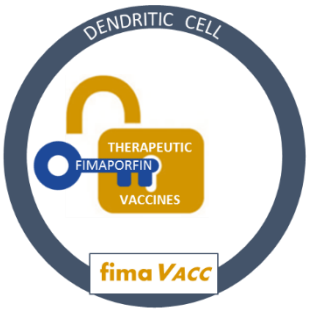
Enabling intracellular delivery

THIRD QUARTER REPORT 2021

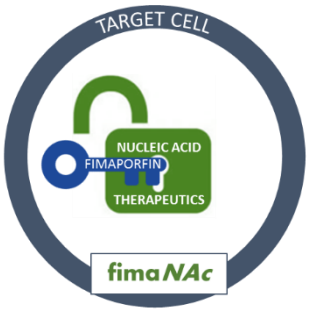
LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS

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 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

- Enrolment of patients into the RELASE study is still challenging and fluctuating – Covid-19 has a continued negative impact on the study and with August being a low recruitment month due to the holiday season, only five patients were enrolled in Q3
- Three patients were enrolled into the RELEASE study in October and the company continues to have a strong focus on recruitment, with the emphasis on regular trial management, including overall performance evaluation and site replacement
- Thirty patients have per end of October been included in the RELEASE study and the expected timeline for interim analysis remains 2H 2023
- Proactively pursuing strategies to address recruitment and retention, including interactions with FDA and EMA about an alternative study design

fimaVACC

- The programme is progressing towards initiation of a Phase II clinical proof-of-concept study, with product definition and study design clarified following comprehensive consultations with international experts

fimaNAc

- Development plan initiated based on strategic research and collaborations, targeting applications suited to the specific strengths of the PCI technology

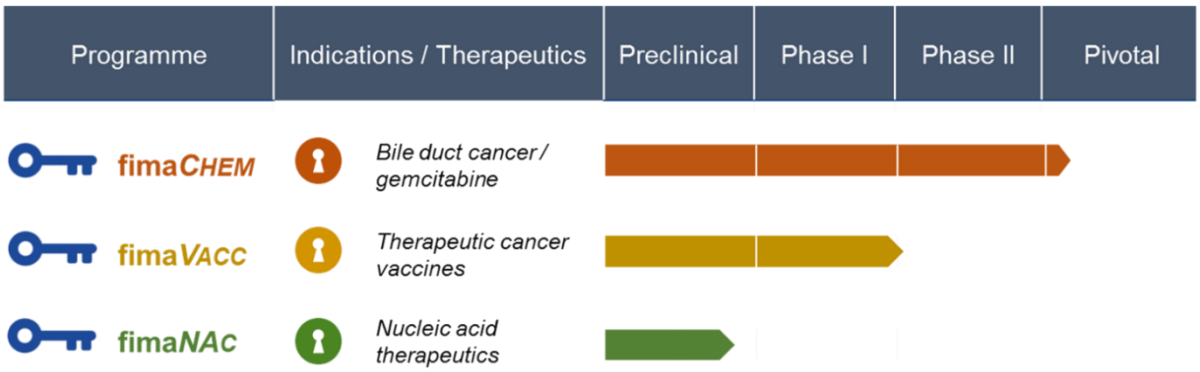
Corporate

- Significantly strengthening the organisation with three highly skilled individuals; an experienced operational leader for RELEASE, and two key employees within clinical science and business development focusing on **fimaVACC** and **fimaNAc**

Key figures

(In NOK 1,000)	2021 Q3	2020 Q3	2021 YTD	2020 YTD	2020 FY
Other income	1 187	1 963	5 085	5 801	7 368
Operating expenses	23 690	24 497	67 842	66 561	89 488
Operating results	-22 503	-22 534	-62 757	-60 760	-82 121
Net financial result	1 080	1 329	-586	14 985	9 881
Comprehensive income	**-21 423**	**-21 204**	**-63 343**	**-45 775**	**-72 239**
Cash & cash equivalents	**135 513**	**210 233**	**135 513**	**210 233**	**187 967**
Cash flow from operating activities	**-13 141**	**-22 443**	**-50 984**	**-61 372**	**-77 391**

Operational review and development programmes overview



Implications of the COVID-19 pandemic

Screening of patients into the RELEASE study was severely affected by the Covid-19 pandemic in 2020. The situation is still fluid in 2021 with continued fluctuating screening activity, making it difficult to quantify and predict the impact on the study going forward. PCI Biotech continues to closely monitor progress in relation to recruitment, timelines and costs. The company has not experienced any major shortage in supplies of investigational products and devices for the trial in 2021.

