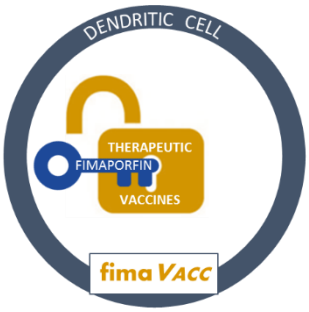
Enabling intracellular delivery

FOURTH QUARTER AND PRELIMINARY FULL YEAR REPORT 2020

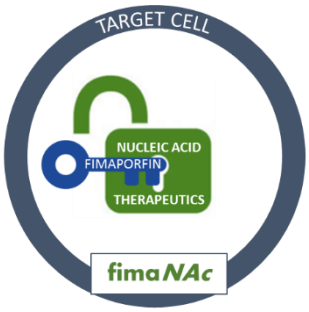
LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS

TRIGGERED ENDOSOMAL RELEASE

Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic vaccines



Providing a delivery solution for nucleic acid therapeutics

ABOUT PCI BIOTECH

PCI Biotech is an oncology-focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies for the treatment of cancer through its proprietary photochemical internalisation (PCI) technology originating from the world-leading research at the Oslo University Hospital – the Norwegian Radium Hospital. The PCI technology works by inducing light-triggered endosomal release which may unlock the true potential of a wide array of therapeutic modalities, such as small molecules, vaccines and nucleic acids.

PCI Biotech's lead programme is fima*CHEM* with the photosensitiser fimaporfin (Amphinex®), which entered the pivotal RELEASE study in May 2019, following the completion of a Phase I study with encouraging tumour response and survival data. The second programme fima*VACC* is a vaccination technology that applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic vaccines. Successful clinical proof of concept was achieved in a Phase I study in healthy volunteers in 2019. The third programme fima*NAC* is a technology for intracellular delivery of nucleic acids, which is currently being evaluated in collaboration with several players in the field.

Highlights

fimaCHEM

- The first Asian patient was enrolled in the RELEASE study in South Korea in October, less than three months after opening of the first study site in Asia. All the nine planned study sites in South Korea and Taiwan have been opened, with initial good screening activity
- Several initiatives have been implemented in the RELEASE study to recoup long-term recruitment projections. Besides going into Asia, the most important initiatives are the protocol amendment made to expand the eligible patient population and the addition of new clinical sites
- A total of 47 RELEASE study sites are open by end-January 2021 across EU, US and Asia and all these sites are operating under the amended protocol
- The second wave of the Covid-19 pandemic is still having a severe impact in many countries, and the full consequences of the pandemic and the recruitment initiatives for the RELEASE study cannot yet be fully established. We are seeing indications of increased screening and enrolment after implementation of the new amended protocol and the opening of Asian sites, although we do not expect to see the full effect of these initiatives until the Covid-19 situation improves
- The company continues to have full focus on enrolment of patients into the RELEASE study. The expected timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023
- European patent for treatment of bile duct cancer granted. The patent provides an extended protection of the intended use of fima*CHEM* lasting several years beyond the potential market exclusivity offered by the orphan drug designation
- In November a case report series from the Phase I study was published in Endoscopy International Open, providing detailed descriptions of treatment effects in three select patients at the dose chosen for the RELEASE study

fimaVACC

- Successful Phase I vaccination proof of concept study published in high impact immunology journal, demonstrating that fima*VACC* enhances the immune response to peptide- and protein-based vaccines in healthy volunteers

fimaNAc

- In October PCI Biotech was informed that AstraZeneca elected not to enter into a definitive agreement for the fima*NAC* technology. Encouraging preclinical results have been achieved with fima*NAC* in this collaboration and the decision not to enter into a definitive agreement is primarily based on a strategic evaluation by AstraZeneca of their current development priorities
- In February 2021 PCI Biotech presented the encouraging mRNA data from this collaboration at the UK based 12th Annual RNA Therapeutics Virtual Conference

Key figures

(In NOK 1,000)	2020 Q4	2019 Q4	2020 FY	2019 FY
Other income	1 567	2 117	7 368	9 392
Operating expenses	22 927	27 446	89 488	98 195
Operating results	-21 361	-25 330	-82 121	-88 804
Net financial result	-5 104	78	9 881	58
Comprehensive income	**-26 464**	**-25 252**	**-72 239**	**-88 746**
Cash & cash equivalents	**187 967**	**261 103**	**187 967**	**261 103**
Cash flow from operating activities	**-16 667**	**-23 761**	**-79 046**	**-83 471**

2020 in review - expanding and optimising the RELEASE study

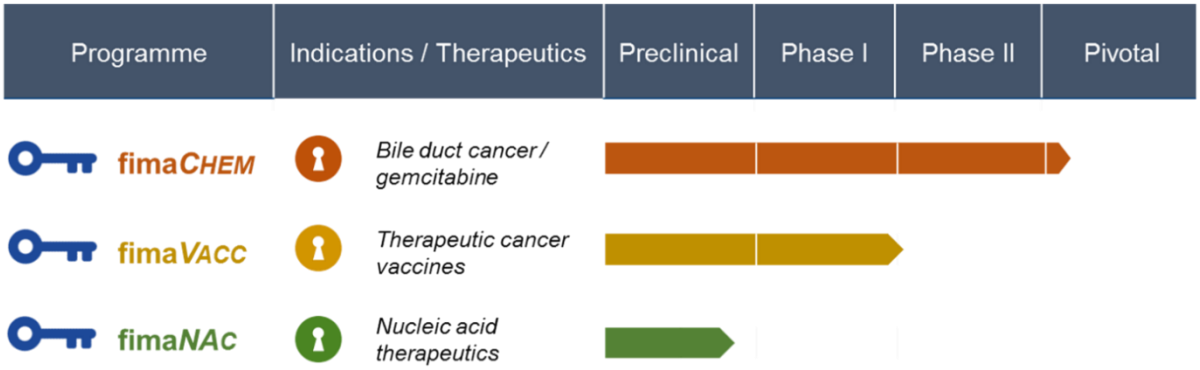
The Covid-19 pandemic has affected all aspects of business and life, and accentuated the importance of being adaptive and agile in response to changes. For PCI Biotech, with a global pivotal study open in many of the countries most affected by the pandemic, the greatest impact has been on clinical study progress in the fimaCHEM programme. The main focus during the year has therefore been on mitigating the effects of the pandemic by both optimising and expanding the pivotal RELEASE study, with the aim to minimise the delays inflicted by the pandemic. The early period of the pandemic was used to analyse eligibility failure logs and review investigator feedback on study design and procedures. The study protocol was thereafter amended, and an optimised protocol implemented during the autumn 2020. The expansion to include new countries and sites have run in parallel and the RELEASE study now spans across 47 sites. The expansion to Asia has shown initial good screening and enrolment. The study communication has also been strengthened, both by the establishment of several online tools, interaction with patient organisations and publication of case reports. We expect to see the full effect of these efforts when the Covid-19 vaccination starts to reduce the effect of the pandemic on the healthcare systems.

