

Unlocking the potential of innovative medicines

ANNUAL REPORT 2018 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).

Both 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 large 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.

ABOUT INOPERABLE BILE DUCT CANCER AND fime CHEM

The fima*CHEM* programme aims to fulfil unmet medical needs by providing localised targeted enhancement of approved chemotherapies for the benefit of the many patients currently left without effective treatment options. Based on findings from two successful Phase I studies in cancer patients, a single pivotal clinical trial, named the RELEASE study, is about to be 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) is a cancer that 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 incidents. 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 several regions. Gemcitabine's anti-cancer effect is significantly enhanced by the fima*CHEM* technology in preclinical studies.

The first line fima *CHEM* 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 fima *CHEM* treatment may be repeated during the background chemotherapy treatment cycles. Local tumour response in the bile duct is important to maintain biliary drainage and locoregional control may therefore be more important for patient outcome than would be the case for many other cancers. The fima *CHEM* 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 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 fima*CHEM* 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 perihilar disease. Across Europe and USA approximately 3,000 patients annually are assumed to be eligible for fima *CHEM* treatment. The price potential is normally attractive for orphan drugs of this rarity. Possible upsides to the targeted patient population include perihilar patients with more extensive metastatic spread, as well as distal bile duct disease. There may also be potential for restaging of patients from inoperable to operable disease by the fima *CHEM* 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 fima*CHEM* 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 general higher incidence of bile duct cancer than the western world.



ABOUT IMMUNOTHERAPY AND fima VACC

In a nutshell, 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 the field of cancer immunotherapy 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 existing disease using the body's natural defences. Whereas in a traditional anti-infectious vaccine, the main component of the vaccine is a disease antigen, in the case of a cancer 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 fima *VACC* technology. In addition to the use in therapeutic vaccination for cancer, fima *VACC* also has the potential to be used for both therapeutic and prophylactic vaccination for several infectious diseases.

fima *VACC* is an endosomal escape technology that may realise the true benefit of innovative therapeutic vaccines by modifying the intracellular machinery of immune cells in such a way that antigens are more efficiently processed and induce antigen specific cytotoxic T-cells. The innovative and well characterised mode of action of fima *VACC* can be applied to a wide range of cancer vaccine technologies and provide PCI Biotech with a strategic opportunity to enter the field of cancer immunotherapy at a time where the understanding of cancer biology and the potential of modulating the immune response to fight cancer is growing at a rapid pace.

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

Vaccine technologies commonly utilise adjuvants to enhance immune responses, but the consensus is that each one of the adjuvants available today has shortcomings, like variation in efficacy and toxicity issues. fima *VACC* is expected to increase vaccines' efficacy and generate the immune response faster, and to be user-friendly since illumination of the target area is overall considered to be a minor inconvenience. fima *VACC* has the potential to increase patient safety if it can reduce the antigen payload and adjuvant volume per treatment and reduce the number of treatments needed. Increased efficacy for a broad range of peptide and protein based vaccines and patient safety are fima *VACC*'s key competitive differentiators.

The proprietary fima VACC technology has entered clinical development after having demonstrated strong preclinical efficacy. The translation of this technology into humans by demonstrating immunogenicity of vaccines is a main priority to establish the Company in the immunotherapy field. It is anticipated that a significant number of the cancer vaccines in development could use fima VACC to boost their activation of T-cells and increase their efficacy. There are competing peptide vaccine enhancing technology platforms; for example adjuvants, liposomes and nanoparticles. For some of these technologies fima VACC has shown synergistic effects in the preclinical setting.



In 2018 there were close to 90 different cancer indications targeted in clinical trials by peptide based therapeutic cancer vaccines across Europe and US. Most players clinically active in the peptide based vaccine area are small and the big pharma players are underrepresented.

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

PCI Biotech's nucleic acid therapeutics program (fima*NAc*) aims at improving the efficacy of novel nucleic acid based therapies. The fima*NAc* technology addresses a main hurdle in the development of nucleic acid based therapies: Sufficient release of 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 fima*NAc*, and preclinical experiments have shown that fima*NAc* 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 fima*NAc* drug delivery technology has the potential to address this issue, as demonstrated in numerous preclinical models.

There are nucleic acid based technologies like mRNA, plasmid DNA and viral vectors under development for therapeutic vaccines. RNA-based therapeutic modalities, which includes both therapeutics and vaccines, is a new class of medicines with great potential for the treatment of cancer, with 35% of all programmes being developed in oncology indications. mRNA vaccination can be pursued by both intradermal and intra-tumour injection; in the latter case the tumour is used as a factory producing the therapeutic protein medicine that will destroy it.

fima*NAc* 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 fima*NAc* strategy is two-pronged: collaborate with biotech or pharmaceutical companies having difficulties with their clinical stage product in a rescue-type scenario and develop long-term relationship with companies developing early stage innovative nucleic acid based technology.

The fima*NAc* 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)	2018	2017
Other income	9 585	10 250
Operating costs	54 104	53 681
Operating results	-44 519	-43 431
Comprehensive income	-34 780	-42 841
Cash & cash equivalents	349 326	50 789
Total liabilities	17 102	16 594
Cash flow from operating activities	-31 079	-30 620

BOARD OF DIRECTORS REPORT

The past year was an important and transformative year for PCI Biotech, with the Company gearing up towards initiation of pivotal development of the fima CHEM programme. Encouraging early efficacy from Phase I, productive regulatory interactions and confirmed safety of repeated treatment with fimaporfin have all paved the way for initiation of a randomised study that is intended to document the safety and efficacy of the orphan designated product fimaporfin in combination with gemcitabine as first-line treatment in inoperable extrahepatic bile duct cancer. Most importantly, the fully underwritten rights issue completed in October provides the Company with the funds required to develop fimaporfin to a potential accelerated marketing authorisation in EU and US. The Company has also strengthened the organisation with experienced clinical operational expertise and is now fully focused on effective delivery of the pivotal study. The primary focus in the fima VACC programme has been to ensure indepth characterisation of the clinical immune response by analysis of the vast number of blood samples available from the Phase I healthy volunteer study. To this end, collaborations have been established with internationally renowned expert groups to ensure state of the art analytical performance and evaluation, and the Company's Scientific Advisory Committee has also been further strengthened with the appointment of two immunology experts. The analytical work is not yet finished, but results achieved so far are encouraging. The collaborative fimaNAc programme has also progressed nicely the last year with the addition of two new partners (IMV and Bavarian Nordic) and further extension of the top 10 pharma collaboration. On the corporate side, PCI Biotech was listed at Oslo Børs in April, as a transfer from Oslo Axess.



HIGHLIGHTS

New funds raised enabling further progress in development programmes. Rights issue completed in October 2018, generating net proceeds of approximately NOK 328 million is expected to fund the RELEASE study beyond interim read-out of results for potential accelerated/conditional marketing approval.

fime *CHEM* - **Phase I dose-escalation continued to deliver positive early signs of efficacy and preparations for the RELEASE study progressing towards initiation in 1H 2019.** Although the data sample is small, the dose-escalation results indicate a clear improvement over the best comparable published data. The preliminary confirmation of safety read-out from the extension study enables the RELEASE study to start with up to two fima *CHEM* treatments. Full focus is now on initiation and successful execution of the pivotal phase.

fime *Vacc* - Phase I interim data suggest enhancement of several parameters of importance for **vaccination**. Overall the initial data suggest that fima *Vacc* trigger high response rates and early responses, which are highly sought-after features of vaccination platforms.

fime*MAc***-Research collaborations with key players.** Collaboration projects with key players within nucleic acid therapeutics advanced during the year, including extension of collaboration with a top-10 pharma company and two new collaborations entered into with key players.

The clinical organisation and the Scientific Advisory Committee have both been reinforced. By appointing Karin Staudacher, M.Sc. as Clinical Project Director, with her extensive project management experience from multinational clinical research projects, PCI Biotech is well prepared for the pivotal phase. In addition the Scientific Advisory Committee has been reinforced by the appointment of Prof. Kjetil Taskén and Prof. Sjoerd van der Burg to ensure continued progress in our key areas in 2019.

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 and the dormant Icelandic branch PCI Biotech Utibu. PCI Biotech is located at Ullernchausséen 64, Oslo, Norway.

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

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: 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).



The company's lead programme, fima*CHEM,* is about to initiate the RELEASE study, a pivotal clinical trial with the potential of accelerated / conditional marketing approval as a first-line treatment given the rare disease status and unmet medical need. The second clinical stage programme, fima*VACC* applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic cancer vaccines, which works in synergy with several other state-of-the-art vaccination technologies. The preclinical fima*NAC* programme utilises the endosomal release to provide intracellular delivery of nucleic acids, such as mRNA and siRNA therapeutics, thereby addressing one of the major bottlenecks facing this emerging and promising field.