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, 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 EU, US and South Korea. A patent on the intended use of fimaporfin in combination with gemcitabine for the treatment of cholangiocarcinoma is granted in Europe, with approvals pending in the US and key Asian markets.

RELEASE progress and initiatives for increased patient enrolment

The RELEASE study has enthused investigators, which is very important for clinical studies in rare patient groups such as bile duct cancer. By end-October 2021, 47 sites across 14 countries were open for recruitment.

The expansion of the RELEASE trial into Asia and the modification of patient eligibility criteria (expanding the eligible patient population) made in 2H 2020 had clear positive effects on patient screening and enrolment. Screening activity has increased in 2021, but is still impacted by the Covid-19 pandemic and fluctuating significantly over time and across regions. Due to the additional protocol requirements for local administration of light to the bile duct by endoscopy, scheduling of these procedures remains challenging at most clinical trial sites who continue to deal with a backlog of routine patients. The situation will hopefully improve going forward, as hospital capacity is expected to increase with the increase in Covid-19 vaccination rates.

The positive recruitment trend seen in Q1 did not continue in Q2 and Q3, with only eight patients enrolled during these two quarters. Three patients were included in October, giving a total of 30 patients recruited into RELEASE.

The operational focus is on regular trial management, which includes frequent site interactions, performance evaluation and active replacement of underperforming sites, and five sites have been replaced during 2021. Special attention has also been given to monitoring of study specific risks, such as retention of randomised patients and adherence to study procedures and eligibility criteria. Early signs suggest a lower retention in the RELEASE control arm, with some control patients leaving the study immediately upon randomisation. The company is proactively pursuing different strategies to address this during second half 2021. This includes both evaluation of decentralisation opportunities for the study and potential study design changes.

Decentralisation under evaluation includes allowing standard of care treatment in clinics nearer to home and replacing some of the site visits with home visits. The Covid-19 pandemic has catalysed the adoption of decentralised clinical trials, but decentralisation of a pivotal interventional oncology study is a considerable undertaking that presents significant and regionally different logistic and regulatory challenges.

The company is interacting with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) concerning the possibility to enrich the control arm with external control data, using existing patient-level data from past clinical trials and real-world data from a patient registry. The initial responses from regulatory authorities suggest significant challenges for using external control data in a pivotal trial of a first line treatment.

The timeline for RELEASE interim readout was originally estimated to 1H 2022. At the start of the Covid-19 pandemic this was adjusted to a time range (2H'22 - 1H'23) given the fluidity of the situation. The impact of the pandemic continued in 2021, with substantial fluctuations in screening activity during the year. The expected timing for interim readout was at Q2 reporting revised to 2H 2023. This timeline requires an average inclusion of 12 patients per quarter. The IDMC safety review of the first eight patients receiving two **fimaCHEM** treatments is expected 2H 2021.

The company is fully focused on RELEASE and continues to evaluate all identified opportunities to optimise the overall performance of the study. To further strengthen the operational team for RELEASE an additional Clinical Project Director commenced 1st July. Maria Norling has worked in biotech, big pharma, and clinical research organisations. She has long clinical operational experience, including oncology, orphan disease and pivotal trials.