The foundation of the fimaVACC programme has been reinforced by the granting of two key patents in the US, providing protection for the combination with two important classes of immunomodulators commonly used in the development of vaccines. The publication of the Phase I results in a high-impact immunology journal was another important fimaVACC milestone. The focus is now on utilising the Phase I results in partnering efforts and planning for clinical proof-of-concept in a disease setting.

The fimaNAC collaboration with AstraZeneca ended in 2020, but it has produced important data for the further development of this platform. The results, which were recently presented at a conference on RNA therapeutics, suggest that the fimaNAC technology provides an appealing intracellular delivery solution for certain applications within this class of therapeutics. The rapid development progress of mRNA-based vaccines against Covid-19 has generated a lot of attention to the potential of this class of drugs and we will now focus our efforts towards the most attractive opportunities.

On the corporate side, the medical and business development areas of the organisation have been further strengthened by the appointment of Dr. Amir Snapir as CMO and Mr. Ludovic Robin as CBO. The organisation will continue to be reinforced as we are pursuing multiple potential business opportunities.

Operational review and development programmes overview



Implications of the COVID-19 pandemic

PCI Biotech is closely monitoring potential implications on its short- and long-term operations during the course of the COVID-19 pandemic. PCI Biotech's overriding priority has been the safety of its staff and patients participating in the clinical trial and its collaborators. Other key priorities include identification and implementation of potential mitigating actions for the delays in progress of the **fimaCHEM** RELEASE study in collaboration with our contract research organisation, as well as identification and removal of unnecessary recruitment hurdles in the study protocol. Screening of patients was severely affected in 2020 and the situation is still challenging. Initial indications of increased screening and enrolment under the amended protocol despite the second wave of the pandemic is encouraging, but the full effect of the initiatives is not expected until the Covid-19 vaccination starts to reduce the effect of the pandemic on the healthcare systems. PCI Biotech has per date of this report not a complete picture of consequences regarding timelines and costs for the RELEASE study. Given the uncertainty surrounding long-term consequences of the unprecedented situation with the COVID-19 pandemic, the anticipated timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023, and the current cash-position may therefore not be sufficient to reach interim read of the RELEASE trial. The company will continue to closely monitor progress in relation to timelines and costs in the coming months.

For the **fimaVACC** and **fimaNAc** programmes the main identified implications have been transient downturn in business development activities.

fimaCHEM

The **fimaCHEM** programme for local enhancement of cancer treatments is the most advanced of PCI Biotech's development programmes. The main focus is now to bring the lead candidate to the market through successful completion of the pivotal RELEASE trial for treatment of inoperable bile duct cancer.

RELEASE is a single randomised pivotal study with registration intent, building on encouraging results from the Phase I study. The first patient of a total of 186 patients was enrolled in May 2019 after final confirmation of the safety of up to two **fimaCHEM** treatments in the Phase I extension study in April the same year.

RELEASE will evaluate PCI Biotech's Amphinex® product -an intravenous formulation of fimaporfin- in combination with the standard of care chemotherapy with gemcitabine and cisplatin.

Bile duct cancer is a rare disease with high unmet medical need and the combination of Amphinex and chemotherapy will be evaluated as a first line treatment, with orphan drug designation granted in both EU and the US.

RELEASE progress and new initiatives for increased patient enrolment

The RELEASE study has enthused investigators, which is very important for clinical studies in rare patient groups such as cholangiocarcinoma. The study is however impacted by the COVID-19 pandemic, which has significantly affected patient recruitment and study recruitment projections.

Scale-up and optimisation activities for the RELEASE study have been performed during 2020, with site contract negotiations, regulatory approvals and site activations, following the protocol harmonisation and optimisation. Most of the study optimisation work has now been implemented and the focus going forward will be on regular trial management, including performance evaluation and potential replacement of sites.

Several initiatives have been implemented to recoup long-term recruitment projections, with the intention to accelerate patient inclusion under the constraints on clinical trials inflicted by the COVID-19 pandemic. Besides expanding the RELEASE trial into Asia, the most important initiative is the modification of patient eligibility criteria, made to expand the eligible patient population and thereby increase the enrolment rate. The company has scrutinised the study screening log, consulted investigators and external KOL's, and assessed feasible modifications that causes a limited increase of the overall study risk. These modifications have been included in an amendment to the study protocol and full approvals for the amended protocol were achieved in all countries during 2020. Other recruitment initiatives include patient and clinician study awareness, including online recruitment activities; and expansion of the trial from the planned 40 to more than 50 sites. Ukraine has been added to the country mix in Europe, replacing UK due to approval delays and trial competition. By end-January 2021, 47 sites across 14 countries had opened for recruitment. All open sites are screening for patients under the amended protocol with broadened inclusion criteria.

The consequences of the pandemic and the new recruitment initiatives for the RELEASE study cannot yet be fully established, but early indications after implementation of the amended protocol are encouraging with increased screening and enrolment. The opening of sites in Asia has also shown promise as the first patient was enrolled in South Korea in October, less than three months after opening of the first Asian site. The situation has been difficult in the US, but the new amendment has now been implemented at all sites. First patient enrolled in the US is expected 1H 2021.

The anticipated timeline for interim read is retained as a range from second half 2022 to first half of 2023. The current cash position may therefore not be sufficient to reach interim read of the RELEASE study and the company will closely monitor progress in relation to timelines and costs in the coming months, as the second wave of the COVID-19 pandemic is still affecting most countries.

Expansion of RELEASE to Asia

The expansion of RELEASE to Asia has been done to enhance patient recruitment and provide access to hospitals and key opinion leaders in this region with higher prevalence of bile duct cancer, and the expansion may also open up the potential upside from a business perspective. The trial is open in South-Korea and Taiwan. Other commercially interesting countries in Asia are considered to be Japan, Hong Kong and China. The Asian market is known to be fragmented and PCI Biotech do not foresee to commercialise fimaCHEM for bile duct cancer in Asia without a partner.

