



*Enabling intracellular delivery*

SECOND QUARTER AND  
FIRST HALF-YEAR REPORT  

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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 fimaCHEM 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 fimaVACC 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 fimaNAC is a technology for intracellular delivery of nucleic acids, which is currently being evaluated in collaboration with several players in the field.

## Highlights

### fima *CHEM*

- The implementation of the amended protocol and the opening of Asian sites provided increased screening and enrolment to RELEASE in Q1, but the activity declined significantly in Q2 with only three patients included. The expected timeline for the interim analysis for potential accelerated approval is revised to 2H 2023
- Recruitment in Q3 started stronger with four patients included in July and the company continues to focus on enrolment of patients into the RELEASE study, with the emphasis on regular trial management, including overall performance evaluation and site replacement
- First US patient enrolled in the RELEASE study
- Orphan drug designation granted in South Korea

### fima *VACC*

- Successful Phase I vaccination proof of concept study published in the high impact immunology journal, *Frontiers in Immunology*, demonstrating that fimaVACC enhances the immune response to peptide- and protein-based vaccines in healthy volunteers
- US patent granted for the use of fimaVACC in combination with immune checkpoint inhibitors

### fima *NAC*

- Encouraging data on enhanced delivery of mRNA for various medical applications presented at the UK based 12<sup>th</sup> Annual RNA Therapeutics Virtual Conference
- Established extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics

## 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 1H	2020 1H	2021 Q2	2020 Q2	2020 FY
Other income	3 898	3 838	2 310	1 919	7 368
Operating expenses	44 152	42 064	21 393	24 171	89 488
Operating results	-40 254	-38 226	-19 083	-22 252	-82 121
Net financial result	-1 665	13 656	937	-6 745	9 881
<b>Comprehensive income</b>	<b>-41 919</b>	<b>-24 570</b>	<b>-18 146</b>	<b>-28 997</b>	<b>-72 239</b>
<b>Cash &amp; cash equivalents</b>	<b>147 732</b>	<b>231 370</b>	<b>147 732</b>	<b>231 370</b>	<b>187 967</b>
<b>Cash flow from operating activities</b>	<b>-37 843</b>	<b>-38 927</b>	<b>-14 958</b>	<b>-16 556</b>	<b>-77 391</b>

## Operational review and development programmes overview

Programme	Indications / Therapeutics	Preclinical	Phase I	Phase II	Pivotal
 <b>fimaCHEM</b>	 <i>Bile duct cancer/ gemcitabine</i>				
 <b>fimaVACC</b>	 <i>Therapeutic cancer vaccines</i>				
 <b>fimaNAC</b>	 <i>Nucleic acid therapeutics</i>				

## 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, but expected to improve as the vaccination rates increase. The company 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 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 EU, US and South Korea.

### 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 mid-August 2021, 47 sites across 14 countries were open for recruitment and Ukraine is the last country added to the country mix.

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, which increased in Q1 2021 in both Europe and Asia. The situation has been difficult in the US but is slowly easing, with increased screening activity and the first US patient enrolled in April. Close to 60% of screened patients are randomised into the trial (similar rates across regions).

The positive trend in Q1 did unfortunately not continue in Q2, which showed a significant decline in screening activity with only three patients enrolled during the quarter. Other companies have reported similar effects, possibly as a result of the spread of the Covid-19 delta virus variant. However, we have seen a better start of Q3, with four patients recruited in July. August is usually a low recruitment month, due to the holiday season. The focus is now primarily on regular trial management, which includes performance evaluation and replacement of underperforming sites, as well as monitoring study specific risks, such as retention of randomised patients and adherence to study procedures and eligibility criteria. Early signs suggest a somewhat lower retention in the RELEASE control arm and the company is proactively pursuing strategies to address this during second half 2021.

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) depending on the further development of the pandemic and the effect of the planned measures to enhance recruitment. This communicated time range for interim readout was based on a recruitment plan that required an average quarterly inclusion of 14-18 patients going forward, which is above our best quarter to date (n = 10). This recruitment target was ambitious, but considered achievable based on previous experience, data from literature and expected effects of all measures implemented. It also assumed no further recruitment impact by Covid-19, which is now considered unlikely. On this basis, the company is now revising the expected timing for interim readout to 2H 2023 (data available approximately 3 months after recruitment of 120 patients; data cleaning and analysis expected to take 5-8 weeks). The current cash position provides a financial runway for the company's ongoing operations into 2H 2022 and is therefore not sufficient to reach the data readout inflection point.

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 1<sup>st</sup> July. Maria Norling has worked in both 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 Asia 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. The trial is open in South-Korea and Taiwan. Other commercially interesting countries 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.