RELEASE in Asia

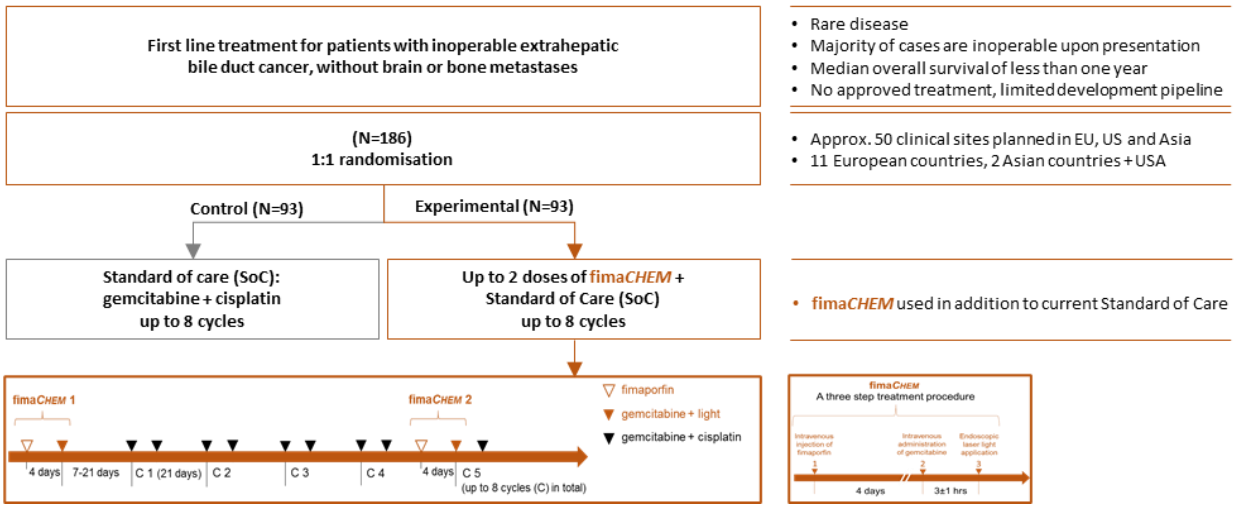
The expansion of RELEASE to South Korea and Taiwan during second half of 2020 enhanced patient recruitment and provided access to hospitals and key opinion leaders in this region with higher prevalence of bile duct cancer, and may also open up the potential upside from a business perspective. Other commercially interesting countries are considered to be Japan 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 novel treatments, PCI Biotech estimates potential access to more than 4,000 patients annually in the commercially interesting part of the Asian market. These preliminary figures are based on publicly available epidemiological information[2].

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 US Food and Drug Administration (FDA).

Study overview:



[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 US patient enrolled April 2021	• Enrolling patients on three continents
Seamless safety review by IDMC* when 8 patients have undergone 2 fima*CHEM* treatments	• IDMC safety review expected 2H 2021
Tumour response interim analysis when 120 patients have been through the 3 months scan	• Interim analysis expected 2H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 2H 2024

*IDMC = Independent Data Monitoring Committee

Endpoints:

Interim analysis:	Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in Europe, USA and S Korea • 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

Recruitment has been difficult during the pandemic and continues to be challenging. The planned communication milestones for the pivotal RELEASE study are therefore modified to provide more detailed insight into the recruitment challenges. The quarterly updates will now include number of recruited patients, in addition to the previously reported number of countries and clinical sites open for recruitment and 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 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.

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.

Phase I study results presented and published

The early encouraging results from the Phase I study have over time been presented at several relevant conferences as the data matured. In November 2020 a case report series from the Phase I study was published in Endoscopy International Open.[3]

[3] Endosc Int Open 2020; DOI: 10.1055/a-1276-6366

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.

Selected relevant ongoing clinical studies
Pivotal clinical studies for first line treatment of bile duct cancer covering the RELEASE patient population include two studies with immune checkpoint inhibitors (durvalumab and pembrolizumab) and one study with a modified version of gemcitabine (acelarin). The most advanced study (durvalumab) recently reported a positive interim analysis, but nothing has yet been communicated on effect size or results for the subpopulations that are included in RELEASE.

fima*VACC*

The fima*VACC* technology aims to enhance immunotherapy responses and has proven excellent preclinical efficacy with protein- and peptide-based vaccines. The technology has shown particularly strong CD8 T-cell responses, which are important for therapeutic vaccination, as well as enhanced helper (CD4) T-cell and antibody responses. Immune responses and safety have been successfully translated to healthy volunteers in a Phase I study and the next development step is a Phase II clinical proof-of-concept study for therapeutic vaccination in a relevant cancer disease. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based immunotherapy technologies.