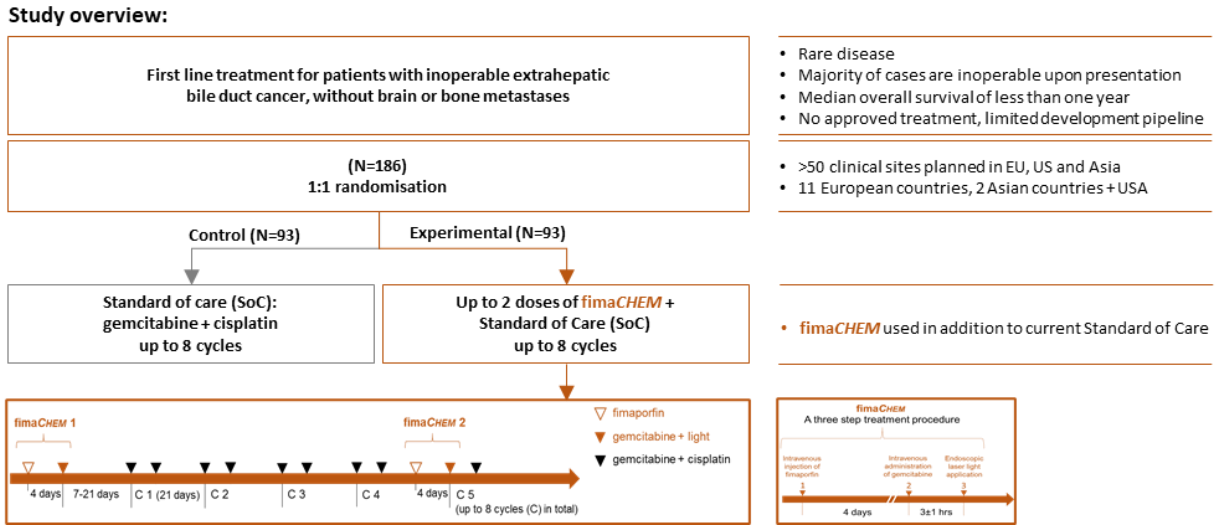
The target population for fimaCHEM is inoperable patients, and applying a projection of inoperable patients based on the estimated inoperable portion from the Western world (approx. 75%[1]) and taking into account that not all parts of the population in China will have access to the treatment, it can be estimated potentially more than 4,000 patients annually in the commercially interesting part of the Asian market. This preliminary figure is based on publicly available epidemiological information[2].

Conference and online activities

PCI Biotech sponsored the US based Cholangiocarcinoma Foundation (CCF) Annual Conference in April 2020, and a poster of the RELEASE study was provided to both caregivers and patients at this online meeting. A webinar presenting the RELEASE trial, the fimaCHEM technology and the results achieved from Phase I was co-hosted with the CCF in October. CCF is a patient organisation with a strong position in the US bile duct cancer community, and the aim of this webinar was to reach out to and make potential US patients and caregivers aware of the RELEASE study. In addition, specific online recruitment efforts are implemented targeting Germany, France, Spain and US.

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

The RELEASE study design is based on the outcome of several interactions with the two leading regulatory authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).



[1] PCIB internal CCA market analysis and KOL advisory meeting

[2] Translational Gastrointestinal Cancer, 2012

Milestones and timelines:

First EU patient enrolled in May 2019; first Asian patient enrolled in October 2020	• First patient in the US expected 1H 2021
Seamless safety review by IDMC when 8 patients have undergone 2 fima*CHEM* treatments	• IDMC = Independent Data Monitoring Committee
Tumour response interim analysis when 120 patients have been through the 3 months scan	• Interim analysis expected 2H 2022 – 1H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 1H 2024

Endpoints:

Interim analysis:	Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in Europe and USA • Potentially accelerated/conditional approval
Final analysis:	Primary endpoint: Progression Free Survival (PFS) Key secondary endpoint: Overall Survival (OS)	• Single randomised trial sufficient based on interaction with US and EU regulatory authorities

Regular communication milestones for the RELEASE study

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

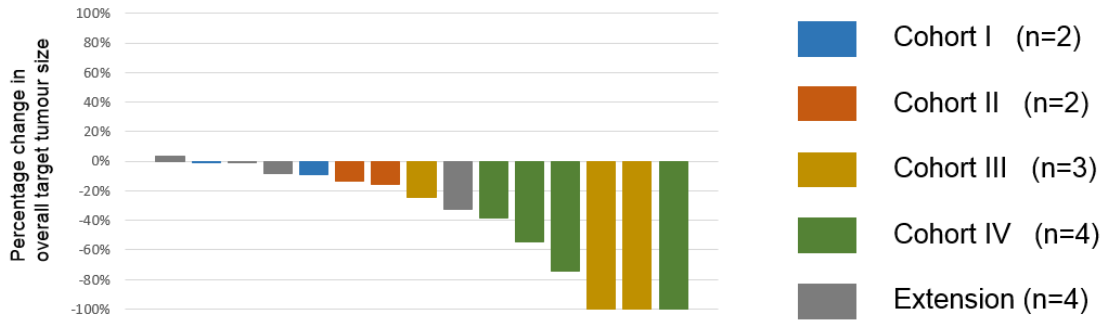
Phase I results paved the way for the pivotal RELEASE trial with registration intent

The RELEASE study builds on the favourable safety results and encouraging early signs of efficacy in the Phase I study, with more than 80% of the patients being progression-free at 6 months.

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

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

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



Tumour response translates into encouraging survival data

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

The group in the dose escalation study that received the RELEASE study dose (n=6, cohort IV) had a mOS of 22.8 months and half of these patients exceeded 30 months survival. The mOS in the extension group (n=7), where patients received up to two **fima*CHEM*** treatments of the RELEASE dose was 16.6 months, with one patient still alive at final censoring. Five of the seven extension patients received two **fima*CHEM*** treatments.

Although these are small patient groups with considerable heterogeneity, positive signs of objective tumour response seem to translate into encouraging survival data.

Publication of a case report series

In November 2020 a case report series from the Phase I study was published in Endoscopy International Open. The article provides detailed descriptions of treatment effects in three select patients at the dose chosen for the RELEASE study. The title of the publication is "Photochemical Internalisation and gemcitabine combined with first-line chemotherapy in perihilar cholangiocarcinoma – observations in three patients".

Endoscopy International Open (EIO) is an open access journal in the field of gastrointestinal endoscopy. It covers all aspects of endoscopic diagnosis, therapeutic procedures and technical developments. EIO offers a fast and independent quality process with free, broad and easy access for everybody, and all articles submitted to EIO undergo rigorous blind scientific peer review.

European patent for treatment of bile duct cancer granted

The European Patent Office (EPO) informed the company in November 2020 that a new European patent has been granted. The European patent covers the intended use of fima*CHEM* in combination with gemcitabine for the treatment of cholangiocarcinoma (bile duct cancer). The patent secure protection until 2037, which is several years beyond the potential market exclusivity offered by the orphan designation in Europe. The patent approvals are still pending in US and key Asian markets.

Bile duct cancer and the fima*CHEM* technology

Bile duct cancer originates in the ducts that drain bile from the liver into the small intestine. It is a rare disease with an annual incidence rate of 1-2 cases per 100,000 in the Western world but higher prevalence (1-4 cases per 100,000) in the most relevant Asian countries.

There is currently no approved treatment specifically for extrahepatic bile duct cancer and the development pipeline for new potential treatments is limited. Bile duct cancer is also characterised by a remarkable resistance to common chemotherapy, leaving surgery as the only possibly curative treatment today. However, the majority of new cases are deemed inoperable upon presentation, meaning that there is a high unmet need for new drug classes, improved treatment technologies, or alternative methods in order to increase overall survival and quality of life for these patients.

The current Standard of Care (SoC) for inoperable extrahepatic bile duct cancer patients is stenting to keep the bile duct open, followed by a combination treatment with the chemotherapies gemcitabine and cisplatin. In preclinical studies, the fima*CHEM* technology has significantly enhanced the effect of gemcitabine, which is the most studied and used chemotherapy drug in bile duct cancer treatment.