Development resources were in 2018 focused towards the opportunities the PCI technology offers within the fima *CHEM* and fima *VACC* programmes. In parallel PCI Biotech has made further progress with its collaborative strategy for the fima *NAC* programme, where established preclinical data are utilised to pursue out-licensing opportunities.

fima*CHEM* - RELEASE study for inoperable bile duct cancer

Encouraging overall survival data in Phase I

The Phase I dose-escalation study with fima *CHEM* for the treatment of inoperable extrahepatic bile duct cancer aimed to demonstrate the candidate's safety and tolerability as well as finding the right dosing regimen for further clinical studies. Emerging data continued to provide encouraging interim survival results through 2018. The median overall survival from all dose cohorts in the Phase I dose escalation part (sixteen patients in total) was 14.4 months. The group treated with the selected dose (Cohort IV; six patients) for the upcoming pivotal study had a median overall survival of 21.7 months. Although the data sample is small, the results suggest a clear improvement of survival over the best comparable published data showing a median survival of 11-12 months.

Professor Jörg Trojan, a key investigator of PCI Biotech's Phase I dose-escalation study, presented the study results in a poster session at the largest European oncology congress, ESMO, held in Munich, Germany, during October 2018.

Extension study to enable repeated fima CHEM treatment in the RELEASE study

The promising early signs of efficacy in the Phase I dose-escalation study described above were based on a single fima *CHEM* treatment when added to the current standard of care (SoC) as background treatment. A Phase I extension study was initiated with the objective to determine safety and tolerability of repeated treatments with fima *CHEM*, as this may well increase the encouraging signs of efficacy. In this study, the second fima *CHEM* treatment is administered approximately three to four months after the initial treatment.

Preliminary confirmation of achieved safety endpoint (at least five out of six patients without schedule limiting toxicity) in the Phase I extension study was reported in December 2018, supporting the proposed plan of including up to two fima *CHEM* treatments in the pivotal study. The final confirmation of successful safety read-out after a formal review by the appointed Cohort Review Committee (CRC) was reported in April 2019. The formal review confirmed the Company's preliminary report that no adverse reactions have been reported that would limit the delivery of up to two fima *CHEM* treatments in the pivotal RELEASE study with registration intent. The Phase I Extension study is completed and recruitment will be formally closed.

Based on this positive safety data, the plan is to initiate the pivotal RELEASE study with up to two fima *CHEM* treatments and include a seamless safety review by an Independent Data Monitoring Committee (IDMC) when eight patients have completed two treatments in the pivotal RELEASE study.



Pivotal phase preparations underway for initiation in first half of 2019

The pivotal RELEASE study is expected to start during the first half of 2019; the interim analysis of progression free survival (PFS) and objective response rate (ORR) for potential accelerated/conditional marketing approval is expected to be available approximately 36 months after study initiation, while the final analysis is expected approximately 50 months from initiation. The pivotal study will be performed at clinical sites that first will open in Europe, followed by a roll-out in the U.S.

Feasibility work to provide a solid foundation for clinical site selection

In preparation for the pivotal study, PCI Biotech has during 2018 performed an extensive feasibility study reaching out to hospitals across Europe and the U.S., to provide a solid foundation for selection of clinical sites for optimal patient recruitment.

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

The pivotal RELEASE study design is based on the outcome of meetings with the two leading regulatory authorities EMA and FDA. The study programme consists of a single open randomised twoarm study with 186 patients (93 patients per arm), having a control arm with the SoC treatment of up to eight cycles of the chemotherapies gemcitabine and cisplatin, and an experimental arm with up to two fima *CHEM* treatments in addition to SoC. The study's primary endpoint is PFS, with overall survival (OS) as a key secondary endpoint. The study includes an interim analysis of PFS followed by analysis of ORR, with the potential of accelerated/conditional marketing approval. In addition, the study contains several other secondary endpoints that provide the opportunity to generate robust comparative data of importance for market acceptance of fima *CHEM* as a first-line treatment for inoperable bile duct cancer.

Regular communication milestones for the RELEASE study

The planned communication milestones for the pivotal RELEASE study will be the initiation of the study, meaning first patient treated, and thereafter quarterly updates on the number of countries and clinical sites open for recruitment. Other milestones will be communicated as appropriate, including outcome of the IDMC reviews, as well as further details regarding timing and plan for interim analysis. In addition, the company will as appropriate continue with quarterly updates on survival data from the Phase I study.

fime *VACC* - Vaccination program

Encouraging initial clinical results

The fima VACC technology has proven excellent preclinical efficacy with protein and peptide based vaccines, with particularly strong CD8 T-cell immune responses that are considered important for therapeutic vaccination, but also enhanced helper T-cell and antibody responses. The initial clinical translation of this preclinical efficacy is done through a Phase I study in healthy volunteers, designed to determine immune responses, safety and tolerability. The study is performed with two model vaccines; both a large immunogenic protein (KLH) and two smaller less immunogenic peptides (HPV).

To date more than 90 subjects have been included, and tolerability of intradermal treatment with fima *VACC* is established. The interim clinical results reported so far have shown that fima *VACC* may enhance T-cell responses, especially the response to the less immunogenic HPV peptide. Both earlier responses and higher response rates are seen in groups treated with well tolerated fima *VACC* dosing regimens compared to the control group, which is treated with a state-of-the-art adjuvant technology (Hiltonol).

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 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. In the two dose



groups analysed to date and which were demonstrated to be well tolerated, the number of volunteers showing CD8 responses upon completion of the vaccination schedule was higher in the two fima *VACC* treated groups than in the control group.

Overall the initial data suggest that fima *VACC* trigger high response rates and early responses, which are highly sought-after features of vaccination platforms. Analyses of further groups will be completed with the aim of confirming these preliminary positive findings prior to publication. Next steps for the Phase I study and the overall development strategy for fima *VACC* will be assessed following completion of these analyses.

Collaboration with international immunotherapy experts

The in-depth characterisation of the T-cells (CD4 and CD8) involved in the fima *VACC* immune response is done in collaboration with a renowned international expert institute; the laboratory of Experimental Cancer Immunology and Therapy of the department of Medical Oncology at Leiden University Medical Center in the Netherlands under the leadership of Professor Sjoerd van der Burg.

New US patent granted

A patent application filed in 2013 for a "band-aid-like" illumination/injection device for fima VACC vaccination, as well as other potential skin applications, has been granted in the US in October 2018.

Research and development supported by a grant

The fima *VACC* 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 three and a half years, 2017-2020.

Research collaboration with Ultimovacs ended based on strategic considerations

In January 2016, PCI Biotech announced the initiation of a preclinical research collaboration with the Norwegian privately held pharmaceutical company, Ultimovacs AS, developing novel immunotherapy against cancer. The purpose of the collaboration was to utilise the companies' complementary scientific platforms to explore potential compatibility and synergy based on preclinical *in vivo* studies. The research collaboration was supported by a grant from Innovation Norway of NOK 0.5 million in 2017.

The collaboration generated positive preclinical *in vivo* data, but based upon strategic considerations the companies agree that the potential for further partnership is limited and the collaboration is therefore ended. The generated positive data is planned to be published in a scientific journal.

fima*NAC* - delivery of nucleic acid therapeutics

PCI Biotech employs a collaborative strategy for fima*NAc*. Currently, the delivery technology is used in six preclinical research collaborations in the area of nucleic acid therapeutics. All the collaborators have the same purpose of exploring synergies between the partners' proprietary nucleic acid technologies and the fima*NAc* technology. Thereafter, if successful, the intention is to explore the potential for further partnerships.

The ongoing collaboration with an undisclosed top-10 pharma company has been extended several times, most recently until the end of June 2019 with the possibility for further extension. The collaboration was in 2017 also expanded to include evaluation of technological compatibility and synergy based on *in vivo* studies.

In May 2018 PCI Biotech entered into a preclinical research collaboration with IMV Inc, a clinical stage Canadian biopharmaceutical corporation focused on developing state-of-the-art immunotherapies. In brief, the collaborators will evaluate the formulation compatibility of their respective technologies and evaluate the potential immunogenicity and therapeutic benefit with *in vivo* studies. In August 2018 a



similar agreement was signed with the Danish company Bavarian Nordic A/S, a key player in the emerging field of immunotherapy, with multiple clinical programmes in cancer and infectious diseases.

PCI Biotech is engaged in a collaborative research program with BioNTech AG, an immunotherapy leader with bench-to-market capabilities, developing truly personalised, well tolerated and potent treatments for cancer and other diseases. The aim of the preclinical research collaboration is to evaluate technological compatibility and synergy based on *in vivo* studies performed by the University of Zürich and PCI Biotech. A collaborative research programme was also entered into with eTheRNA immunotherapies NV, a Belgian company focusing on mRNA-based immunotherapies. In brief, the collaborators will evaluate technology compatibility and synergy based on *in vivo* studies.

