade accounts payables	150	0	150
Public duties payables	119	0	119
Other current liabilities	872	0	872
TOTAL FINANCIAL LIABILITIES	1 141	0	1 141
31.12.2018			
	Financial instruments at amortised cost	Financial instruments at fair value through OCI	Total
Assets			
Receivables from group company	92 840	0	92 840
Other current receivables	252	0	252
Cash and cash equivalents	0	192 373	192 373
TOTAL FINANCIAL ASSETS	93 092	192 373	285 465
Liabilities			
Trade accounts payables	1 196	0	1 196
Public duties payables	110	0	110
Other current liabilities	790	0	790
TOTAL FINANCIAL LIABILITIES	2 096	0	2 096

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 are recognised at year end 2019 or 2018.

Other current receivables - specification

(Figures in NOK 1,000)

	Group		Parent	
	31.12.2019	31.12.2018	31.12.2019	31.12.2018
Recognised not received government grants	6 725	7 012	0	0
Prepaid payables	7 634	317	36	0
VAT receivables	288	384	33	252
Total other receivables	14 646	7 713	69	252

The parent company has supported its wholly owned subsidiary, PCI Biotech AS, with loans and capital increases during the year. The capital increase during 2019 was NOK 135 million (2018: NOK 80 million) and per year end the loan balance is NOK 28.0 million (2018: NOK 92.8 million).

19 CASH AND CASH EQUIVALENTS

(Figures in NOK 1,000)

	Group		Parent	
	31.12.2019	31.12.2018	31.12.2019	31.12.2018
Cash and cash equivalents, restricted ⁽¹⁾	1 127	698	0	0
Cash and cash equivalents, non-restricted	259 976	348 628	122 794	192 373
Sum	261 103	349 326	122 794	192 373

(1) Restricted cash and cash equivalents are security for the employees' withholding tax and a bank deposit of NOK 50 thousand.

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 2019 or 2018.

Conversion effects for bank deposits in foreign currency (Euro) versus NOK as functional currency for the annual group accounts was NOK -1.6 million for 2019 and NOK 9.1 million for 2018 and for the parent accounts NOK -1.5 million in 2019 and NOK 9.1 million in 2018.

20 SHARE CAPITAL

	No. of shares	Nominal value per share in NOK	Share capital in NOK
Share capital as per 31.12.2017	24 986 890	3,00	74 960 670
Share issues in 2018	12 178 000	3,00	36 534 000
Share capital as per 31.12.2018	37 164 890	3,00	111 494 670
Share issues in 2019	101 000	3,00	303 000
Share capital as per 31.12.2019	37 265 890	3,00	111 797 670

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 2019 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition the board of directors were authorised to execute share capital increases with up to NOK 12,004,700 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 2019

In February 2019 participants of the Company's share option program for employees exercised a total number of 61,000 share options on 20 February 2019. 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 29 May 2018, decided to increase the Company's share capital with NOK 183,000 by issuing 61,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting. The transaction was completed 25 February 2019. The capital increase resulted in net proceeds of NOK 0.8 million.

In September 2019 participants of the company's share option program for employees exercised a total number of 40,000 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 29 May 2019, decided to increase the company's share capital with NOK 120,000 by issuing 40,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the company's general meeting. The transaction was completed 9 September 2019. The capital increase resulted in net proceeds of NOK 0.3 million.

Subsequent to the two transactions in 2019 the company's share capital is NOK 111,797,670 divided into 37,265,890 shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the company's general meeting.

Share issues in 2018

The Company carried out a fully underwritten rights issue of NOK 360 million, resolved at an extraordinary general meeting held on 14 September 2018, by a share capital increase of NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting. The rights issue was completed 10 October 2018.

The rights issue was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received an underwriting fee equal to 3.5 per cent of their respective underwriting obligations.