The bile duct is easily accessible for light application through routinely used endoscopic methods.

Comparator data for inoperable bile duct cancer

The median overall survival (mOS) in the studies that established the combination of gemcitabine and cisplatin as Standard of Care in bile duct cancer was 11.7 and 11.2 months respectively (Valle *et al.* NEJM (2010) 362:1273-81 and Okusaka *et al.* BJC (2010) 103:469-74).

While these results represent the best available published comparator data it should be noted that the results are not directly comparable to the data on inoperable extrahepatic bile duct cancer in the fima*CHEM* Phase I study. The published studies include a wide range of different inoperable bile duct cancer patients, while the fima*CHEM* treatment is focused solely on inoperable extrahepatic bile duct cancer.

fima*VACC*

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

Successful clinical proof-of-concept in healthy volunteers

PCI Biotech successfully translated the vaccination technology into humans through a Phase I study in healthy volunteers that was completed in May 2019. The immune results provided Proof-of-Concept and clinical support of **fima*VACC***'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers.

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

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

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

More than 90 subjects were included, and tolerability of intradermal treatment with **fima*VACC*** is established across a wide range of doses.

As a next development step, PCI Biotech is actively exploring potential further clinical proof-of-concept studies for the technology in relevant diseases.

Proof-of-concept study results presented and published

The overall study results were presented at the ESMO Immuno-Oncology Congress in December 2019 and the full study results were published early January 2021 in Frontiers in Immunology, a high impact immunology journal. The study was performed in collaboration with international experts, including staff at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg.

Research collaboration with DCprime to explore novel cancer vaccination concepts

A new research collaboration was established in September 2020 with DCprime to explore novel cancer vaccination concepts. DCprime is a clinical stage cancer immunotherapy company developing vaccines and located in The Netherlands. All shares of DCprime were recently acquired by Immunicum AB, a Swedish listed company. The partnership is governed by a research collaboration agreement, under which the collaborators will perform an extensive evaluation of technology compatibility and synergy based on preclinical studies. The collaboration pursues the development of novel cancer vaccination concepts based on tumour-independent antigens (TIAs). The companies will evaluate results achieved from this research collaboration and then explore the potential for further development and partnership. Both the **fima*VACC*** and **fima*NAC*** technologies will be utilised in the collaboration.

US patents granted during Q1 2020

In January 2020, a US patent was granted providing a broad coverage for the combination of various cytokines with the **fima*VACC*** technology. In March 2020, a further US patent was granted providing a broad coverage for the combination of the **fima*VACC*** technology with a new important class of adjuvants, called toll like receptor agonists. These US patents secure protection until 2035, while patent approvals are still pending in Europe and key Asian markets, except for the toll like receptor agonist combination patent which is granted in Japan. These patents are important for PCI Biotech's development strategy, as it supplements the company's ability to potentially generate an internal vaccine pipeline, in addition to bringing value for the **fima*VACC*** technology in partnering efforts.

Potential COVID-19 opportunities
Significant efforts are being invested by the global health community to research and develop potential treatments against COVID-19. Most vaccine companies are currently focused on reaching or progressing clinical development of their own established technologies and may not be open for the inclusion of new technologies in the short term. PCI Biotech is nevertheless closely monitoring and exploring potential **fima*VACC*** compatible opportunities, as the immune response characteristics of the PCI technology may fit well with the medical needs.

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 four years, 2017-2021.

Immunotherapy with the fima*VACC* technology

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

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

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

fima*NAc*

The **fima*NAc*** programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage collaborative programme, with four research collaborations established.

The collaboration partners include DCprime, eTheRNA immunotherapies, IMV and Aposense. In all these collaborations, partners are exploring synergies between their proprietary nucleic acid technologies and the **fima*NAc*** technology, with potential for further deepening of the partnerships. Previous collaborative interactions and results with other key players have provided valuable data and knowhow for PCI Biotech to be utilised for the further development of **fima*NAc***.

The preclinical research collaboration with AstraZeneca was established in 2015 and the experimental phase of the collaboration ended in 2019. This was followed by an evaluation period until end of 2020 for AstraZeneca to determine whether to move the collaboration into a definitive agreement. In October 2020, PCI Biotech was informed that AstraZeneca elected not to enter into a definitive agreement for the **fima*NAc*** technology. Encouraging preclinical results have been achieved with the **fima*NAc*** platform in this collaboration and the decision not to enter into a definitive agreement was primarily based on a strategic evaluation by AstraZeneca of their current development priorities.

In February 2021 the encouraging data from this collaboration was included in a presentation at the 12th Annual RNA Therapeutics Virtual Conference, a UK based online event. The conference was set to explore the latest developments in RNA delivery agents and RNA-based therapeutics with the latest case studies on advanced mRNA technologies, oligonucleotide delivery, therapeutic applications and future trends and innovations. PCI Biotech's presentation focused on the delivery of RNA molecules, including the most recent data on the use of the **fima*NAc*** delivery technology in the exciting field of RNA based therapies. PCI Biotech also sponsored the event.

The collaboration with AstraZeneca has provided PCI Biotech with valuable scientific knowhow from working with a big biopharma company over the last 5 years and the company will utilise this important knowhow, together with the generated preclinical results, for the further development of the **fima*NAc*** asset. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of mRNA.

In August 2020 PCI Biotech provided the Israeli company Aposense with the **fima*NAc*** technology for synergy testing with their molecular nano-motors. In September 2020 PCI Biotech entered into a research collaboration with DCprime, a privately held clinical stage cancer immunotherapy company developing vaccines and located in The Netherlands. This collaboration is a combined **fima*VACC*** and **fima*NAc*** project; please see under '**fima*VACC***' for more information about the collaboration.

All collaborations were during 2020 reviewed for progress and value to PCI Biotech, and prioritised accordingly. Three of the collaborations (Phio Pharmaceuticals, Bavarian Nordic and BioNTech) were closed as a result of these evaluations.

PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fima*NAc*** programme.

The fima*NAc* technology and nucleic acid therapy

Several forms of nucleic acids are widely acknowledged to have significant therapeutic potential and numerous clinical trials are underway.

The therapeutic potential of compounds such as nucleic acids is however limited by the challenge of delivering sufficient amounts of large molecules into the cells. PCI Biotech believes the fima*NAc* technology may resolve this issue through enhanced delivery of the majority of nucleic acid types.

Corporate

Management changes in Q2 2020

PCI Biotech appointed Dr Amir Snapir, MD, PhD as Chief Medical Officer (CMO), commencing May 2020. Dr Snapir serve as a member of PCI Biotech's executive management team. He leads the execution of all clinical development programmes. Dr Snapir brings extensive experience in global clinical development of novel therapeutics, from early clinical translation to marketing authorisation, combined with extensive international regulatory experience. Dr Snapir also brings years of experience in business collaborations, alliances and product co-developments. Since 2007 Dr Snapir has held various positions at Orion Pharma, Espoo, Finland, spanning from leader of clinical pharmacogenomics to clinical development leader in Oncology. In his most recent role, Dr Snapir held the position as Director, Rare Disease Development. Dr Snapir has a PhD from the University of Turku, Finland and an MD from the University of Tel Aviv, Israel. Dr. Snapir is the author of numerous scientific publications.