Successful clinical proof-of-concept in healthy volunteers

PCI Biotech has successfully translated fima*VACC* with peptide- and protein-based vaccines into humans through a Phase I study in healthy volunteers. The immune results provide Proof-of-Concept and clinical support of fima*VACC*'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. More than 90 subjects were

included, and tolerability of intradermal treatment with **fima*VACC*** is established across a wide range of doses.

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

Phase I proof-of-concept in healthy volunteers published

The full study results were published early January 2021 in Frontiers in Immunology[4], a high impact immunology journal. The study was performed in collaboration with international experts, including staff at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg.

Development considerations for the fima*VACC* platform

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

The company is using international experts to assess the best possible development opportunities across vaccination technologies and diseases. The aim is to leverage the expected strengths of the **fima*VACC*** technology, such as combination with relevant immunomodulation therapy and application of both intratumoural and intradermal vaccine delivery, initially focusing on a two-stage study in the most apposite cancer indication before a potential broadening of the deployment of this versatile platform. Preparations are currently focused on product activities, study protocol and the establishment of a network of investigators.

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

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 intracellular delivery and vaccine presentation through these pathways.

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

fimaNAc

The **fimaNAc** programme provides a targeted intracellular delivery technology for many potential therapeutic applications with different classes of nucleic acids. It is currently a preclinical stage collaborative programme, with established research collaborations with companies developing nucleic acid based therapies.

The results from these collaborations suggest that the **fimaNAc** technology provides an appealing intracellular delivery solution for certain applications within this emerging class of therapeutics. Based on these results and other strategic considerations, the Company focus on selected applications suited to the specific strengths of the PCI technology. The initial focus will primarily be on clinical conditions which are easily illuminable and have supporting preclinical results.

Research collaborations

PCI Biotech has an active collaborative strategy for **fimaNAc** and **fimaVACC**. The collaboration partners include OliX Pharmaceuticals, Immunicum, eTheRNA immunotherapies, IMV and Aposense. In these collaborations, partners are exploring synergies between their proprietary technologies and the PCI technology, with potential for further expansion of the partnerships. Previous collaborative interactions and results with other key players have provided valuable data and knowhow for further development of PCI Biotech's programmes. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAc** and **fimaVACC** programmes.

Corporate

Financial review

Income Statement

(Figures in brackets = same period 2020 unless stated otherwise)
The Group has not recorded revenues for the financial years 2021 or 2020. Grants received from public sources as the Norwegian Research Council "BIA" and "SkatteFUNN" are recorded as other income. Q2 2021 represented the end of the BIA grant. Other income for Q3 and YTD 2021 amounted to NOK 1.2 million (NOK 2.0 million) and NOK 5.1 million (NOK 5.8 million) respectively.

Research and development (R&D) expenses for Q3 and YTD 2021 ended at NOK 18.6 million (NOK 20.0 million) and NOK 50.8 million (NOK 54.2 million) respectively. General and administrative (G&A) expense for Q3 and YTD 2021 ended at NOK 5.1 million (NOK 4.5 million) and NOK 17.1 million (NOK 12.4 million) respectively. The change in G&A for YTD 2021 compared to last year, is partly driven by increased number of employees, but mainly due to accounting effect fluctuations for the share option scheme, without direct cash flow effects. Operating expenses for Q3 and YTD 2021 were NOK 23.7 million (NOK 24.5 million) and NOK 67.8 million (NOK 66.6 million) respectively. Operating expenses are mainly driven by the R&D activity level and the pivotal fimaCHEM trial (RELEASE) is the main cost driver.

Net financial results for Q3 and YTD 2021 were NOK 1.1 million (NOK 1.3 million) and NOK -0.6 million (NOK 15.0 million) respectively. The variations in net financial results are mainly driven by exchange rate fluctuations on bank deposits placed in foreign currency, as a hedge of the foreign currency risk for the pivotal RELEASE study.

Net loss for Q3 and YTD 2021 were NOK 21.4 million (NOK 21.2 million) and NOK 63.3 million (NOK 45.8 million) respectively. The main driver of the change for YTD 2021 compared to last year was a net positive financial result in 2020, resulting from the above mentioned exchange rate fluctuations.