On the 4 October 2018, the day after expiry of the subscription period, the board of directors of PCI Biotech approved the final allocation of the shares offered in the rights issue based on the allocation criteria set out in the prospectus dated 17 September 2018. A total of 12,000,000 new shares were allocated and the rights issue was subscribed with 87 per cent of the shares offered. Approximately 9.2 million new shares were allocated to subscribers on the basis of exercised subscription rights. Approximately 0.9 million new shares were allocated to holders of subscription rights as a result of oversubscription. Approximately 0.3 million new shares were allocated to subscribers without subscription rights. Approximately 1.6 million new shares were allocated to the underwriters in accordance with the underwriting commitments of the respective underwriters to the extent the underwriters have not fulfilled such commitments by subscribing for offer shares in the subscription period. The capital increase resulted in net proceeds of NOK 327.6

Participants of the Company's share option program for employees exercised a total number of 8,000 share options on 12 April 2018. 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 29 May 2017, decided to increase the Company's share capital with NOK 24,000 by issuing 8,000 new shares,

each share of par value NOK 3.00 and each share giving one vote at the Company's general meeting. The transaction was completed 17 April 2018. The capital increase resulted in net proceeds of NOK 40 thousand.

Participants of the Company's share option program for employees exercised a total number of 170,000 share options on 17 October 2018. 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 29 May 2018, decided to increase the Company's share capital with NOK 510,000 by issuing 170,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting. The transaction was completed 24 October 2018. The capital increase resulted in net proceeds of NOK 1.2 million.

Ownership structure per 31 December 2019:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,09 %
Myrlid AS	2 415 000	6,48 %
MP PENSJON PK	2 258 206	6,06 %
RADIUMHOSPITALET'S FORSKNINGSSTIFT.	1 281 415	3,44 %
NORDNET LIVSFORSIKRING AS	1 065 216	2,86 %
GRESSLIEN	665 320	1,79 %
Nordnet Bank AB	554 231	1,49 %
Jandersen Kapital AS	540 200	1,45 %
BERG-LARSEN	462 400	1,24 %
ESTI AS	391 000	1,05 %
Total 10 largest shareholders	13 393 431	35,94 %
Others	23 872 459	64,06 %
Total	37 265 890	100,00 %

Shares owned, directly or indirectly, by members of the board and executive management, and their personally related parties per 31.12.2019 and per 31.12.2018:

Name	Position	Number of shares	
		31.12.2019	31.12.2018
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen (Stocken Invest AS)	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)	Board member*	4 000	NA
Andrew Hughes	Board member**	0	0
Hilde H. Steineger	Board member***	NA	0
Per Walday	CEO	68 300	68 300
Anders Høgset	CSO	63 300	63 300
Ronny Skuggedal	CFO	43 000	28 300
Kristin Eivindvik	CDO	18 800	18 800
Gaël L'Hévéder	CBDO***	NA	62 000
Hans Olivecrona	CMO****	NA	0
Total		344 028	387 328

* Hilde Furberg was elected as board member in the annual general meeting in May 2019 and holdings are reported from that date. The shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.

** Andrew Hughes was elected as board member in the annual general meeting in May 2018 and holdings are reported from that date.

*** Hilde Steineger, board member, ended her term at the annual general meeting in May 2019 and holdings are reported up to that date.

**** Gaël L'Hévéder resigned by end of March 2019 and holdings are reported to that date.

***** Hans Olivecrona transitioned into a consultancy position from 1 July 2019 and holdings are reported to that date.

The board of directors and management (primary insiders) made the following exercise of subscription rights in the fully underwritten rights issue of NOK 360 million completed in October 2018:

The chairman of the board, Hans Peter Bøhn, exercised all 40,106 subscription rights allocated in the rights issue. Stocken Invest AS, a company wholly owned by Lars Viksmoen, a member of the board, bought and exercised 1,580 subscription rights, in addition to all the 1,920 subscription rights allocated in the rights issue. In addition, Stocken Invest AS had entered into the underwriting agreement with a commitment of NOK 1.0 million of the rights issue. The corresponding underwriting fee was settled in October 2018. The rights issue was subscribed with approximately 87% of the shares offered and new shares were allocated to underwriters in accordance with the underwriting commitment to the extent the underwriters had not fulfilled such commitments by subscribing for offer shares in the subscription period. Stocken Invest AS was allocated 5,466 shares and these shares are part of the shareholding portfolio pursuant of completion of the rights issue on 10 October 2018.

The board member Christina Herder exercised 1,645 out of the 4,010 subscription rights allocated in the rights issue. The allocated subscription rights that were not exercised were sold in the market. The board members, Hilde H. Steineger and Andrew Hughes, held no shares in the Company and hence were not allocated any subscription rights in the rights issue.