From July 2019, the previous CMO Dr. Olivecrona operated via a consultancy agreement, and from May 2020 he holds no formal positions in the company.

In April 2020, PCI Biotech announced the appointment of Mr Ludovic Robin, PharmD, MBA, as Chief Business Officer (CBO), commencing May 2020. Mr Robin serves as a member of PCI Biotech's executive management team and leads all business and commercial development activities. Over the last twenty-five years, Ludovic has held numerous international managerial positions providing leadership in the pharmaceutical industry in the areas of international research and development, business development, as well as marketing and sales. In particular, he has participated in the launch of more than fifteen original orphan drugs or specialty pharmaceuticals. Mr Robin joined Shire in 2004 serving as Marketing Manager, Business Unit Director, Marketing Director and Commercial Operations Head of France/Benelux. In 2016 he joined Advicenne, a French biotech listed on Euronext as CBO, deputy CEO, responsible for commercial strategy of the drug candidates under development/registration

in EU and US. Mr Robin holds a Doctorate of Pharmacy (PharmD) from Lyon I University, a Master's in Industrial Pharmacy from Lyon Institute of Industrial Pharmacy, and an MBA from HEC Paris.

Financial review

Income Statement

(Figures in brackets = same period 2019 unless stated otherwise)
The Group has not recorded revenues for the financial year 2020 nor 2019. Grants received from public sources as the Norwegian Research Council "BIA" and "SkatteFUNN" are recorded as other income. Other income for Q4 and full year 2020 amounted to NOK 1.6 million (NOK 2.1 million) and NOK 7.4 (NOK 9.4 million) respectively. The SkatteFUNN tax scheme has been modified by the authorities with effect from 2020, reducing the maximum benefit level. Timelines for PCI Biotech's BIA supported project has been extended with a half year, until end of June 2021. These changes cause reduction in other income compared to 2019.

Research and development (R&D) expenses for Q4 and full year 2020 ended at NOK 21.4 million (NOK 21.8 million) and NOK 75.6 million (NOK 83.3 million). The reduction compared to 2019 is mainly due to start-up costs for the RELEASE trial in 2019. General and administrative expense for Q4 and full year 2020 ended at NOK 1.6 million (NOK 5.7 million) and NOK 13.9 million (NOK 14.9 million). The change in general and administration costs (G&A) in Q4 2020 compared to last year, is mainly due to accounting effect fluctuations for the share option scheme without direct cash effects. Operating expenses for Q4 and full year 2020 were NOK 22.9 million (NOK 27.4 million) and NOK 89.5 million (NOK 98.2 million). Operating expenses are mainly driven by the R&D activity level and the pivotal fima*CHEM* trial (RELEASE) is the main cost driver.

The variations in net financial results are mainly driven by exchange rate fluctuations on bank deposits placed in foreign currency, as a hedge of the foreign currency risk for the pivotal RELEASE study. Net financial results for Q4 and full year 2020 were NOK -5.1 million (NOK 0.1 million) and NOK 9.9 million (NOK 0.1 million) respectively.

Net loss for Q4 and full year 2020 were NOK 26.5 million (NOK 25.3 million) and NOK 72.2 million (NOK 88.7 million) respectively.

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 188.0 million at year-end 2020, compared to NOK 261.1 million per year-end 2019. Cash flow from operations is mainly dependent on R&D activities. Cash flow from operating activities was NOK -79.0 million for full year 2020, compared to NOK -83.5 million for 2019. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 8.5 million positive for 2020, compared to NOK 1.6 million negative for 2019.

Other long-term liabilities relate to potential future social security liabilities in connection with the company's share option program, and the liability fluctuates with the share price and number of outstanding 'in-the-money' share options. Social security liabilities for share options that are vested, or may vest during the next 12 months, are disclosed as other short-term liabilities.

Capital increase following exercise of share options

Participants in the Company's share option program exercised on 2 September 2020 a total number of 60,500 share options, out of these 26,000 share options were exercised at a strike price of NOK 7.84 and 34,500 share options were exercised at a strike price of NOK 3.26. All of the exercised share options were about to expire unless exercised.

Following the exercise of share options, the Company's Board of Directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 27 May 2020, decided to increase the Company's share capital with NOK 181,500 by issuing 60,500 new shares, each share of par value NOK 3.00. The

transaction was registered in the Norwegian Register of Business Enterprises on 8 September 2020, and the capital increase has thus been completed.

The Company's new share capital is NOK 111,979,170 divided by 37,326,390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The capital increase resulted in gross proceeds of NOK 316,310.

Employee share option scheme

In accordance with the authorisation granted by the Annual General Meeting 27 May 2020, the Board of Directors of PCI Biotech Holding ASA awarded a total of 540,000 share options to key employees in October 2020. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 50.36, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date.

The share options can be exercised with 1/3 of the options after approximately one year, further 1/3 after approximately two years and the last third after approximately three years. To ensure long term ownership by executive management, shares shall be held for at least three years after exercise, except shares to be sold immediately to cover transaction costs and tax under a so called cash less exercise. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2025.

The current authorisation, as of 27 May 2020, allows for a total of 2,790,000 share options, of which 1,245,500 have been granted by the Board of Directors.

Other

Risks and uncertainty factors for 2020

PCI Biotech is exposed to uncertainties and risk factors, which may influence some or all of the company's activities. As described in the Annual Report 2019, the most important risks the company is exposed to in 2020 are associated with progress and performance of R&D programmes, and the associated regulatory affairs and market risk. No circumstances have been identified that significantly change the uncertainties and risk factors described in the Annual Report 2019, which also covers implications of the COVID-19 pandemic.

Related party transactions

PCI Biotech is relying on services provided by third parties, including related parties, as a result of its organisational set-up. PCI Biotech considers its business relationship with The Norwegian Radium Hospital Research Foundation as the only material ordinary related party transactions per end of December 2019. No services were provided by related parties in 2020. Please see note 7 Related party transactions for further details.

Post-closing events

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

Outlook

PCI Biotech's proprietary PCI technology enables intracellular delivery, which provides the possibility to unlock the true potential of certain classes of innovative medicines. Supported also by external collaboration partners' opinion, the PCI technology has the opportunity to play a significant role in the realisation of several new therapeutic modalities, including immunotherapy (**fima*VACC***) and nucleic acid therapeutics (**fima*NAC***).

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

The company is fully committed to advance the **fima*CHEM*** programme with the ambition of helping patients currently left without effective treatment options to achieve a good quality of life. The ongoing COVID-19 pandemic affects the progress of the pivotal study and the company is currently focusing on both mitigating actions and study expansion and optimisation, with the aim to recoup as much as possible of the delays.