PCI Biotech signed its first collaborative research programme with Phio Pharmaceuticals (formerly named RXi Pharmaceuticals). The aim is to explore potential synergies between the companies' complementary fima*NAc* technology and siRNA platform. Phio Pharmaceuticals is a US biotechnology company focused on discovering and developing innovative therapeutics based on their proprietary sd-rxRNA platform. The collaboration with Phio Pharmaceuticals was extended in 2017 and supported by a new preclinical research collaboration agreement reflecting both Phio's acquisition of Mirlmmune and PCI Biotech's focus in oncology. In brief, the preclinical research collaboration will evaluate technology compatibility and synergy based on *in vivo* studies.

Corporate

Strengthening organisation with clinical expertise

PCI Biotech is focused towards initiation of the pivotal RELEASE study with fima *CHEM* and has further strengthened the organisation by appointing Karin Staudacher, M.Sc. as Clinical Project Director, from November 2018. Staudacher will assume operational responsibility for PCI Biotech's pivotal study RELEASE. Staudacher brings extensive project management experience from multinational clinical research projects including Algeta's Phase III trial for Xofigo, a product marketed by Bayer that reached the market in 2013. Most recently, Staudacher held the position as Director Clinical Development at the biotechnology company Targovax ASA.

Scientific Advisory Committee reinforced

After three years of invaluable service Professor Christoph Huber unfortunately had to retire from PCI Biotech's Scientific Advisory Committee (SAC). Following Professor Huber's departure, SAC has been reinforced by the appointment of Professor Kjetil Taskén as a committee member. Professor Taskén has been a Board of Directors member of PCI Biotech since 2008, but had to step down when he took on the position as Head and Director of the Institute for Cancer Research (ICR) of Oslo University Hospital in Norway.

Professor Taskén holds an MD and a PhD degree from University of Oslo (UiO) and is authorised to practice as a physician in Norway. Dr. Taskén is Professor of Medicine at UiO since 2001, has published some 275 peer-reviewed scientific papers (cited more than 10,000 times, h-index 55) and is an inventor of more than 15 patent families. His current research is in immune regulation, tumour immune evasion mechanisms and cancer cell signalling. He has also established the Norwegian chemical biology initiative, the academic HTS screening platform at UiO and started cancer drug sensitivity screening for future implementation in precision medicine pipelines. Prof. Taskén won the Anders Jahre Medical Award for Younger Scientists in 2002 (Nordic Prize), was elected to the Norwegian Academy of Science and Letters in 2005 and won the King Olav V's Prize for Cancer Research in 2016 (life achievement award by the Norwegian Cancer Society). He was Director of the Biotechnology Centre of Oslo, UiO, from 2003 to 2016 and founded Centre for Molecular Medicine Norway, Nordic EMBL Partnership, UiO, where he served as the Director from 2008 to 2018. From January 2018, Prof. Taskén holds the position as Head and Director of the Institute for Cancer Research (ICR) of Oslo University Hospital. He serves on several scientific advisory boards and holds a number of commissions of trust and was recently appointed to the EU/EFPIA Innovative Medicines Initiative (IMI) Scientific Committee.



In addition, 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.

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 fima*NAc* 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, fima *CHEM* for bile duct cancer, is in preparation for initiation of a pivotal clinical trial with the potential of accelerated / conditional marketing approval as a first-line treatment given the rare disease status and unmet medical need.

An important value-creating step for the fima *VACC* programme is a successful clinical translation of the promising preclinical data, through the ongoing Phase I study in healthy volunteers. A successful clinical validation would provide substantial risk reduction for the fima *VACC* asset, as well as significant value enhancement and opening up for new partnering opportunities enabling PCI Biotech to enter into the immunotherapy field. Next steps for the overall development strategy for fima *VACC* will be assessed following completion of Phase I.

The fima*NAc* 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

<u>The Board of Directors</u> –The Board of Directors consist of Hans Peter Bøhn (Chairman), Hilde H. Steineger, Christina Herder, Lars Viksmoen and Andrew Hughes. Prof. Taskén notified PCI Biotech Holding ASA's Nomination Committee and Board of Directors that he 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 2018. Professor Andrew Hughes was elected as new Director at the same meeting.

<u>Employees</u> - The Group had 13 employees at the end of 2018 (12 at year end 2017). 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 Chief Business Development Officer, Gaël L'Hévéder, has resigned from end March 2019, but was part of the management team up until that date.

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 2018 or 2017. Absence due to illness was 42 days, approximately 1.65% in 2018 (2017: 312 days, approximately 11.6%). The majority of the absence in 2017 was related to a long term sick leave of one employee.



PCI Biotech's goal is to be a workplace with gender equality and discrimination is not accepted. As of 9 April 2019 the Group has 40% female representation in the board of directors and 17% in the executive management team. 8 out of 13 employees as of year-end 2018 were women. Working time and remuneration of the Group employees are not related to gender.

Transfer of listing to Oslo Børs

On 27 April 2018 PCI Biotech was listed at Oslo Børs, as a transfer from Oslo Axess.

FINANCIAL REVIEW

Fully underwritten rights issue of NOK 360 million

The Company carried out a fully underwritten rights issue of NOK 360 million, resolved at an extraordinary general meeting held on 14 September 2018 and completed on 10 October 2018.

The net proceeds, NOK 327.6 million, and the existing cash is expected to finance the Company well into 2022, which is beyond the anticipated interim read-out of the pivotal fima*CHEM* study in inoperable bile duct cancer. Further, a minor part of the net proceeds will be used to finance the completion of the ongoing clinical Phase I trial of fima*VAcc* in healthy volunteers, selective preclinical and illumination device development for fima*VAcc*, continue collaborations with external partners for fima*NAc* as well as general corporate purposes.

Share capital

PCI Biotech Holding ASA finalised in October 2018 a fully underwritten rights issue of 12,000,000 new shares with a nominal value of NOK 3.00 per share, with gross proceeds of NOK 360 million and net proceeds of NOK 326.7 million. The rights issue was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received in October 2018 an underwriting fee equal to 3.5 per cent of their respective underwriting obligations.

On 4 October 2018, the day after the 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. The rights issue was subscribed with approximately 87% of the 12,000,000 new shares offered. 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. The Company's share capital was increased with NOK 36 million, by issuing 12 million new shares, each share with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

Stocken Invest AS, a company wholly owned by Lars Viksmoen, a member of the board, had entered into the underwriting agreement with a commitment of NOK 1.0 million of the rights issue and the corresponding underwriting fee has been settled in October 2018.

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 giving one vote at the Company's general meeting. The transaction was completed 24 October 2018 and resulted in net proceeds of NOK 1.2 million.

In addition 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 with a nominal value of NOK 3.00 and each 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 44 thousand.

Following completion of the rights issue of NOK 360 million and two capital increases following exercise of share options during 2018 the Company's share capital per 31 December 2018 is NOK 111,494,670 divided into 37,164,890 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

Profit and loss

(All amounts in brackets are comparative figures for 2017 unless otherwise specifically stated)

The Group did not record revenues in 2018 nor 2017. Grants received from various public sources such as the Research Council of Norway and "SkatteFUNN" were recorded as other operating income amounting to NOK 9.6 million (NOK 10.3 million). The parent company did not record any revenue for 2018 or 2017.

The fima *VACC* programme received in 2017 a grant of up to NOK 13.8 million from the Research Council of Norway (BIA-programme). The grant will be distributed over the course of three and a half years, 2017-2020, and for 2018 a total of NOK 3.9 million (NOK 1.9 million) has been recorded as other income. In 2017 a similar BIA-programme ended and a total of NOK 1.9 million was recorded.

Total operating expenses were NOK 54.1 million in 2018 (NOK 53.7 million). Expenditure on research activities is recognised as an expense in the period in which it was incurred. The Group had no development expenditure qualifying for recognition as an asset under IAS 38 in 2018 and as for previous years all research expenses are charged through the profit and loss statement. Research and development costs amounted to NOK 40.3 million in 2018 (NOK 41.0 million). Other operating (general and administrative) expenses were NOK 13.8 million (NOK 12.7 million). Operating result in 2018 were NOK -44.5 million (NOK -43.4 million) for the Group. Operating result for the parent company were NOK -4.7 million in 2018 (NOK -3.2 million), mainly driven by increased costs related to financing activities.

The total operating expenses are stable compared to 2017. The general and administrative costs are increased by around NOK 1 million compared to 2017, mainly driven by increased costs related financing activities.

Net financial results for the Group were NOK 9.7 million in 2018 (NOK 0.6 million). The increase is mainly driven by a net positive effect from cash deposits placed in Euro, as a hedge of the foreign currency risk for the RELEASE study to be initiated in first half of 2019. The parent company has in previous years partly written down its investment in, and intercompany loan to, the wholly owned subsidiary PCI Biotech AS, based on the observable fair value of the Group at Oslo Stock Exchange per year end. Applying the same valuation method per year end 2017 resulted in reversal of the previous year's write downs of NOK 33.9 million, disclosed as financial income in 2017 for the parent company.

The Board of Directors proposes that the comprehensive income of NOK 7.5 million for the parent company in 2018 is transferred to retained earnings.