Per Walday, CEO, exercised 3,167 out of the 31,263 subscription rights allocated in the rights issue. Ronny Skuggedal, CFO, exercised 3,234 out of the 12,031 subscription rights allocated in the rights issue. Gaël L'Hévéder, CBDO (at that time), exercised none of the 4,800 subscription rights allocated in the rights issue. Kristin Eivindvik, PD, exercised 852 out of the 8,615 subscription rights allocated in the rights issue. Anders Høgset, CSO, exercised 844 out of the 29,978 subscription rights allocated in the rights issue. The allocated subscription rights that were not exercised by management were sold in the market.

21 FINANCING STRUCTURE

The Group had no external interest bearing debt as of 31.12.2019 or 31.12.2018.

22 OTHER CURRENT LIABILITIES BY YEAR END

(Figures in NOK 1,000)

	Group		Parent	
	31.12.2019	31.12.2018	31.12.2019	31.12.2018
Accruals for incurred external R&D expenses	7 201	9 519	0	0
Accruals for employee bonus, holiday payments, board remuneration etc.	3 459	3 597	847	780
Other accruals	25	10	25	10
Total other current liabilities	10 685	13 126	872	790

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 2019							
Per Walday, CEO	0	1 812	346	18	132	2 307	
Ronny Skuggedal, CFO*	0	1 290	182	751	132	2 355	
Anders Høgset, CSO	0	1 092	143	18	111	1 364	
Gaël L'Hévéder, CBDO**	0	553	0	198	28	779	
Kristin Eivindvik, PD	0	1 090	82	13	113	1 298	
Hans Olivecrona, CMO***	0	681	100	273	65	1 119	
Total senior executives remuneration	0	6 518	853	1 271	580	9 222	

* "Other benefits" include salary benefits in relation to exercise of 40,000 share options during 2019.

** "Other benefits" include salary benefits in relation to exercise of 11,000 share options during 2019. Mr. L'Hévéder resigned from his position by end of March 2019.

*** "Other benefits" include salary benefits in relation to exercise of 30,000 share options during 2019. Mr. Olivecrona transitioned from an employee to an external consultant from 1 July 2019. Mr. Olivecrona has received SEK 233 thousand in consultancy fee's for 2019.

(Figures in NOK 1,000)

	Board remuneration		Salary	Bonus	Other benefits	Pension benefits	Total
Senior executives 2018							
Per Walday, CEO	0	1 727	300	22	126	2 175	
Ronny Skuggedal, CFO*	0	1 209	172	143	127	1 651	
Anders Høgset, CSO	0	1 053	122	23	106	1 304	
Gaël L'Hévéder, CBDO**	0	1 182	88	1 775	125	3 170	
Kristin Eivindvik, CDO	0	1 023	78	116	103	1 220	
Hans Olivecrona, CMO	0	993	0	5	195	1 193	
Total remuneration	0	7 187	760	1 984	782	10 713	

*The lifetime of 40,000 share options originally expiring during the rights issue process was extended with one year and the executive received a compensation for lost subscription rights. The compensation of NOK 118 thousand is disclosed as "Other benefits".

** The lifetime of 70,000 share options originally expiring during the rights issue process was extended with one year and the executive received a compensation for lost subscription rights. The compensation of NOK 204 thousand is disclosed under "Other benefits". "Other benefits" also include salary benefits in relation to exercise of share options in 2018.

(Figures in NOK 1,000)

	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Board of Directors 2019						
Hans Peter Bøhn, Chairman	330	0	0	0	0	330
Hilde Furberg*	0	0	0	0	0	0
Hilde H. Steineger*	200	0	0	0	0	200
Christina Herder	200	0	0	0	0	200
Lars Viksmoen	200	0	0	0	0	200
Andrew Hughes	200	0	0	0	0	200
Total remuneration	1 130	0	0	0	0	1 130

*Hilde Furberg joined the Board of Directors in May 2019

**Hilde H. Steineger ended her term in May 2019

(Figures in NOK 1,000)

	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Board of Directors 2018						
Hans Peter Bøhn, Chairman	300	0	0	0	0	300
Kjetil Taskén*	185	0	0	0	0	185
Hilde H. Steineger	185	0	0	0	0	185
Christina Herder	185	0	0	0	0	185
Lars Viksmoen	185	0	0	0	0	185
Andrew Hughes**	0	0	0	0	0	0
Total remuneration	1 040	0	0	0	0	1 040

*Mr Taskén ended his term in May 2018

**Mr Hughes joined the Board of Directors in May 2018

PCI Biotech's policy as regards the determination of salary and other remuneration to senior executives is to have market based remuneration and provide other benefits that are competitive in employment for senior executives. It is important to attract the required expertise and experience to create value and contribute to the mutual interests between owners and senior executives. The performance-based remuneration shall be linked to value creation for shareholders or long term performance of the Group.