In parallel, the two other programmes, **fima*VACC*** and **fima*NAC***, are proceeding in accordance with the established development strategy. The Phase I study in healthy volunteers provided affirmative results on translation of the **fima*VACC*** technology into humans and key data to support the programme's further development. 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*** clinical development programme in inoperable extrahepatic bile duct cancer towards the market
- Implement the strategy for the next phase of development for **fima*VACC***
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 23 February 2021

Hans Peter Bøhn Chairman (sign)	Christina Herder Director (sign)	Hilde Furberg Director (sign)
Andrew Hughes Director (sign)	Lars Viksmoen Director (sign)	Per Walday CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS *(in NOK '000)*	Note	Q4 2020	Q4 2019	FY 2020	FY 2019
Other income	*6*	**1 567**	**2 117**	**7 368**	**9 392**
Research and development	*7,9*	21 373	21 767	75 571	83 312
General and administrative		1 554	5 679	13 917	14 883
Operating expenses		**22 927**	**27 446**	**89 488**	**98 195**
Operating results		**-21 361**	**-25 330**	**-82 121**	**-88 804**
Financial income and expenses					
Financial income		362	3 677	23 344	2 737
Financial expenses		5 466	3 599	13 463	2 680
Net financial result	*8*	**-5 104**	**78**	**9 881**	**58**
Profit/Loss before income tax		**-26 464**	**-25 252**	**-72 239**	**-88 746**
Income tax	*10*	0	0	0	0
Net profit/loss		**-26 464**	**-25 252**	**-72 239**	**-88 746**
Other comprehensive income		0	0	0	0
Total comprehensive income	*5*	**-26 464**	**-25 252**	**-72 239**	**-88 746**

Balance sheet *(in NOK '000)*	Note	31.12 2020	31.12 2019
Non-current assets			
Property, plant and equipment	*17*	7 388	5 072
Right to use asset	*16*	605	1 211
Total non-current assets		**7 994**	**6 283**
Current assets			
Short term receivables	*8*	13 162	14 646
Cash & cash equivalents	*8*	187 967	261 103
Total current assets		**201 129**	**275 749**
Total assets		**209 123**	**282 032**
Equity and liabilities			
Equity			
Paid in capital	*11,12*	562 442	562 126
Other reserves		-373 198	-307 297
Total equity		**189 245**	**254 828**
Long term liabilities			
Other long term liabilities	*14*	32	2 037
Lease liabilities	*16*	0	539
Total long term liabilities		**32**	**2 576**
Short term liabilities			
Trade debtors		5 191	8 601
Lease liabilities	*16*	673	657
Other short term liabilities	*7,13*	13 982	15 370
Total short term liabilities		**19 846**	**24 628**
Total liabilities		**19 878**	**27 204**
Total equity and liabilities		**209 123**	**282 032**

CHANGE IN EQUITY

(in NOK '000)	Q4 2020	Q4 2019	FY 2020	FY 2019
Equity at beginning of period	**212 080**	**278 771**	**254 828**	**339 954**
Capital increase	0	0	316	1 183
Share option scheme	3 629	1 309	6 339	2 436
Comprehensive income in the period	-26 464	-25 252	-72 239	-88 746
Equity at end of period	**189 245**	**254 828**	**189 245**	**254 828**

CASH FLOW

(in NOK '000)	Q4 2020	Q4 2019	FY 2020	FY 2019
Ordinary profit before taxes	-26 464	-25 252	-72 239	-88 746
Depreciation, amortisation and write off	616	345	2 208	955
Leasing interest cost	19	9	75	37
Share options	3 629	1 309	6 339	2 436
Currency gain(-)/ loss(+) not related to operations	5 356	644	-8 526	1 649
Net interest paid/received	-647	-1 372	-1 654	-1 776
Changes in working capital and other non-cash adjustments	823	556	-5 248	1 973
Cash flow from operating activities	**-16 667**	**-23 761**	**-79 046**	**-83 471**
Net interest paid/received	647	1 372	1 654	1 776
Acquisition of non-current assets	-722	-32	-3 919	-5 405
Net cash flow from investing activities	**-76**	**1 339**	**-2 265**	**-3 629**
Cash flow from financial activities				
Payment principal portion of lease liabilities	-167	-164	-668	-657
Net proceeds from share issues	0	0	316	1 183
Net cash flow from financial activities	**-167**	**-164**	**-352**	**526**
Net change in cash during the period	**-16 910**	**-22 585**	**-81 662**	**-86 574**
Exchange rate effect on bank deposits in foreign currency	-5 356	-644	8 526	-1 649
Cash and cash equivalents at the beginning of the period	210 233	284 332	261 103	349 326
Cash and cash equivalents at the end of the period	**187 967**	**261 103**	**187 967**	**261 103**

SELECTED EXPLANATORY NOTES:

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA and the fully owned subsidiary PCI Biotech AS. The PCI Biotech shares have been listed on Oslo Børs since 27 April 2018 under the ticker PCIB, as a transfer of listing from Oslo Axess. The company is headquartered in Oslo, Norway.

PCI Biotech has developed a unique and patented photochemical intracellular drug delivery technology for use in cancer therapy and other diseases. The technology may also be used to enhance the immunological response of vaccines. The company collaborates closely with The Norwegian Radium Hospital in Oslo, Norway and receives funding on several projects from the Research Council of Norway. The company has an extensive international collaboration network with recognised expert groups in both drug delivery and vaccination. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release.

The PCI technology has potential to improve the efficacy of both existing drugs and new classes of drugs, such as therapeutic vaccines, gene therapy and other therapies based on nanotechnology or on biotechnological principles. The company's objective is to prove the clinical usefulness of the technology with various drugs and subsequently license out the technology to partners for further development and marketing. Revenues will be generated at the time of partnering and onwards from up-front payments, milestone payments and royalties from sales. PCI Biotech works on the development of PCI products for enhanced delivery of existing cancer drugs (fima*CHEM)*, and as a platform that may both potentiate the effect of vaccines (fima*VACC*) and delivery of nucleic acids (fima*NAC*). PCI Biotech has two active clinical development programmes; one project in the fima*CHEM* programme and the other in the fima*VACC* programme. The fima*CHEM* project runs the pivotal clinical RELEASE study with registration intent for the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agent gemcitabine for treatment of inoperable extrahepatic bile duct cancer. The fima*VACC* project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fima*VACC'S* ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fima*NAC* programme is in preclinical stage.

2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2019 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 23 February 2021.

PCI Biotech has Norwegian kroner (NOK) as its functional currency and presentation currency. In the absence of any statement to the contrary, all financial information is reported in whole thousands. As a result of rounding adjustments, the figures in the condensed interim financial statements may not add up to the totals.

3. Summary of significant accounting policies

The accounting policies applied and the presentation of the interim condensed consolidated financial information for 2020 is consistent with the consolidated financial statements for the year ended 31 December 2019.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2020 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the consolidated financial statements for 2019. In the 2019 financial statements, PCI Biotech applied the accounting standard *IFRS 16 Leases* for the first time. Please see note 16 Rights to use assets and lease liabilities for further details.

4. Important accounting valuations, estimates and assumptions

Estimates and judgments are evaluated on an on-going basis and are based on historical experience and other factors, including expectations of future events that are considered to be relevant.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31st, 2019.