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 135.5 million at end of Q3 2021, compared to NOK 188.0 million per year-end 2020. Cash flow from operations is mainly dependent on R&D activities and may vary between periods due to ordinary timing differences. Cash flow from operating activities was NOK -13.1 million for Q3 2021 (NOK -22.4 million), and NOK -51.0 million (NOK -61.4 million) for YTD 2021. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 1.1 million positive for Q3 2021 (NOK 1.2 million positive). For YTD, the effect was 0.8 million negative in 2021, compared to 13.9 million positive YTD 2020. At current cost base the cash position is expected to give the company a financial runway into Q4 2022.

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

Other

Risks and uncertainty factors for 2021

PCI Biotech is exposed to uncertainties and risk factors, which may influence some or all of the company's activities. As described in the Annual Report 2020, the most important risks the company is exposed to in 2021 are associated with progress and performance of R&D programmes, and the associated regulatory affairs and market risk. No circumstances have been identified that significantly change the uncertainties and risk factors described in the Annual Report 2020, which also covers implications of the COVID-19 pandemic.

Further strengthening the organisation

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

Collaboration with Norwegian Institute for Marine Research (NIMR)

NIMR (Havforskningsinstituttet) has received NOK 4.5 million from the Norwegian Seafood Fund for a collaboration project with PCI Biotech exploring the use of photochemical treatments to combat salmon lice in fish farming. NIMR will perform the research, and PCI Biotech will provide expertise and compounds and retain commercial rights to the results of the project.

Employee share option scheme

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

The share options are granted without consideration and are subject to service based vesting conditions, with a three-year vesting term and one third vested each year. The share options are lapsing in Q3 2026. Further details about the share option program are described in PCI Biotech's remuneration policy, available on https://www.pcibiotech.no/s/PCI-Biotech-Remuneration-Policy-6-May-2021.pdf .

Post-closing events

PCI Biotech is not aware of any 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 has affected the progress of the pivotal study and the company is currently focusing on effective execution of the study, 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 the most attractive areas for the technology.

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
- 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, 16 November 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	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Other income	*6*	**1 187**	**1 963**	**5 085**	**5 801**	**7 368**
Research and development	*8,16*	18 611	19 978	50 790	54 198	75 571
General and administrative	*15*	5 080	4 520	17 052	12 363	13 917
Operating expenses		**23 690**	**24 497**	**67 842**	**66 561**	**89 488**
Operating results		**-22 503**	**-22 534**	**-62 757**	**-60 760**	**-82 121**
Financial income and expenses						
Financial income		1 289	1 551	2 493	22 982	10 796
Financial expenses		209	221	3 079	7 997	915
Net financial result	*7*	**1 080**	**1 329**	**-586**	**14 985**	**9 881**
Profit/Loss before income tax		**-21 423**	**-21 204**	**-63 343**	**-45 775**	**-72 239**
Income tax	*9*	0	**0**	0	**0**	0
Net profit/loss		**-21 423**	**-21 204**	**-63 343**	**-45 775**	**-72 239**
Other comprehensive income		0	**0**	0	**0**	0
Total comprehensive income	*5*	**-21 423**	**-21 204**	**-63 343**	**-45 775**	**-72 239**

Balance sheet *(in NOK '000)*	Note	30.09 2021	30.09 2020	31.12 2020
Non-current assets				
Property, plant and equipment	*16*	6 290	7 131	7 388
Right to use asset	*15*	1 965	757	605
Total non-current assets		**8 255**	**7 888**	**7 994**
Current assets				
Short term receivables	*7*	10 913	18 070	13 162
Cash & cash equivalents	*7*	135 513	210 233	187 967
Total current assets	*14*	**146 427**	**228 303**	**201 129**
Total assets		**154 682**	**236 190**	**209 123**
Equity and liabilities				
Equity				
Paid in capital	*10,11*	562 443	562 442	562 443
Other reserves		-426 307	-350 362	-373 199
Total equity		**136 136**	**212 080**	**189 244**
Long-term liabilities				
Other long-term liabilities		0	376	32
Lease liabilities	*15*	1 386	84	0
Total long-term liabilities	*13*	**1 386**	**460**	**32**
Short term liabilities				
Trade debtors		2 090	2 659	5 191
Lease liabilities	*15*	623	668	673
Other short-term liabilities	*7,12*	14 446	20 324	13 983
Total short-term liabilities		**17 159**	**23 650**	**19 847**
Total liabilities	*14*	**18 546**	**24 110**	**19 879**
Total equity and liabilities		**154 682**	**236 190**	**209 123**