The main principles for remuneration of the Group's senior executives are as follows:

- Salaries are reviewed annually
- Bonuses are calculated on the basis of goals for the Group established by the Board of Directors and achievement of personal goals. The Group's Chief Executive Officer (CEO) has a bonus agreement for up to 25% of annual salary, other senior executives have bonus agreements of up to 10 - 20% of annual salary.
- Senior executives, and other key employees, participate in the Group's share option incentive scheme
- Senior executives participate in the Group's general pension scheme

Bonuses for senior executives are calculated on the basis of the Group's financial results and development, and achievement of personal goals.

The senior executives participate in the Group's pension plan that is a defined contribution plan which

entails payment of 7% to 17% 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.

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 in 2019 are presented in the table below:

Overview share options, Senior executives	Total holdings				Total holdings		Average exercise price in NOK
	31.12.2018	Allocated	Lapsed	Exercised	Expired	31.12.2019	
Per Walday, CEO	104 000	60 000	0	0	0	164 000	22,05
Ronny Skuggedal, CFO	116 000	40 000	0	40 000	0	116 000	19,67
Anders Høgset, CSO	66 000	40 000	0	0	0	106 000	22,07
Gaël L'Hévéder, CBDO*	21 000	0	0	11 000	10 000	0	-
Kristin Eivindvik, PD	33 500	40 000	0	0	0	73 500	20,85
Hans Olivecrona, CMO**	90 000	0	0	30 000	60 000	0	-
Sum	430 500	180 000	0	81 000	70 000	459 500	

* Mr. L'Hévéder resigned from his position by end of March 2019 and all unexercised share options were terminated.

** Mr. Olivecrona transitioned from an employee to an external consultant from 1 July 2019 and all unexercised share options were terminated.

Related parties:

The Norwegian Radium Hospital Research Foundation:

PCI Biotech has a long-standing research relationship with the Norwegian Radium Hospital Research Foundation (RF), which is affiliated to the Norwegian Radium Hospital (NRH), now named Oslo Universitetssykehus HF (OUS). Some of PCI Biotech's main patents were filed by the NRH and later transferred to PCI Biotech. Under the terms of research agreements with RF from 2002 and 2007 and later amendments, the PCI Biotech supports the RF with research and development funding, and gets rights of use and an option on certain conditions to acquire the new technologies developed by the RF.

PCI Biotech has a right of first refusal to purchase from the RF, completely or in part, any new technology within the field of Photochemical Internalisation. If PCI Biotech is not interested in purchasing such technology at the terms offered, RF can offer the technology to a third party. An offer to a third party cannot be at terms inferior to those offered to PCI Biotech, and PCI Biotech has the right to perform an independent assessment of any agreement entered into between RF and a third party, to ensure that RF has offered no more favourable terms to the third party than those previously rejected by PCI Biotech. If the terms are found more favourable, PCI Biotech may request that the agreement between RF and the third party is to be cancelled.

The Group has for delivery of R&D services, related to the described agreements, paid NOK 2.1 million on commercial terms to RF in 2019 (2018: NOK 1.8 million). As of 31.12.2019 the Group had account payables of NOK 0.5 million to RF (2018: NOK 0.3 million).

Rights Issues in the Company

In relation to the rights issue of NOK 360 million finalised in October 2018 several shareholders contributed to the underwriting syndicate and received a guarantee fee of 3.5% for their respective commitment.

PCI Biotech AS:

PCI Biotech AS is a fully owned subsidiary of the parent company in the Group, PCI Biotech Holding ASA. The parent company 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 2.0 million in 2019 (2018: NOK 2.2 million). The parent company has charged PCI Biotech AS interest expenses for intercompany loans of NOK 6.7 million during 2019 (2018: NOK 3.2 million). Net current receivables from PCI Biotech AS at year-end 2019 were NOK 28.0 million (2018: NOK 92.8 million). In 2019 an intercompany loan to PCI Biotech AS of NOK 135 million was utilised as contribution in kind from PCI Biotech Holding ASA for a capital increase in PCI Biotech AS.