5. Earnings per share

Earnings per share

	Q4 2020	Q4 2019	FY 2020	FY2019
Result allocated to shareholders (in NOK '000)	(26 464)	(25 252)	(72 239)	(88 746)
Weighted average of outstanding shares (in NOK '000)	37 326	37 266	37 286	37 229
Earnings per share (NOK per share)	-0,71	-0,68	-1,94	-2,38

Diluted earnings per share:

	Q4 2020	Q4 2019	FY 2020	FY 2019
Result allocated to shareholders (in NOK '000)	(26 464)	(25 252)	(72 239)	(88 746)
Weighted average of outstanding shares (in NOK '000)	37 971	37 971	37 931	37 935
Earnings per share (NOK per share)	-0,71	-0,68	-1,94	-2,38

Weighted average of outstanding diluted shares is weighted number of average number of shares adjusted with share options that are in the money. Earnings per share is not affected by the dilution if negative results in the period.

6. Segment information and Other income

PCI Biotech reports only one segment and had no revenues for the reporting period. Government grants are not recognised until it is probable that the conditions attached to the contribution will be achieved. The grants are recognised in the statement of profit and loss in the same period as the related expenses and are disclosed as other income. The Company has recognised grants from the Norwegian Research Council (BIA) and the tax incentive scheme (SkatteFUNN) in the period.

7. Related party transactions

PCI Biotech is relying on services provided by third parties, included related parties, as a result of its organisational set-up. PCI Biotech considers that its business relationship with The Norwegian Radium Hospital Research Foundation regarding research and overall PCI technology development represent related party transactions up until 31 December 2019. Thereafter no services have been purchased from the related party.

The following table shows the extent of such transactions in the reported periods (all figures in NOK '000):

Purchase of services	Q4 2020	Q4 2019	FY 2020	FY 2019
The Norwegian Radium Hospital Research Foundation	0	451	0	2 091

At the end of the quarter PCI Biotech had no short-term liability (2019: NOK 0.5 million) to The Norwegian Radium Hospital Research Foundation.

8. Credit risk, foreign currency risk and interest risk

Credit risk
PCI Biotech has no sales for 2019 and 2020 and faces therefore no credit risk on trade receivables.

Maturity profile on other receivables at the end of the quarter (all figures in '000 NOK):

	Not due (prepaid expenses)	Less than 3 months	3 to 12 months	More than 12 months	Total
Other receivables	7 111	1 236	4 815	-	13 162
Total receivables	**7 111**	**1 236**	**4 815**	**-**	**13 162**

Most of the short-term receivables relates to accrued, not received government grants (BIA) and tax incentive scheme (SkatteFUNN). A major part of prepaid expenses relates to the RELEASE study.

Foreign currency risk
PCI Biotech has transactional currency exposure arising from purchases in currencies other than the functional currency (NOK). In October 2018 PCI Biotech placed parts of the net proceeds from the rights issue of NOK 360 million in Euro deposits as a hedge of the foreign currency risk for the pivotal RELEASE study, which was initiated in Q2 2019. Foreign currency expenses covered by the Euro deposits have since inception been beneficial compared to spot currency exposure towards NOK. PCI Biotech has not implemented any other hedging strategy to reduce foreign currency risk.

In 2020 exchange rate fluctuation on cash deposits placed in Euro generated a positive accounting effect of NOK 8.5 million. From inception in October 2018 the Euro deposits have had a net positive accounting effect of NOK 16.0 million.

Interest risk
PCI Biotech has no interest-bearing debt. PCI Biotech faces interest risk on cash deposits.

9. Research and Development

All figures in '000 NOK

	Q4 2020	Q4 2019	FY 2020	FY 2019
Clinical studies	16 618	13 127	57 761	62 971
Pre-clinical studies	1 969	1 380	6 607	6 198
CMC and equipment	1 612	6 418	6 637	10 716
Patents	1 174	841	4 566	3 427
Other costs	0	0	0	0
Total	**21 373**	**21 767**	**75 571**	**83 312**

PCI Biotech has no development expenditure that qualifies for recognition of an asset under IAS 38 Intangible assets. Expenditure on research activities is recognised as an expense in the period in which it was incurred and all research expenses are recorded in the profit and loss statement, in line with previous years.

10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 128.1 million in non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

11. Share options

Participants in the Company's share option program exercised on 2 September 2020 a total number of 60,500 share options, out of these 26,000 share options were exercised at a strike price of NOK 7.84 and 34,500 share options were exercised at a strike price of NOK 3.26. All of the exercised share options were about to expire unless exercised.

In accordance with the authorisation granted by the Annual General Meeting 27 May 2020, the Board of Directors of PCI Biotech Holding ASA awarded a total of 540,000 share options to key employees on 6th October 2020. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 50.36, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date.

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

The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value is assessed to NOK 20.7 million which will be charged to the profit and loss statement over the vesting period for the share options.

The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2025.

Of the 540,000 share options, 400,000 share options were allotted to the following primary insiders:
90,000 share options were allotted to Amir Snapir, CMO. After the allotment, Amir Snapir holds a total portfolio of 90,000 unexercised share options and 0 shares.

90,000 share options were allotted to Ludovic Robin, CBO. After the allotment, Ludovic Robin holds a total portfolio of 90,000 unexercised share options and 0 shares.

70,000 share options were allotted to Per Walday, CEO. After the allotment, Per Walday holds a total portfolio of 225,000 unexercised share options and 72,700 shares.

50,000 share options were allotted to Anders Høgset, CSO. After the allotment, Anders Høgset holds a total portfolio of 150,000 unexercised share options and 64,800 shares.

50,000 share options were allotted to Ronny Skuggedal, CFO. After the allotment, Ronny Skuggedal holds a total portfolio of 140,000 unexercised share options and 55,000 shares.

50,000 share options were allotted to Lucy Wabakken, CDO (acting). After the allotment, Lucy Wabakken holds a total portfolio of 120,000 unexercised share options and 0 shares. Her related parties holds 10,008 shares.

Share options outstanding from the company's share option program for employees have the following expiry date and exercise prices:

		Number of share options	
Expiry date	**Exercise price in NOK per share option**	**31.12.2019**	**31.12.2020**
2020 - Q3	7.84	26 000	-
2020 - Q3	3.26	34 500	-
2022 - Q3	21.48	325 000	325 000
2024 - Q3	25.78	320 000	320 000
2025 – Q3	50.36	-	540 000
Total		**705 500**	**1 185 000**

The current authorisation, granted by the Annual General Meeting in 27 May 2020, for the employee share option program allows for a total of 2,790,000 share options, of which 1,245,500 have been granted by the Board of Directors per end of the quarter.