Balance sheet

Total equity for the Group were NOK 340.0 million per year-end 2018 (NOK 41.8 million). Total equity of the parent company amounts to NOK 669.7 million in 2018 (NOK 329.3 million) and NOK 328.8 million of the increase in total equity compared to last year is a result of the net proceeds from the share issues completed during 2018.

Equity in the wholly owned subsidiary PCI Biotech AS was NOK 56.6 million at the end of 2018 (NOK 14.7 million). The equity in PCI Biotech AS were increased in 2018 by NOK 80 million, through a capital increase from the parent company PCI Biotech Holding ASA.



Total assets of the Group at the end of 2018 were NOK 357.1 million (NOK 58.4 million) and the increase from last year is mainly due to net proceeds from share issues partly offset by cash expenses on operational activities. Total assets in the parent company amounted to NOK 671.8 million per yearend 2018 (NOK 330.4 million) and the increase from last year is mainly due to proceeds from share issues.

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 2018 were NOK 89.5 million (NOK 77.7 million).

Cash flow

Net cash flow from operating activities amounted to NOK -31.1 million in 2018 (NOK -30.6 million) for the Group and for the parent company to NOK 5.2 million for 2018 (NOK -2.9 million). Net change in cash and cash equivalents for the Group was NOK 298.6 million in 2018 (NOK 36.8 million) impacted by net proceeds from share issues during 2018. Net change in cash and cash equivalents for the parent company were NOK 191.6 million in 2018 (NOK 0.2 million). Net proceeds from share issues in the parent company in 2018 are partly transferred to the operating company, PCI Biotech AS.

The Group's cash and cash equivalents at the end of 2018 amounted to NOK 349.3 million (NOK 50.8 million) and NOK 192.4 million for the parent (NOK 0.8 million). The Group employs a prudent cash management strategy for its cash and cash equivalents and assets are invested in low risk short-term money market instruments or held as bank deposits. All cash and cash equivalents were held as bank deposits at the end of 2018 and 2017.

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



PCI Biotech's lead programme, fima*CHEM*, 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 fima*CHEM*.

PCI Biotech has also performed a market opportunity assessment for the fima *VACC* technology platform, guiding management to understand the opportunity space based on the key attributes fima *VACC* may offer for peptide and protein based vaccines.

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

The 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.

<u>Currency risk</u> - 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 was converted into EURO as a hedge of the foreign exchange rate risk for the fima *CHEM* programme.

<u>Interest rate risk -</u> 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 invested in low risk short-term money market instruments or 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 financial flexibility in the short and long term 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 Board of Directors is reviewing available alternatives to secure 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

Participants in the Company's share option program have on 20 February 2019 exercised 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 are exercised by the primary insider Gaël L'Hévéder (CBDO), who has sold 5,300 shares in the market in order to finance the cash and tax impact of the share option exercise. After the transaction Mr. L'Hévéder hold 67,700 shares and 10,000 share options in the Company.

Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 are exercised by the primary insider Hans Olivecrona (CMO), who has sold all 30,000 shares in the market. After the transaction Mr. Olivecrona hold 0 shares and 60,000 share options in the Company.

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. Subsequent to the transaction, completed on 25 February 2019, the Company's share capital will be NOK 111,677,670 divided into 37,225,890 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The capital increase will result in gross proceeds of NOK 838 060.

28 February 2019 the Chief Business Development Officer (CBDO), Gaël L'Hévéder resigned and left PCI Biotech per end of March 2019 to pursue other career opportunities. The 10,000 share options Mr. L'Hévéder holds in the Company per 28 February 2019 are terminated due to his resignation.

The final confirmation of successful safety read-out after a formal review by the appointed Cohort Review Committee (CRC) was reported in April 2019. The formal review confirmed the Company's preliminary report that no adverse reactions have been reported that would limit the delivery of up to two fima*CHEM* treatments in the pivotal RELEASE study with registration intent. The Phase I Extension study is completed and recruitment will be formally closed.

PCI Biotech is not aware of any other subsequent events since year-end 2018 which is of material significance to the financial statements as of 31 December 2018.



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 of playing a significant role in the realisation of several new therapeutic modalities, including immunotherapy (fima VACC) and nucleic acid therapeutics (fima NAC).

Although the company's focus is three-pronged, divided over the three programmes, most resources are currently spent on progressing the lead project of fima*CHEM*, which is the clinical development programme 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 the key regulators in Europe and the U.S. receiving important guidance which informs the design for a pivotal phase study. The final pivotal study design has thus been determined and funding expected to finance the study beyond interim read-out is now in place. During this next step, the company will maintain its full commitment of advancing the programme with the ambition of helping the patients currently left without effective treatment options achieve a good quality of life.

In parallel, the two other programmes, fima VACC and fima NAC, are proceeding in accordance with the established development strategy. The clinical validation of the fima VACC technology is essential for PCI Biotech's role within the immunotherapy space and the Phase I study in healthy volunteers will provide results on clinical translation of the technology into humans. The initial results are encouraging, and the study is expected to provide key data to support decisions of the programme's further development strategy. The fima NAC 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 fima *CHEM* development programme in inoperable extrahepatic bile duct cancer towards the market;
- Complete the clinical translation of the fima VACC technology and determine the further development strategy
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform.

Oslo, 9 April 2019 Board of Directors and Chief Executive Officer, PCI Biotech Holding ASA

Hans Peter Bøhn Chairman

Christina Herder

Director

Lars Viksmoen Director

Hilde H. Stees Hilde H. Steineger

Director

Andrew Hughes Director

Per Walday CEO

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RESPONSIBILITY STATEMENT FROM THE BOARD OF DIRECTORS AND CEO 2018

We confirm that the financial statements for the period 1 January to 31 December 2018, 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, 9 April 2019 Board of Directors and Chief Executive Officer, PCI Biotech Holding ASA

Hans Peter Bøhn Chairman

Christina Herder

Director

Lars Viksmoen

Lars Viksmoer Director

Hilde H. Stee Hilde H. Steineger 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 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. The 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.

Guidelines on corporate governance can be found in the Company's annual report and website. 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 13 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 areas and staff are regularly updated within their fields.

The group is concerned with animal welfare, human rights, labour rights and social issues. 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.

The Group has not identified any material issues based on the corporate social responsibility procedures performed in 2018. 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.

2.3. Ethical guidelines

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

3. Equity and dividends

PCI Biotech's equity as of 31 December 2018 was NOK 340.0 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 2018.

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 2018 to

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increase the share capital by share issue of up to 1,865,000 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 2018.

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 2018 and 2017. The PCI technology originates from the Norwegian Radium Hospital and the Norwegian Radium Hospital Research Foundation owns 3.56% of PCI Biotech at year end 2018. 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 2018 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 valuated independently by a third party. No such transactions exist for 2018. 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 negotiability

The shares in PCI Biotech are freely negotiable with no form of restriction. No restrictions regarding voting, ownership or negotiability 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 always 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 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 two members: Jónas Einarsson (chairperson) and Erik Must. The current members have been elected by the general meeting with a term until the Company's ordinary general meeting in 2019. 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,

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responsibilities and functions of the Board of Directors and the CEO are in compliance with rules and standards applicable of 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 fourteen meetings in 2018. Board members had the following attendance at these meetings:

Hans Peter Bøhn, 14/14 Kjetil Taskén, 5/5 Christina Herder 14/14 Lars Viksmoen, 13/14 Hilde H. Steineger, 11/14 Andrew Hughes 9/9

Kjetil Taskén ended his term as member of the Board of Directors in May 2018. Andrew Hughes was elected as new member at the Annual General Meeting in May 2018.

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 insider regulations relating to the handling of inside 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.

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

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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 2018

(1.1 - 31.12)

Ра	arent			Gro	oup
2017	2018	(figures in NOK 1,000)	Note	2018	2017
0	0	Other income	5,6	9 585	10 250
0	0	Total income		9 585	10 250
0	0	Research and development	7	40 337	40 988
3 182	4 711	General and administrative	7,8	13 767	12 693
3 182	4 711	Total operating expenses	7,8,9,10,23	54 104	53 681
-3 182	-4 711	Operating results		-44 519	-43 431
37 333	12 278	Financial income	11	9 890	677
0	117	Financial expenses	11	151	87
37 333	12 161	Net financial results		9 739	590
34 151	7 450	Profit/Loss before income tax		-34 780	-42 841
0	0	Income tax	12	0	0
34 151	7 450	Net profit/loss for the year		-34 780	-42 841
		Other comprehensive income, net of income tax			
0	0	Items that will not be reclassified to income statement		0	0
0	0	Items that subsequently may be reclassified to income statement		0	0
34 151	7 450	Total comprehensive income for the year		-34 780	-42 841
		Loss per share basic and diluted (figures in NOK)	13	-1.25	-1.76