CHANGE IN EQUITY

(in NOK '000)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Equity at beginning of period	**153 961**	**232 495**	**189 244**	**254 828**	**254 828**
Capital increase	0	316	0	316	316
Share option scheme	3 599	473	10 235	2 709	6 339
Comprehensive income in the period	-21 423	-21 204	-63 343	-45 775	-72 239
Equity at end of period	**136 136**	**212 080**	**136 136**	**212 080**	**189 244**

CASH FLOW

(in NOK '000)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Ordinary profit before taxes	-21 423	-21 204	-63 343	-45 775	-72 239
Depreciation, amortisation and write off	635	583	1 892	1 592	2 208
Leasing interest cost	10	19	29	56	75
Share options	3 599	473	10 235	2 709	6 339
Currency gain (-) / loss (+) not related to operations	-1 090	-1 156	793	-13 882	-8 526
Changes in working capital and other non-cash adjustments	5 128	-1 157	-590	-6 072	-5 248
Cash flow from operating activities	**-13 141**	**-22 443**	**-50 984**	**-61 372**	**-77 391**
Acquisition of non-current assets	0	0	-341	-3 196	-3 919
Net cash flow from investing activities	**0**	**0**	**-341**	**-3 196**	**-3 919**
Cash flow from financial activities					
Payment principal portion of lease liabilities	-168	-167	-336	-501	-668
Net proceeds from share issues	0	316	0	316	316
Net cash flow from financial activities	**-168**	**149**	**-336**	**-185**	**-352**
Net change in cash during the period	**-13 309**	**-22 294**	**-51 661**	**-64 753**	**-81 662**
Exchange rate effect on bank deposits in foreign currency	1 090	1 156	-793	13 882	8 526
Cash and cash equivalents at the beginning of the period	147 732	231 370	187 967	261 103	261 103
Cash and cash equivalents at the end of the period	**135 513**	**210 233**	**135 513**	**210 233**	**187 967**

SELECTED EXPLANATORY NOTES:

1. Nature of operation

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

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

The PCI technology has potential to improve the efficacy of 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 potential 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 2020 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 16 November 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 2021 is consistent with the consolidated financial statements for the year ended 31 December 2020.

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

4. Important accounting valuations, estimates and assumptions

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

In preparing these condensed interim financial statements, the significant judgements made by management in applying the group's accounting policies and the key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31st, 2020.

5. Earnings per share

	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Result allocated to shareholders (in NOK '000)	(21 423)	(21 204)	(63 343)	(45 775)	(72 239)
Weighted average of outstanding shares (in NOK '000)	37 326	37 286	37 326	37 272	37 285
Earnings per share (NOK per share)	-0,57	-0,57	-1,70	-1,23	-1,94

Earnings per share is not affected by dilution from outstanding share options if negative results in the period. The weighted average number of outstanding shares for YTD 2021, that are in the money, are 475 thousand share options. For Q3 there are no outstanding share options that are in the money.

6. Segment information and Other income

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

7. Credit risk, foreign currency risk and interest risk

Credit risk
PCI Biotech has no sales for 2020 and 2021 and faces therefore no credit risk on trade receivables.

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

	Not due (prepaid expenses)	Less than 3 months	3 to 12 months	More than 12 months	Total
Other receivables	6 946	181	224	3 563	10 913
Total receivables	**6 946**	**181**	**224**	**3 563**	**10 913**

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

Foreign currency risk
PCI Biotech has transactional currency exposure arising from purchases in currencies other than the functional currency (NOK). PCI Biotech has placed parts of the cash positions in Euro deposits as a hedge of the foreign currency risk for the pivotal RELEASE study. PCI Biotech has not implemented any other hedging strategy to reduce foreign currency risk.