Overview share options, Senior executives	**Total holdings 31.12.2019**	**Allocated**	**Lapsed**	**Exercised**	**Expired**	**Total holdings 31.12.2020**
Per Walday, CEO	164 000	70 000	0	9 000	0	225 000
Ronny Skuggedal, CFO	116 000	50 000	0	26 000	0	140 000
Anders Høgset, CSO	106 000	50 000	0	6 000	0	150 000
Kristin Eivindvik, CDO	73 500	0	0	13 500	0	60 000
Lucy Wabakken, CDO (acting)	70 000	50 000	0	0	0	120 000
Ludovic Robin, CBO*	0	90 000	0	0	0	90 000
Amir Snapir, CMO*	0	90 000	0	0	0	90 000
Total	**529 500**	**400 000**	**0**	**54 500**	**0**	**875 000**

* Joined the company in May 2020.

12. Share capital

	No. of shares	**Nominal value per share in NOK**	**Share capital in NOK**
31.12.2019	**37 265 890**	**3.00**	**111 797 670**
Share option exercise	60 500	3.00	181 500
31.12.2020	**37 326 390**	**3.00**	**111 979 170**

Following the exercise of share options on the 2 September 2020, the Company's Board of Directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 27 May 2020, have decided to increase the Company's share capital with NOK 181,500 by issuing 60,500 new shares, each share of par value NOK 3.00. The transaction was registered in the Norwegian Register of Business Enterprises in the 8 September 2020, and the capital increase has thus been completed.

The Company's new share capital is NOK 111,979,170 divided by 37,326,390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The capital increase resulted in gross proceeds of NOK 316,310.

The annual general meeting in May 2020 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition the board of directors were authorised to execute share capital increases with up to NOK 12,016,700 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has around 6,800 shareholders at year-end 2020.

10 largest shareholders per 31 December 2020:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,07 %
Myrlid AS	2 720 000	7,29 %
MP PENSJON PK	1 836 729	4,92 %
RADIUMHOSPITALETS FORSKNINGSSTIFT.	1 281 415	3,43 %
NORDNET LIVSFORSIKRING AS	722 253	1,93 %
GRESSLIEN	720 792	1,93 %
Nordnet Bank AB	714 617	1,91 %
Jandersen Kapital AS	510 000	1,37 %
BERG-LARSEN	481 650	1,29 %
VERDIPAPIRFONDET KLP AKSJENORGE IN	354 374	0,95 %
Total 10 largest shareholders	**13 102 273**	***35,10 %***
Others	*24 224 117*	*64,90 %*
Total	*37 326 390*	*100,00 %*

Out of the total number of 60,500 share options exercised on 2 September 2020, 54,500 share options were exercised by the following primary insiders:

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

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

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

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

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties per year-end 2020:

		No. of shares	
Name	**Position**	**31.12.2019**	**31.12.2020**
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)*	Board member	4 000	4 000
Andrew Hughes	Board member	0	0
Per Walday	CEO	68 300	72 700
Anders Høgset	CSO	63 300	64 800
Ronny Skuggedal	CFO	43 000	55 000
Kristin Eivindvik	CDO	18 800	25 200
Lucy Wabakken, and related parties	CDO (acting)	NA	10 008
Ludovic Robin**	CBO	NA	0
Amir Snapir**	CMO	NA	0
Total		**344 028**	**378 336**

* Hilde Furberg's shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.
** Joined the company in May 2020.

13. Other short-term liabilities

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

14. Other long-term liabilities

Other long term liabilities include public duties payables due in 1-5 years for potential future exercises of "in-the-money" share options per end of the quarter in PCI Biotech's employee share option scheme.

15. Financial assets and liabilities

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

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

IFRS 16 was adopted by PCI Biotech with effects as of 1 January 2019, applying the modified retrospective method. Office lease was identified as the only applicable right-to-use asset. The relevant non-cancellable operating lease commitment per 1 January 2019 was NOK 2.0 million for 2019-2021, not including an extension option due to not reasonable certainty about option exercise. Discounted value applying an incremental borrowing rate of 6% was NOK 1.8 million per 1 January 2019.

On transition to IFRS 16, PCI Biotech recognised NOK 1.8 million as right to use assets and a corresponding lease liability which are disclosed in the balance sheet as long- and short-term liabilities depended on maturity of the corresponding principal lease payments. Accounting principles applied are described in the annual financial statement for the year ended 31 December 2019, under accounting principles section 2.4 and see also note 24.

The implementation effect of IFRS 16 in 2019, movements of the rights-of-use assets and lease liabilities and income statement and cash flow effects are presented below:

All figures in NOK '000

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisition costs 31.12.2019	**1 815**
Acquisitions FY 2020	0
Acquisition costs 31.12.2020	**1 815**
Depreciation FY 2019	604
Depreciation FY 2020	606
Accumulated depreciation and impairment as of 31.12.2020	**1 210**
Total right to use assets - office lease as of 31.12.2020	**605**
Lower of remaining lease term or economic life	1.0 years
Depreciation method	Linear

Lease liabilities - office	
Initial recognition 01.01.2019	1 815
Payments principal portion of the lease liability FY 2019	-657
Payments principal portion of the lease liability FY 2020	-668
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Total lease liabilities for office as of 31.12.2020	**673**
Whereof:	
Short term lease liabilities < 1 year	673
Long term lease liabilities > 1 year	0

Income statement effects FY 2020 – office lease	
Depreciation of right to use asset	-606
Effect on Operating results net of tax	**-606**
Interest expenses on the lease liabilities	-144
Effect on Net financial result net of tax	**-144**
Comprehensive income effect net of tax	**-750**

Cash flow effects FY 2020 - office lease	
Payments principal portion of the lease liability	-668

Payments of principal portion of the lease liabilities are not charged to profit and loss under IFRS 16 and will only have cash flow effects. Lease liabilities due in more than 12 months are disclosed as long-term lease liabilities.

17. Property, plant and equipment

PCI Biotech acquired the first lots of lasers to be used in the RELEASE study during 2019 and further lasers have been acquired during 2020. A linear depreciation method over the expected lifetime of five years for the equipment is applied.

Equipment	31.12 2020	31.12 2019
Carrying value at the beginning of the period	**5 072**	**17**
Acquisitions	3 919	5 405
Depreciation	1 603	350
Carrying value at the end of the period	**7 388**	**5 072**

18. Subsequent events

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

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
FDA:	US Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
fima*CHEM*:	PCI Biotech's development program for enhancement of generic chemotherapies
fima*NAC*:	PCI Biotech's development program for delivery of nucleic acids
fima*VACC*:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
ODD:	Orphan Drug Designation
ORR:	Overall Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
PFS:	Progression Free Survival
RELEASE:	Name of PCI Biotech's pivotal study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
SoC:	Standard of Care
NOK:	Norwegian kroner
FY:	Financial year (1st January – 31st December)
1H:	First half year (1st January – 30th June)
2H:	Second half year (1st July – 31st December)
Q1:	First quarter (1st January – 31st March)
Q2:	Second quarter (1st April – 30th June)
Q3:	Third quarter (1st July – 30th September)
Q4:	Fourth quarter (1st October – 31st December)
YTD:	Year to date

FINANCIAL CALENDAR

Annual Report 2020	21 April	2021
Q1 Report 2021	07 May	2021
First half year report 2021	25 August	2021
Q3 Report 2021	17 November	2021

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FORWARD LOOKING STATEMENTS

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

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