The primary insider, Hans Olivecrona, transition from an employee to an external consultant by 1 July 2019. After that date he has received consultancy fee of SEK 0.2 million for his CMO position, invoiced through the company Olive & Crown AB.

Board of Directors:

In relation to the rights issue in the Company finalised in October 2018 the Director Lars Viksmoen contributed to the underwriting syndicate and underwrote separately NOK 1 million of the rights issue with a guarantee fee of 3.5%. The corresponding underwriting fee was settled in 2018.

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 2018, but PCI Biotech exercised an option for three more years and the lease now runs to 31 December 2021 with an option for additional three more years. The lease is NOK 0.7 million per annum. The lease agreement is subject to annual adjustment according to changes in the consumer price index. Amounts of minimum lease payment for non-cancellable operating leases is NOK 1.3 million (non-discounted contractual payments) per year end 2019 for the next two years.

The Group adopted for the first time IFRS 16 Leases from 1 January 2019, applying the modified retrospective method and 2018 figures have therefore not been restated. As of year-end 2018 PCI Biotech had no agreements that classified as financial lease under IAS 17. Under the new standard for leases, IFRS 16, PCI Biotech identified office lease as the only applicable right-to-use asset.

On transition to IFRS, PCI Biotech recognised NOK 1.8 million in right of use assets and a corresponding lease liability which is disclosed in the balance sheet as long- and short-term liabilities depending on maturity of the corresponding lease payments. The initial recognised amount is based upon contractual minimum lease payments for 2019-2021 and discounted by the incremental borrowing rate at the date of initial application. The relevant non-cancellable operating lease commitment per 1 January 2019 was NOK 2.0 million for 2019-2021, not including an extension option due to not reasonable certainty about option exercise. Discounted value of the operating lease commitment applying an incremental borrowing rate of 6% was NOK 1.8 million.

The implementation effect of IFRS 16, movements of the rights-of-use asset and lease liabilities and income statement and cash flow effects for 2019 are presented below. Payments for the principal portion of the lease liabilities are not charged to profit and loss under IFRS 16 and will only have cash flow effects for 2019, while for 2018 these payments were charged directly to profit and loss. The

Group's operating profit is improved, while its interest expense is increased, but without significant net effect on the total comprehensive income for 2019.

(Figures in NOK 1,000)

Right to use asset - office lease	2019
Initial recognition 01.01.2019	1 815
Acquisition costs 31.12.2019	1 815
Depreciation	604
Accumulated depreciation and impairment as of year-end	604
Total right of use assets - office lease as of year-end	1 211
Lower of remaining lease term or economic life	2.0 years
Depreciation method	Linear
Lease liabilities – office lease	
Initial recognition 01.01.2019	1 815
Payments of principal portion of the lease liability	-657
Interest expenses on the lease liability	38
Total lease liabilities for office as of year-end	1 196
Whereof:	
Short term lease liabilities < 1 year	657
Long term lease liabilities > 1 year	539
Income statement effects – office lease	
Depreciation of right to use asset	-604
Payments of principal portion of lease liability	657
Effect on Operating results net of tax	53
Interest expenses on the lease liabilities	-38
Effect on Net financial result net of tax	-38
Comprehensive income effect net of tax	15

25 SUBSEQUENT EVENTS

PCI Biotech has closely monitored potential implications on its short- and long-term operations following the development of the COVID-19 pandemic in 2020. PCI Biotech's overriding priority has been the safety of its staff, patients participating in the clinical trial and its collaborators. PCI Biotech has per date of this report not a complete picture of the long-term consequences regarding timelines and costs for the RELEASE study, but delays and increased costs are expected.

The main identified near-term implications concern the RELEASE study in bile duct cancer. The COVID-19 pandemic has negatively impacted both the opening of new sites and new patient enrolment into the trial, by postponement of site activation dates, and by the changing priorities and physical constraints that are being implemented at the hospitals as a consequence of the pandemic. By date of this report a total number of 34 out of the originally planned 40 sites in Europe and US are activated. In addition, PCI Biotech has made regulatory progress in the process of adding Asian sites into the RELEASE study, having secured regulatory approval in Taiwan in 2020. PCI Biotech has not identified any major short-term shortage in supplies of investigational products and devices for the trial. The main priorities are now identification and implementation of potential mitigating actions for

RELEASE study progress during the pandemic, as well as removal of unnecessary recruitment hurdles in the study protocol. For the fimaVACC and the fimaNAC programmes the main identified implications are transient downturn in business development activities. PCI Biotech has a solid cash position per year-end, placed in NOK and EUR, and the pandemic situation in 2020 has not impacted the 2019 figures.