BALANCE SHEET for the year ended 31 December 2018

Parent				Group		
2017	2018	ASSETS (figures in NOK 1,000)	Note	2018	2017	
		Non-current assets				
0	0	Property, plant and equipment	14	17	22	
302 236	386 294	Shares in subsidiaries	15	-	-	
302 236	386 294	Total non-current assets		17	22	
		Current assets				
27 345	92 840	Receivables from group companies		-	-	
43	252	Other short term receivables	18	7 713	7 625	
27 388	93 092	Total receivables	17	7 713	7 625	
759	192 373	Cash and cash equivalents	17, 19	349 326	50 789	
28 147	285 465	Total current assets		357 039	58 414	
330 383	671 760	Total assets		357 056	58 436	



BALANCE SHEET for the year ended 31 December 2018

Parent				Group		
2017	2018	EQUITY AND LIABILITIES (figures in NOK 1.000)	Note	2018	2017	
		Equity				
74 961 67 833 5 853	111 494 360 133 9 912	Share capital Share premium Other paid-in capital	20	111 494 449 448 0	74 961 157 148 0	
180 673	188 124	Retained earnings		-220 988	-190 266	
329 320	669 663	Total equity	8,23	339 954	41 842	
0	0	Liabilities Non-current liabilities Other long term liabilities	16	107	2 009	
0	0	Total non-current liabilities Current liabilities		107	2 009	
97	1 196	Trade accounts payable		1 889	1 497	
104	110	Public duties payable		1 980	1 793	
861	790	Other current liabilities	22	13 126	11 295	
1 063	2 096	Total current liabilities	16,21	16 995	14 585	
1 063	2 096	Total liabilities	17	17 102	16 594	
330 383	671 760	Total equity and liabilities		357 056	58 436	

Oslo, 9 April 2019 Board of Directors and Chief executive Officer, PCI Biotech Holding ASA

Hans Peter Bøhn Chairman

Andrew Hughes Director

Christina Herder Director

Lars Viksmoen Director

Hilde H. Stees Hilde H. Steineger Director

Per Walday

CEO

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CONSOLIDATED STATEMENT OF CHANGES IN EQUITY for the year ended 31 December 2018

(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 2017	20	44 701	120 678	0	-152 293	13 086
Loss for the period		-	-	-	-42 841	-42 841
Other comprehensive income,						
net of tax		-	-	-	-	-
Total comprehensive income for the period		_	_	_	-42 841	-42 841
Capital increase		30 260	41 462		-42 041	71 721
Capital increase expenses			-4 992	-	-	4 992
Share-based payments		-	-	4 867	-	4 867
Allocation				-4 867	4 867	0
Equity at 31 December 2017	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



STATEMENT OF CHANGES IN EQUITY – PARENT for the year ended 31 December 2018

(figures in NOK 1,000)	Note	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
Equity at 1 January 2017	20	44 701	31 363	986	146 523	223 573
Loss for the period		-	-	-	34 151	34 151
Other comprehensive income,						
net of tax		-	-	-	-	-
Total comprehensive income for						
the period		-	-	-	34 151	34 151
Share-based payments in						
subsidiary		-	-	4 867	-	4 867
Capital increase		30 260	41 462	-	-	71 721
Capital increase expenses		-	-4 992	-	-	-4 992
Equity at 31 December 2017	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
Share-based payments in					1 100	
subsidiary		-	-	4 059	-	4 059
Capital increase		36 534	324 686	-	-	361 220
Capital increase expenses		-	-32 387	-	-	-32 387
Equity at 31 December 2018	20	111 494	360 133	9 912	188 124	669 663



CASH FLOW STATEMENT for the year ended 31 December 2018

	Parent	(figures in NOK 1,000)	Group		o
2017	2018		Note	2018	2017
34 151	7 450	Profit/Loss before income tax		-34 780	-42 841
-	-	Depreciation and amortisation	7,14	5	6
-33 868	-	Write downs / reversal of write downs	11	0	0
-	-	Share-based payments	8	4 059	4 867
-3 464	-3 054	Interest income	11	-782	-677
300	-209	Changes in accounts receivable		-87	766
-34	1 099	Changes in accounts payable		392	-584
42	-65	Changes in other net operating assets and liabilities		115	7 843
-2 874	5 221	Cash flow from operating activities		-31 079	-30 620
-30 607 3 464 -40 000 3 464	-73 163 7 669 -80 000 3 054	Proceeds from intragroup interest bearing loan Repayment from intragroup interest bearing loan Investment in subsidiary Interest income received	15 11	- - 782	- - 677
-63 679	-142 440			782 782	677
		Net cash flow from investing activities		-	-
71 721	361 220	Proceeds from issue of new equity	20	361 220	71 721
-4 992	-32 387	Expenses in relation to issue of new equity		-32 387	-4 992
66 730	328 834	Net cash flow from financing activities		328 834	66 730
176	191 615	Net changes in cash and cash equivalents		298 537	36 787
583 759	759 192 373	Cash and cash equivalents at 1 January Cash and cash equivalents at 31 December	19	50 789 349 326	14 002 50 789



PCI BIOTECH HOLDING ASA – ACCOUNTING PRINCIPLES 2018

1. Corporate information

The annual accounts for 2018 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 9th April 2019.

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 2018.

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, the fully owned subsidiary PCI Biotech AS and the dormant Icelandic branch PCI Biotech Utibu are presented as a single economic entity. The subsidiary and the branch are 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/noncurrent 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) <u>Taxes</u>

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) <u>Cash dividend distribution to equity holders of the parent</u>

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 writedowns. 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 5 years
- Furniture and equipment 3-5 years

g) <u>Leases</u>

The determination of whether an arrangement is (or contains) a lease is based on the substance of the arrangement at the inception of the lease. The arrangement is, or contains, a lease if fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset or assets, even if that right is not explicitly specified in an arrangement.

Group as a lessee

A lease is classified at the inception date as a finance lease or an operating lease.

Operating lease payments are recognised as an operating expense in the statement of profit or loss on a straight-line basis over the lease term.

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

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- 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) <u>Financial instruments</u>

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 shortterm deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value. For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined above, net of outstanding bank overdrafts as they are considered an integral part of the Group's cash management.

I) <u>Provisions</u>

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) <u>Share-based payments</u>

Employees (including senior management) of the Group receive remuneration in the form of sharebased payments, whereby employees render services as consideration for equity instruments (equitysettled 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 had 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. See Note 6 for further information.

q) <u>Cash-flow statement</u>

The cash flow statement has been prepared in accordance with the indirect method. Cash and cash equivalents consists of cash, bank deposits and other current investments like money market funds.

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.

t) Changes in disclosures

In 2017 the Group reviewed the internal allocation of operating expenses for disclosure of the sub categories in the statement of comprehensive income; research and development expenses versus general and administrative expenses. The review is made based on the current operational set-up of the organisation which has changed and developed over the years, from an early stage clinical company towards a pivotal stage ready company. The outcome of the review has led to reallocation of expenses between the two relevant P&L sub categories with no net change in the disclosed total operating expenses. In the statement of comprehensive income 2017 and 2018 for the Group the new allocation routines are applied prospectively, as this reflects the underlying operations. The review has no disclosure effect regarding the separate financial reporting for the parent company.

Accounting policies only relevant for the Parent:

u) 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 9 Financial Instruments for the first time in 2018 and the new standard have no significant impacts on the Group's financial position, performance and/or disclosure. Several other standards, amendments and interpretations apply for the first time in 2018, but do not have an impact on the consolidated financial statements of the Group. The Group is in the research and development phase and the new IFRS 15 Revenue from Contracts with Customers effective from 1 January 2018 have no effect on the financial statements at current stage of operations.

IFRS 9 Financial Instruments

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement for annual periods beginning on or after 1 January 2018, bringing together all three aspects of the accounting for financial instruments: classification and measurement; impairment; and hedge accounting. IFRS 9 does not change an entity's cash flows, cash or cash equivalents, it may affect the balance sheet presentation and, indirectly, may have an impact on the presentation of the statement of cash flows as well.

The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

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. 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 will 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 15 for further information.

4. Standards issued, but not yet effective

The 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 standards, if applicable, when they become effective. Only standards and interpretations that are expected to may have an impact on the Group's financial position, performance, and/or disclosures are included.

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 will be required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

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

The Group will elect 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.

During 2018, the Group has performed an impact assessment of IFRS 16. The Group has leases of a printing machine that is considered of low value. The Group will apply the exemptions for lease contracts of which the underlying asset is of low value for this lease agreement. The impact of IFRS 16 adoption is expected to be relevant for renting of offices and the financial impact to the balance sheet is estimated to be a lease asset of NOK 1.3 million and a corresponding lease liability at initial application 1 January 2019, applying the modified retrospective method. The amount is based upon contractual minimum lease payments for 2019-2021 and discounted by the incremental borrowing rate

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at the date of initial application. The Group's operating profit is expected to improve, while its interest expense will increase, without any expected significant effect on the net total comprehensive income for 2019.