For the first nine months of 2021 a negative accounting effect of NOK 0.8 million has been charged as financial expenses for 2021, resulting from converting Euro cash deposits into NOK as functional currency for the interim report. The effect for same period in 2020 (first nine months) was NOK 13.9 million positive.

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

8. Research and Development

All figures in '000 NOK

	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Clinical studies	14 887	14 489	39 614	41 143	57 761
Pre-clinical studies	1 720	1 767	5 172	4 638	6 607
CMC and equipment	580	1 724	2 654	5 025	6 637
Patents	1 425	1 998	3 350	3 392	4 566
Other costs	0	0	0	0	0
Total	**18 611**	**19 978**	**50 790**	**54 198**	**75 571**

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

9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 137.9 million in non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

10. Share options

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

		Number of share options	
Expiry date	Exercise price in NOK per share option	31.12.2020	30.09.2021
2022 - Q3	21.48	325 000	310 000
2024 - Q3	25.78	320 000	300 000
2025 - Q3	50.36	540 000	520 000
2026 - Q3	19.41	0	485 000
Total		**1 185 000**	**1 615 000**

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

In accordance with the authorisation granted by the Annual General Meeting 28 May 2021, the Board of Directors of PCI Biotech Holding ASA awarded a total of 485,000 share options to key employees on 6th September 2021. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 19.41, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2026.

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

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

Overview share options, Senior executives	Total holdings 31.12.2020	Allocated	Lapsed	Exercised	Expired	Total holdings 30.09.2021
Per Walday, CEO	225 000	70 000	0	0	0	295 000
Ronny Skuggedal, CFO	140 000	50 000	0	0	0	190 000
Anders Høgset, CSO	150 000	40 000	0	0	0	190 000
Kristin Eivindvik, CDO	70 000	40 000	0	0	0	110 000
Lucy Wabakken, CDO (acting)	120 000	40 000	0	0	0	160 000
Ludovic Robin, CBO	90 000	40 000	0	0	0	130 000
Amir Snapir, CMO	90 000	60 000	0	0	0	150 000
Total	**885 000**	**340 000**	**0**	**0**	**0**	**1 225 000**

11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2020	**37 326 390**	**3.00**	**111 979 170**
Transactions	-	-	-
30.09.2021	**37 326 390**	**3.00**	**111 979 170**

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

The annual general meeting in May 2021 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition, the board of directors were authorised to execute share capital increases with up to NOK 12,034,000 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has 6,200 shareholders at end of the quarter.

10 largest shareholders per 30 September 2021:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,07 %
MYRLID AS	2 110 501	5,65 %
MP PENSJON PK	1 684 529	4,51 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
NORDNET LIVSFORSIKRING AS	884 909	2,37 %
GRESSLIEN, ODD R.	803 000	2,15 %
NORDNET BANK AB	757 774	2,03 %
BERG-LARSEN, ALEXANDER	467 500	1,25 %
JANDERSEN KAPITAL AS	460 000	1,23 %
FORENEDE FORVALTNING AS	348 577	0,93 %
Total 10 largest shareholders	**12 359 648**	***33,11 %***
Others	*24 966 742*	*66,89 %*
Total	*37 326 390*	*100,00 %*

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties:

		No. of shares	
Name	**Position**	**31.12.2020**	**30.09.2021**
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)*	Board member	4 000	4 000
Andrew Hughes	Board member	0	0
Per Walday	CEO	72 700	72 700
Anders Høgset	CSO	64 800	64 800
Ronny Skuggedal	CFO	55 000	55 000
Kristin Eivindvik	CDO	25 200	25 200
Lucy Wabakken, and related parties	CDO (acting)	10 008	10 008
Ludovic Robin	CBO	0	0
Amir Snapir	CMO	0	0
Total		**378 336**	**378 336**

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

12. Other short-term liabilities

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

13. Long-term liabilities

Total long-term liabilities include public duties payables due in 1-5 years for potential future exercises of "in-the-money" share options in PCI Biotech's employee share option scheme and lease liabilities for right-to-use assets due in more than 12 months.

14. Financial assets and liabilities

Cash and cash equivalents are measured as financial instruments at fair value through other comprehensive income (OCI). The carrying amount of cash and cash equivalents is applied and disclosed since this approximately equals to fair value since these instruments have a short term to maturity. 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.