In January 2020, a US patent were granted providing a broad coverage for the combination of various cytokines with the fimaVACC technology. In April 2020, a further US patent were granted providing a broad coverage for the combination of the fimaVACC technology with a new important class of adjuvants, called toll like receptor agonists. These US patents secure protection until 2035, while patent applications are still pending in Europe and key Asian markets.

In March 2020, PCI Biotech announced the appointment of Dr Amir Snapir, MD, PhD as Chief Medical Officer (CMO). Dr Snapir will also serve as a member of PCI Biotech's executive management team. He will lead the execution of all clinical development programmes, and be a key contributor to the identification and implementation of new opportunities and pipeline expansions. Dr Snapir brings extensive experience in global clinical development of novel therapeutics, from early clinical translation to marketing authorisation, combined with extensive international regulatory experience. Dr Snapir also brings years of experience in business collaborations, alliances and product co-developments. Since 2007 Dr Snapir has held various positions at Orion Pharma, Espoo, Finland, spanning from leader of clinical pharmacogenomics to clinical development leader in Oncology. In his most recent role, Dr Snapir held the position as Director, Rare Disease Development. Dr Snapir has a PhD from the University of Turku, Finland and an MD from the University of Tel Aviv, Israel. Dr. Snapir is the author of numerous scientific publications. Dr Snapir will commence as CMO no later than 1 May 2020.

PCI Biotech is not aware of any other subsequent events since year-end 2019 which is of material significance to the financial statements as of 31 December 2019.

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, which comprise the financial statements for the parent company and the Group. The financial statements for the parent company and the Group comprise the balance sheets as at 31 December 2019, statements of comprehensive income, the statements of cash flows and 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 have been prepared in accordance with laws and regulations and present fairly, in all material respects, the financial position of the Company and the Group as at 31 December 2019 and their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

Basis for opinion

We conducted our audit in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including 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 ethical requirements that are relevant to our audit of the financial statements in Norway, and we have fulfilled our ethical responsibilities as required by law and regulations. We have also complied with our other ethical obligations 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.

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 of the current period. 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 Company's annual report other than the financial statements and our auditor's report thereon. The Board of Directors and Chief Executive Officer (management) are 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 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, we are required to report that fact. We have nothing to report in this regard.

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 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 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 law, regulations and generally accepted auditing principles in Norway, including ISAs, we exercise professional judgment and maintain professional scepticism 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 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 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 evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company 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 those charged with governance 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 those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

Report on other legal and regulatory requirements

Opinion on the Board of Directors' report and on the statements on corporate governance and corporate social responsibility

Based on our audit of the financial statements as described above, it is our opinion that the information presented in the Board of Directors' report and in the statements on corporate governance and corporate social responsibility concerning the financial statements, the going concern assumption and proposal for the allocation of the result is consistent with the financial statements and complies with the law and regulations.

Opinion on registration and documentation

Based on our audit of the financial statements as described above, and control procedures we have considered necessary in accordance with the International Standard on Assurance Engagements (ISAE) 3000, *Assurance Engagements Other than Audits or Reviews of Historical Financial Information*, it is our opinion that management has fulfilled its duty to ensure that the Company's accounting information is properly recorded and documented as required by law and bookkeeping standards and practices accepted in Norway.

Oslo, 21. April 2020
ERNST & YOUNG AS

Revisjonsberetningen er signert elektronisk

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
fimaCHEM:	PCI Biotech's development program for enhancement of generic chemotherapies
fimaNAC:	PCI Biotech's development program for delivery of nucleic acids
fimaVACC:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
IFRS:	International Financial Report Standards
IND	Investigational New Drug
<i>In vitro</i> :	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.
<i>In vivo</i> :	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 2020 report	6 May 2020
Ordinary general meeting 2020	27 May 2020
Second quarter 2020 report	26 August 2020
Third quarter 2020 report	11 November 2020

INVESTOR CONTACT

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FORWARD LOOKING STATEMENTS

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



Unlocking the potential of innovative medicines

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