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5 OTHER INCOME

(figures in NOK 1,000)	Group	
	2018	2017
Grants from the Research Council of Norway	3 890	3 755
Tax incentive scheme - SkatteFUNN	5 695	5 717
Other grants	0	778
Total other income	9 585	10 250

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. For the period May 2014 through June 2017, the Group was awarded a grant from The Research Council of Norway (user-driven research-based innovation programme (BIA)) of up to NOK 12.5 million in total. For the period June 2017 through December 2020, the Group has been awarded another BIA grant of up to NOK 13.8 million in total. For the full year ended 31 December 2018, the Company has recognised NOK 3.9 million (2017: NOK 3.8 million) from BIA grants as other income. A grant of NOK 0.4 million was awarded in 2017 from Innovation Norway for the preclinical research collaboration with Ultimovacs AS. Grant receivables as of 31 December 2018 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.		Grou	ıp	Par	ent
(figures in NOK 1,000)	Note	2018	2017	2018	2017
Salary expenses*	8	20 509	23 946	1 240	1 165
R&D exclusive salary and other operating expenses		25 662	23 022	0	0
Depreciation and amortisation	14	5	6	0	0
Other operating expenses		7 928	6 706	3 471	2 017
Total operating expenses		54 104	53 681	4 711	3 182
Specification of other operating expenses		2018	2017	2018	2017
Travel expenses		1 086	789	48	29
Patent, legal and other fees		3 654	3 404	2 375	1 218
Other expenses		3 188	2 514	1 048	770
Total other operating expenses		7 928	6 706	3 471	2 017

*Please see Note 8 for breakdown of salary expenses



R&D expenses by category:	2018	2017
Clinical studies	27 499	23 886
Pre-clinical studies	5 943	12 539
CMC and equipment	3 846	1 770
Patents	3 049	2 793
Other expenses	0	0
Total R&D expenses	40 337	40 988

Of the total salary expenses NOK 14 356 relates to R&D activities (2017: NOK 17 040).

The Group has no development expenditure that qualifies for recognition of an asset under IAS 38. Per year end 2018 there is stock of the product under development (fimaporfin) at a cost value of NOK 0.4 million not recognised in the balance sheet (2017: NOK 0.4 million). Intangible assets and all research expenditures are charged through the income statement, in line with previous years.

In 2017 the Group has reviewed the internal allocation of operating expenses for disclosure of the sub categories in the statement of comprehensive income; research and development expenses versus general and administrative expenses. The review is made based on the current operational set-up of the organisation which has changed and developed over the years, from an early stage clinical company towards a pivotal stage ready company. The outcome of the review has led to reallocation of expenses between the two relevant P&L sub categories with no net change in the disclosed total operating expenses. In the statement of comprehensive income 2017 and 2018 for the Group the new allocation routines are applied prospectively, as this reflects the underlying operations. The review has no disclosure effect regarding the separate financial reporting for the parent company.

8 SALARY EXPENSES AND OTHER REMUNERATION

(figures in NOK 1,000)		Group		Par	rent
		2018	2017	2018	2017
Wages and Board of Directors remuneration	า	14 568	13 731	1 080	1 022
Social security contributions		2 186	1 901	159	143
Share-based payments		2 166	7 245	0	0
Pension costs	9	1 326	943	0	0
Other expenses		263	127	1	0
Total salary expenses		20 509	23 946	1 240	1 165
No. of full-time equivalent positions		11,0	11,5	0	0

Share based payments

Employees (including senior management) of the Group receive remuneration in the form of sharebased payments, whereby employees render services as consideration for equity instruments (equitysettled 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.



The general meeting held 29 May 2018 authorised the Board of Directors to grant the employees with a total of 1,865,000 share options and the authorisation applies for one year. A total of 556,500 share options are outstanding at year-end 2018 (2017: 738,500).

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 transactions did not lead to share based payment expenses.

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.

In January 2017 a share issue was completed and the strike price for outstanding share options were adjusted in accordance with the employee incentive program agreement. The fair value assessments were adjusted accordingly, leading to a total increase of share based payment expenses of NOK 0.4 million charged through the P&L in 2017.

In May 2017 a total of 340,000 share options were awarded in the employee incentive program, at a strike price of NOK 24.95 and the share options laps in Q3 2022.

In September 2017 a total of 86,500 share options granted in 2012 were exercised with a strike price of NOK 19.90. The transaction did not lead to share based payment expenses.

In October 2017 90,000 share options were awarded in the employee incentive program, at a strike price of NOK 22.35 and the share options laps in Q3 2022.

The P&L effect for share-based payments for 2018 were a net cost of NOK 4.1 million (2017: NOK 4.9 million) in addition to NOK -1.9 million (2017: NOK 2.3 million) for a potential social security liability for future exercises. The potential social security liability for future exercises are calculated based upon share options that are in-the-money per reporting date.

For the parent company, PCI Biotech Holding ASA, the Group's net cost of NOK 4.1 million is recognised as an investment in subsidiary.

The Board of Directors have not been granted any share options. See note 23 Related party transactions for further information.



Expiry date	Exercise price in NOK per share	Number of share	es
		2018	2017
2018 - Q3	10.55	0	85 000
2019 - Q3	8.63	40 000	40 000
2020 - Q3	7.84	41 000	73 500
2020 - Q3	3.26	45 500	110 000
2022 – Q3	21.48	340 000	340 000
2022 – Q3	19.24	90 000	90 000
Sum		556 500	738 500

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

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

	2018		2017	
	Number	Average exercise price in NOK per share	Number	Average exercise price in NOK per share
Outstanding at the beginning of the year	738 500	17.44	395 000	14.30
Granted during the year	0	0	430 000	24.41
Lapsed during the year	4 000	7.12	0	0
Exercised during the year	178 000	6.86	86 500	10.55
Expired during the year	0	0	0	0
Outstanding at year end	556 500	17.70	738 500	17.44
Exercisable options at year end	269 833	14.18	247 333	6.71

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

Number of options 2018 / 2017	Exercise price in NOK per share	Average remaini (years)	
		2018	2017
0 / 85 000	9.08	0	0.7
40 000 / 40 000*	8.63	0.7	0.7
41 000 / 73 500	7.84	1.7	2.7
45 500 / 110 000	3.26	1.7	2.7
340 000 / 340 000	21.48	3.7	4.7
90 000 / 90 000	19.24	3.7	4.7

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

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.



No share options were granted in 2018. Fair value for share options granted in 2017 were NOK 9.5 million. The fair value estimated at grant date is amortised over the vesting period of three years.

Options granted in 2017	May 2017	October 2017
Number of options	340 000	90 000
Dividend	0,00	0,00
Historical volatility (%)	131.9 %	120.1 %
Risk free interest rate (%)	1.10 %	1.10 %
Expected lifetime (years)	5	5

9 PENSION EXPENSES

Pensions expenses for the year:	Group	
(figures in NOK 1,000)	2018	2017
Total pension cost from contribution schemes	1,326	943

The contribution pension scheme is in compliance with Norwegian public requirements and a total of eleven employees (2017: ten employees) are included in the scheme at year end.

10 AUDITORS FEE

	Group		Parent		
(figures in NOK 1,000 ex. VAT)	2018	2017	2018	2017	
Statutory audit	157	159	100	75	
Other assurance services	100	52	53	26	
Tax and VAT advising services	0	0	0	0	
Total	257	212	153	101	

11 FINANCIAL INCOME AND EXPENSES

(figures in NOK 1,000)	Grou	Group Par		rent	
	2018	2017	2018	2017	
Interest income	740	677	13	10	
Interest income group	-	-	3 157	3 454	
Other financial income	9 150	0	9 108	33 869	
Total financial income	9 890	677	12 278	37 333	
Interest expense	117	0	117	0	
Other financial expense	34	87	0	0	
Total financial expense	151	87	117	0	

For 2017 the other financial income of NOK 33.9 million in Parent is reversal of previous year's writedowns related to the wholly owned subsidiary PCI Biotech AS. The annual impairment assessment is based on the observable market value of the Group at Oslo Stock Exchange per year end. For 2018 the other financial income of NOK 9.1 million in Parent and Group is related to gain on cash deposits in Euro per 31.12.2018.