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

PCI Biotech has entered into a lease agreement with Oslo Cancer Cluster Incubator at Ullernchausséen 64 Oslo, Norway. The original lease runs to 31 December 2021 with an option for additional three more years. PCI Biotech exercised this lease option in 2021 and the lease now runs to year-end 2024. The lease agreement is subject to annual adjustment according to changes in the consumer price index. Amounts of minimum lease payment for non-cancellable operating leases under the original agreement is NOK 0.2 million (non-discounted contractual payments) for the last quarter of 2021. The minimum lease after exercise of the lease option for the additional three years is estimated to NOK 1.9 million (discounted contractual payments). Payments of principal portion of the lease liabilities are not charged to profit and loss and will only have cash flow effects. Lease liabilities due in more than 12 months are disclosed as long-term lease liabilities. PCI Biotech applies the short-term lease recognition exemption for leases related to office equipment, parking facilities at the office and a flat in Oslo available for disposition for foreign employees. Lease payments for this category of leases are consequently charged directly through profit and loss.

All figures in NOK '000

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions Q1 2021	1 813
Acquisitions Q2 2021	0
Acquisitions Q3 2021	0
Acquisition costs 30.09.2021	**3 628**
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation Q1 2021	151
Depreciation Q2 2021	151
Depreciation Q3 2021	151
Accumulated depreciation and impairment as of 30.09.2021	**1 663**
Total right to use assets - office lease as of 30.09.2021	**1 965**
Lower of remaining lease term or economic life	3.25 years
Depreciation method	Linear

(in NOK 1,000)

Lease liabilities - office	
Initial recognition 01.01.2019	1 815
Payments principal portion of the lease liability FY 2019	-657
Payments principal portion of the lease liability FY 2020	-668
Recognition at exercise of lease option for 3 more years FY 2021	1 813
Payments principal portion of the lease liability Q1 2021	-168
Payments principal portion of the lease liability Q2 2021	-168
Payments principal portion of the lease liability Q3 2021	-168
Interest expenses on the lease liability FY 2019	38
Interest expenses on the lease liability FY 2020	144
Interest expenses on the lease liability Q1 2021	10
Interest expenses on the lease liability Q2 2021	10
Interest expenses on the lease liability Q3 2021	10
Total lease liabilities for office as of 30.09.2021	**2 009**
Whereof:	
Short term lease liabilities < 1 year	623
Long term lease liabilities > 1 year	1 386

(in NOK 1,000)

Income statement effects – office lease	**Q3 2021**	**Q3 2020**	**YTD 2021**	**YTD 2020**	**FY 2020**
Depreciation of right to use asset	-151	-154	-453	-454	-605
Operating expenses for short-term leases	0	0	0	0	-170
Effect on Operating results net of tax	**-151**	**-154**	**-453**	**-454**	**-775**
Interest expenses on the lease liabilities	-10	-19	-29	-56	-144
Effect on Net financial result net of tax	**-161**	**-173**	**-482**	**-510**	**-920**
Comprehensive income effect net of tax	**-161**	**-173**	**-482**	**-510**	**-920**

16. Property, plant and equipment

PCI Biotech acquired the first lots of lasers to be used in the RELEASE study during 2019 and further lasers have been acquired during 2020 and 2021. A linear depreciation method over the expected lifetime of five years for the equipment is applied.

Equipment	**30.09 2021**	**30.09 2020**	**31.12 2020**
Carrying value at the beginning of the period	**7 388**	**5 072**	**5 072**
Acquisitions	341	3 196	3 919
Depreciation	1 439	1 138	1 603
Carrying value at the end of the period	**6 290**	**7 131**	**7 388**

17. Subsequent events

PCI Biotech is not aware of any 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

Q4 Report 2021	18 February 2021
Annual Report 2021	28 April 2022
Annual General Meeting	25 May 2022
Q1 Report 2022	11 May 2022
Q2 Report 2022	31 August 2022
Q3 Report 2022	23 November 2022

INVESTOR CONTACT

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FORWARD LOOKING STATEMENTS

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

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