12 TAX

(figures in NOK 1,000)	Group		Parent	
	2018	2017	2018	2017
Profit/Loss before income tax	-34 780	-42 841	7 450	34 151
Expected nominal rate of tax (2018: 23% / 2017: 24%)	-7 999	-10 282	1 788	8 196
Permanent differences charged through P&L	-379	-207	0	-8 128
Deferred tax asset not recognised in the balance sheet	8 379	10 489	-1 788	-68
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			ent	
	2018	2017	2018	2017	
Fixed assets	-7	-8	0	0	
Receivables	0	0	0	0	
Carry forward loss	-89 445	-77 682	-11 311	-6 111	
Total tax asset (2018: 22% / 2017: 23%)	-89 452	-77 690	-11 311	-6 111	
Deferred tax asset not recognised	89 452	77 690	11 311	6 111	
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 has not been recognised in the balance sheet. Deferred tax asset not recognised in the balance sheet amounts to NOK 89.5 million (2017: NOK 77.7 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 over the year (weighted average number of outstanding shares over 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	2018	2017
Weighted average number of shares (in '000)	27 797	24 348
Dilution effect (in '000)	556	478
Weighted average number of shares fully diluted (in '000)	28 353	24 826
Net loss for the year	-34 780	-42 841
Earnings per share (NOK per share)	-1.25	-1.76
Diluted earnings per share (NOK per share)	-1.25	-1.76



14 FIXED AND INTANGIBLE ASSETS

(figures in NOK 1,000)		Group	
	Software	Equipment	Total
Acquisition cost per 31 December 2016	168	314	482
Additions in 2017	0	23	23
Disposals and scrapping during 2017	0	0	0
Acquisition cost per 31 December 2017	168	337	505
Additions in 2018	0	0	0
Disposals and scrapping during 2018	0	0	0
Acquisition cost per 31 December 2018	168	337	505
Accumulated depreciation per 31 December 2016	168	309	477
Ordinary depreciation 2017	0	6	6
Disposals in 2017	0	0	0
Accumulated depreciation per 31 December 2017	168	315	483
Ordinary depreciation 2018	0	5	5
Disposals in 2018	0	0	0
Accumulated depreciation per 31 December 2018	168	320	488
Book value per 31 December 2017	0	22	22
Book value per 31 December 2018	0	17	17

	Gi	roup
Leasing expenses	2018	2017
Leasing office premises	627	637
Total leasing expenses	627	637

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, Norway from 1 January 2016. The lease runs to 31 December 2018, with an option for extension for three more years. The lease is NOK 0.6 million per annum. The lease agreement is subject to annual adjustment according to changes in the consumer price index from 2017. In 2018 PCI Biotech exercised the option for three more years. Amounts of minimum lease payment for non-cancellable operating leases is NOK 1.5 million (non-discounted contractual payments) per year end 2018 for the next three years.

15 SHARES IN SUBSIDIARIES

Company	Year of acquisition	Share capital of company	Equity participation and share of voting rights	Carrying amount (NOK thousand)	Equity (NOK thousand)	Financial result 2018 (NOK thousand)
PCI Biotech AS, Oslo, Norway	2008	4 848 900	100 %	386 294	56 566	-42 231

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.

In 2017 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 39 676 740, totalling to NOK 40 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 40 million by PCI Biotech Holding ASA.



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 2018 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 2018 the Group has placed cash deposits in EURO to hedge the foreign currency risk for the fima *CHEM* 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 2018.

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

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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 2017 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 2018 or 2017. 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 2018 and 2017.

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
31.12.2018					
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
31.12.2017					
Other long term liabilities	0	0	0	2 009	2 009
Trade accounts payables	1 497	0	0	0	1 497
Public duties payables	797	0	996	0	1 793
Other current liabilities	484	5 427	5 384	0	11 295

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
31.12.2018					
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
31.12.2017					
Trade accounts payables	97	0	0	0	97
Public duties payables	0	0	104	0	104
Other current liabilities	0	121	740	0	861



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.

PCI Biotech strives as far as possible to achieve the lowest possible net currency exposure. The Group's expenses and revenues 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 effect on operating result is due to changes in the value of monetary items.

	Changes in exchange rates	Effect on operating result		
		Parent	Group	
2018	+/- 10 %	+/- 19 047	+/- 20 557	
2017	+/- 10 %	0	+/- 2181	



17 CLASSIFICATION OF FINANCIAL ASSETS AND LIABILITIES

		Group	
31.12.2018		Financial	
	Financial	instruments at fair value	
	instruments at	through	
	amortised cost	OCI	Total
Assets – debt instruments			
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 financial 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	16 995	0	16 995
31.12.2017	1	Other	
	Loans and receivables	financials liabilities	Total
Assets		nabilities	Total
Other current receivables	7 625	0	7 625
Cash and cash equivalents	50 789	0	50 789
TOTAL FINANCIAL ASSETS	58 414	0	58 414
Liabilities			
Other long term liabilities	0	2 009	2 009
Trade accounts payables	0	1 497	1 497
Public duties payables	0	1 793	1 793
Other current liabilities	0	11 295	11 295
TOTAL FINANCIAL LIABILITIES	0	16 594	16 594



		Parent	
31.12.2018		Financial	
	Financial	instruments	
	instruments at	at fair value through	
	amortised cost	OCI	Total
Assets			
Group receivables	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			
	1 196	0	1 196
Trade accounts payables		•	1190
Public duties payables	110	0	-
Other current liabilities	790	0	790
TOTAL FINANCIAL LIABILITIES	2 096	0	2 096
31.12.2017		Other	
51.12.2017	Loans and	financials	
	receivables	liabilities	Total
Assets			
Group receivables	27 345	0	27 345
Other current receivables	43	0	43
Cash and cash equivalents	759	0	759
TOTAL FINANCIAL ASSETS	28 147	0	28 147
Liabilities	-		6-
Trade accounts payables	0	97	97
Public duties payables	0	104	104
Other current liabilities	0	861	861
TOTAL FINANCIAL LIABILITIES	0	1 063	1 063



18 RECEIVABLES BY YEAR END

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 loss allowance are recognised at year end 2018 or 2017.

Other current receivables - specification	Group		Pare	ent
(Figures in NOK 1,000)	2018	2017	2018	2017
Recognised not received government grants	7 012	6 850	0	0
Prepaid payables	317	455	0	18
VAT receivables	384	320	252	25
Total other receivables	7 713	7 625	252	43

19 CASH AND CASH EQUIVALENTS BY YEAR END

	Group		Parer	nt
(Figures in NOK 1,000)	2018	2017	2018	2017
Cash and cash equivalents, restricted ⁽¹⁾	698	592	0	0
Cash and cash equivalents, non-restricted	348 628	50 197	192 373	759
Sum	349 326	50 789	192 373	759

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

At year end 2018 and 2017 the cash and cash equivalents for the Group and the parent company are all deposits in regular bank accounts in NOK and EUR. At year-end 2017 the Group also had a deposit in GBP.

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 different banks with satisfactory credit ratings. The credit risk for these funds is assessed to be low and no impairment test are performed for 2018 and 2017.

20 SHARE CAPITAL

The registered share capital in the parent company PCI Biotech Holding ASA:

	No. of shares	Nominal value per share in NOK	Share capital in NOK
Share capital as per 31.12.2016	14 900 390	3.00	44 701 170
Share issues in 2017	10 086 500	3.00	30 259 500
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

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 held 29 May 2018 authorised the Board of Directors to execute share capital increases by issuing up to 1,865,000 shares with a nominal value of NOK 3.00 in connection with the company's employee incentive program. The authorisation is valid for one year.

The Annual General Meeting held 29 May 2018 authorised the Board of Directors to execute share capital increases with up to NOK 8,029,600 in connection with private placements. The authorisation shall not be used to increase the share capital by an amount in excess of 10% of the share capital, based on the share capital per 29 May 2018 and potential share capital increases in relation to the employee incentive programme. The authorisation may be used for general corporate purposes. The authorisation is valid for one year.

Share issues in 2017

A fully underwritten rights issue of NOK 70 million was completed 19 January 2017. 10,000,000 new shares were issued in the rights issue, with pre-emptive subscription rights for existing shareholder, increasing the share capital of the company with NOK 30,000,000. Through the rights issue, PCI Biotech Holding ASA received gross proceeds in the amount of NOK 70 million and net proceeds of NOK 65.0 million.

The rights issue was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received an underwriting fee equal to 2.0 per cent of their respective underwriting obligations. Hans Peter Bøhn, Chairman of the Board of PCI Biotech Holding ASA, and Lars Viksmoen, member of the Board of PCI Biotech Holding ASA, had both entered into the underwriting agreement and had each separately underwritten NOK 1.0 million of the rights issue. The corresponding underwriting fees were settled in 2017. Net proceeds from the rights issue was NOK 65.0 million.

In addition, a rights issue of 86,500 new shares (nominal value per share NOK 3.00), following the exercise of employee share options was finalised in September 2017.

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 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.

Subsequent to the three capital increase transactions in 2018 the Company's share capital is NOK 111,494,670 divided into 37,164,890 shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting.

Ownership structure per 31 December 2018:

	Number of shares	Ownership in %
FONDSAVANSE AS	3 760 443	10.12
MP PENSJON PK	2 726 305	7.34
MYRLID AS	2 415 000	6.50
RADIUMHOSPITALETS FORSKNINGSSTIFT.	1 321 415	3.56
NORDNET LIVSFORSIKRING AS	739 314	1.99
ODD R. GRESSLIEN	620 850	1.67
ABN AMRO Global Custody Services N	586 537	1.58
NORDNET BANK AB	565 669	1.52
JANDERSEN KAPITAL AS	535 000	1.44
BERG-LARSEN	494 697	1.33
VESLIK AS	419 690	1.13
SYVERTSEN	330 261	0.89
LGJ INVEST AS	324 288	0.87
OLAV OLSEN HOLDING AS	300 000	0.81
NETFONDS LIV	285 312	0.77
MYNA AS	270 000	0.73
ARNULF ELVEVOLD	269 000	0.72
FORENEDE FORVALTNING AS	268 166	0.72
DANSKE BANK A/S	260 535	0.70
KJETIL MYRLID AASEN	260 000	0.70
Total 20 largest shareholders	16 752 482	45.08
Total other shareholders	20 412 408	54.92
Total number of shares	37 164 890	100.00



Shares owned, directly or indirectly, by members of the board and executive management, and their personally related parties per 31.12.2018 and per 31.12.2017:

		No. of	shares
Name	Position	2018	2017
Hans Peter Bøhn	Chairman	123 662	83 556
Lars Viksmoen (via Stocken Invest AS)	Director	12 966	4 000
Christina Herder	Director	10 000	8 355
Hilde H. Steineger	Director	0	0
Andrew Hughes*	Director	0	NA
Kjetil Tasken (via Kjetil Tasken AS)**	Director	NA	4 000
Per Walday	CEO	68 300	65 133
Anders Høgset	CSO	63 300	62 456
Gaël L'Hévéder	CBDO	62 000	10 000
Ronny Skuggedal	CFO	28 300	25 066
Kristin Eivindvik	CDO	18 800	17 948
Hans Olivecrona	CMO	0	0
Total number of shares		387 328	280 514

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

** Kjetil Taskén, board member, ended his term at the annual general meeting in May 2018 and holdings are reported up 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 and are part of their shareholding portfolio after completion of the rights issue 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, 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 31.12.2018 or 31.12.2017.

22 OTHER CURRENT LIABILITIES BY YEAR END

(Figures in NOK 1,000)	Group		Parent		
	2018	2017	2018	2017	
Accruals for incurred external R&D expenses	9 519	7 870	0	0	
Accruals for various remuneration items	3 597	3 305	780	740	
Other accruals	10	120	10	121	
Total other current liabilities	13 126	11 295	790	861	

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 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 under "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.

	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Board of Directors 2018						
Hans Peter Bøhn, Chairman	300	0	0	0	0	300
Kjetil Tasken*	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

*ended his term in May 2018

**joined the Board of Direcors in May 2018



	Board					
Senior executives 2017	remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Per Walday, CEO*	0	1 600	330	88	119	2 137
Ronny Skuggedal, CFO	0	1 145	165	21	109	1 440
Anders Høgset, CSO*	0	1 010	135	70	100	1 315
Gaël L'Hévéder, CBDO	0	1 472	115	4	100	1 691
Kristin Eivindvik, PD*	0	986	75	65	104	1 230
Hans Olivecrona, CMO**	0	237	0	1	0	238
Total remuneration	0	6 449	820	250	531	8 051

(Figures in NOK 1,000)

* Other benefits include salary benefits in relation to exercise of share options in 2017

**Joined the company in October 2017

Board of Directors 2017	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Hans Peter Bøhn, Chairman	275	0	0	0	0	275
Kjetil Tasken	171	0	0	0	0	171
Hilde H. Steineger	171	0	0	0	0	171
Christina Herder	171	0	0	0	0	171
Lars Viksmoen	171	0	0	0	0	171
Total remuneration	959	0	0	0	0	959

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 2018 are presented in the table below:

Senior executives	Total holdings 31.12.2017	Allocated	Lapsed	Exercised	Expired	Total holdings 31.12.2018	Average exercise price in NOK
Per Walday, CEO	104 000	0	0	0	0	104 000	19.90
Ronny Skuggedal, CFO	116 000	0	0	0	0	116 000	13.75
Anders Høgset, CSO	66 000	0	0	0	0	66 000	19.82
Kristin Eivindvik, CDO	33 500	0	0	0	0	33 500	14.96
Gaël L'Hévéder, CBDO	106 000	0	0	85 000	0	21 000	16.27
Hans Olivecrona, CMO	90 000	0	0	0	0	90 000	19.24
Sum	515 500	0	0	85 000	0	430 500	

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 1.8 million on commercial terms to RF in 2018 (2017: NOK 2.6 million). As of 31.12.2018 the Group had account payables of NOK 0.3 million to RF (2017: NOK 0.9 million).

Rights Issues in the Company

In relation to the rights issue of NOK 70 million finalised in January 2017 several shareholders contributed to the underwriting syndicate and received a guarantee fee of 2.0% for their respective commitment.

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 2.2 million in 2018 (2017: NOK 1.0 million). The parent company has charged PCI Biotech AS interest expenses for intercompany loans of NOK 3.2 million during 2018 (2017: NOK 3.5 million). Net current receivables from PCI Biotech AS at year-end 2018 were NOK 92.3 million (2017: NOK 28.7 million). In 2017 an intercompany loan to PCI Biotech AS of NOK 40 million was utilised as contribution in kind from PCI Biotech Holding ASA in a capital increase in PCI Biotech AS.

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 is settled in 2018.

In relation to the rights issue in the Company finalised in January 2017 the Chairman Hans Peter Bøhn and the Director Lars Viksmoen contributed to the underwriting syndicate and underwrote separately NOK 1 million of the rights issue with a guarantee fee of 2.0%. The corresponding underwriting fees were settled in 2017.

24 SUBSEQUENT EVENTS

Participants in the Company's share option program have on 20 February 2019 exercised 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 are exercised by the primary insider Gaël L'Hévéder (CBDO), who has sold 5,300 shares in the market in order to finance the cash and tax impact of the share option exercise. After the transaction Mr. L'Hévéder hold 67,700 shares and 10,000 share options in the Company.

Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 are exercised by the primary insider Hans Olivecrona (CMO), who has sold all 30,000 shares in the market. After the transaction Mr. Olivecrona hold 0 shares and 60,000 share options in the Company.

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. Subsequent to the transaction, completed on 25 February 2019, the Company's share capital will be NOK 111,677,670 divided into 37,225,890 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The capital increase will result in gross proceeds of NOK 838 060.

28 February 2019 the Chief Business Development Officer (CBDO), Gaël L'Hévéder resigned and left PCI Biotech per end of March 2019 to pursue other career opportunities. The 10,000 share options Mr. L'Hévéder holds in the Company per 28 February 2019 are terminated due to his resignation.

The final confirmation of successful safety read-out after a formal review by the appointed Cohort Review Committee (CRC) was reported in April 2019. The formal review confirmed the Company's preliminary report that no adverse reactions have been reported that would limit the delivery of up to two fima*CHEM* treatments in the pivotal RELEASE study with registration intent. The Phase I Extension study is completed and recruitment will be formally closed.



PCI Biotech is not aware of any other subsequent events since year-end 2018 which is of material significance to the financial statements as of 31 December 2018.



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INDEPENDENT AUDITOR'S REPORT

To the Annual Shareholders' Meeting of PCI Biotech Holding ASA

Report on the audit of the financial statements

Opinion

We have audited the financial statements of PCI Biotech Holding ASA 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 2018, statements of comprehens ve 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 2018 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 athical responsibilities as required by law and regulations. We have also complied with our other athical 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.

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.

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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 optimion. 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 auditors 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 cate 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;
- cbtain 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

Independent auditor's report - PCI Biotech Holding ASA

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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, 9 April 2019 ERNST & YOUNG AS 10 Tommy Romskaug State Authorised Public Accountant (Norway)

Independent auditor's report - PCI Biotech Holding ASA



OTHER INFORMATION

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
APC:	Antigen Presenting Cell
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
CPI:	Checkpoint Inhibitor
CRC:	Cohort Review Committee
CSR:	Corporate Social Responsibility
FDA:	US Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fima <i>Cнем</i> :	PCI Biotech's development program for enhancement of generic chemotherapies
fima <i>NAc</i> :	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
In vitro:	Studies performed with cells or biological molecules studied outside their normal
	biological context; for example proteins are examined in solution, or cells in
	artificial culture medium.
In vivo:	Studies in which the effects of various biological entities are tested on whole,
	living organisms usually animals.
KLH	Keyhole limpet hemocyanin
NAA:	Norwegian Accounting Act
ODD:	Orphan Drug Designation
ORR:	Overall Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
PFS:	Progression Free Survival
RELEASE:	Name of PCI Biotech's pivotal study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
SAC:	Scientific Advisory Committee
SoC:	Standard of Care

FINANCIAL CALENDAR

First quarter 2019 report Ordinary general meeting 2019 Second quarter 2019 report Third quarter 2019 report 8 May 2019 29 May 2019 28 August 2019 13 November 2019



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 forwardlooking statements contained in this Report, including assumptions, opinions and views of the Company or cited from third party sources, are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements that are expressed or implied by statements and information in the Report, including, among others, risks or uncertainties associated with the Company's business, segments, development, growth management, financing, market acceptance and relations with customers, and, more generally, general economic and business conditions, changes in domestic and foreign laws and regulations, taxes, changes in competition and pricing environments, and fluctuations in currency exchange rates and interest rates. None of the Company or any of its subsidiaries or any such person's directors, employees or advisors provide any assurance that the assumptions underlying forward-looking statements expressed in this Report are free from errors nor does any of them accept any responsibility for the future accuracy of such forward-looking statements.



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