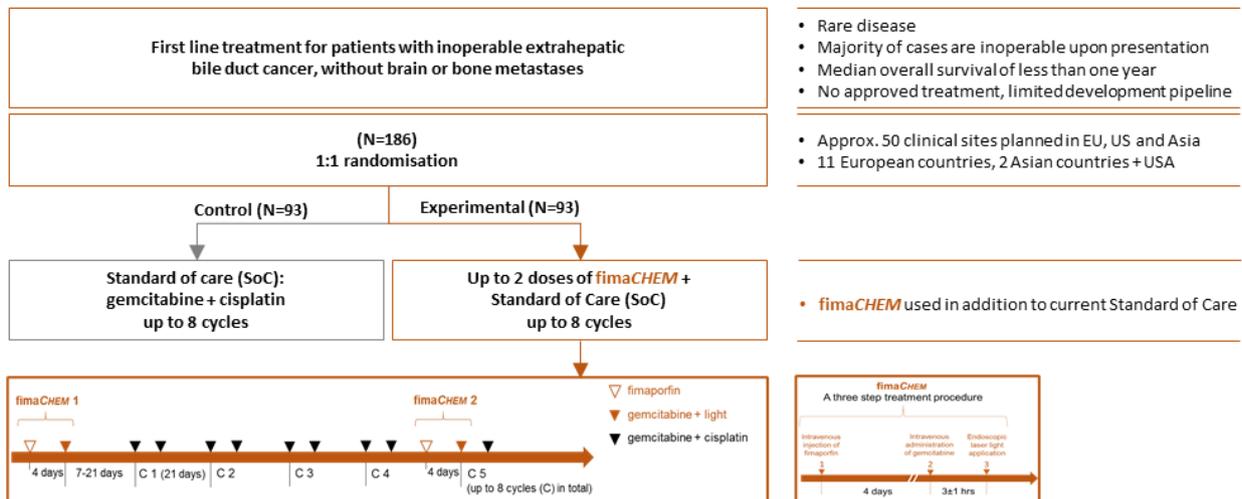
In May 2021, the Ministry of Food and Drug Safety (MFDS) in South Korea granted Orphan Drug Designation (ODD) to fimaporfin for combination treatment with gemcitabine in patients with inoperable locally advanced or metastatic bile duct cancer (cholangiocarcinoma). ODD in South Korea may under certain circumstances provide several benefits, including exemptions from required data, conditional approval and extended market exclusivity.

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%<sup>1</sup>) and taking into account that not all parts of the population in China will have access to the treatment, it can be estimated 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<sup>2</sup>.

### 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:



<sup>1</sup> PCIB internal CCA market analysis and KOL advisory meeting

<sup>2</sup> 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	<ul style="list-style-type: none"> <li>Enrolling patients on three continents</li> </ul>
Seamless safety review by IDMC* when 8 patients have undergone 2 <i>fimaCHEM</i> treatments	<ul style="list-style-type: none"> <li>IDMC safety review expected 2H 2021</li> </ul>
Tumour response interim analysis when 120 patients have been through the 3 months scan	<ul style="list-style-type: none"> <li>Interim analysis expected 2H 2023</li> </ul>
Timing and format for study conclusion may be impacted by outcome of Interim analysis	<ul style="list-style-type: none"> <li>Final analysis expected approximately 2H 2024</li> </ul>

\*IDMC = Independent Data Monitoring Committee

**Endpoints:**

Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	<ul style="list-style-type: none"> <li>Orphan drug designation in Europe, USA and S Korea</li> <li>Potentially accelerated/conditional approval</li> </ul>
Final analysis: Primary endpoint: Progression Free Survival (PFS) Key secondary endpoint: Overall Survival (OS)	<ul style="list-style-type: none"> <li>Single randomised trial sufficient based on interaction with US and EU regulatory authorities</li> </ul>

**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.

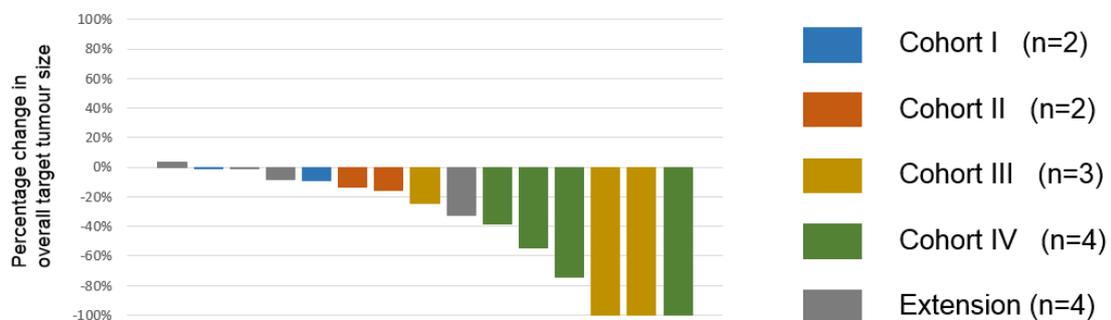
**Phase I results paved the way for the pivotal RELEASE trial with registration intent**

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 *fimaCHEM* 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.

**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 **fimaCHEM** 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 **fimaCHEM** 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<sup>3</sup>.

#### Bile duct cancer and the **fimaCHEM** 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 **fimaCHEM** 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 **fimaCHEM** Phase I study. The published studies include a wide range of different inoperable bile duct cancer patients, while the **fimaCHEM** treatment is focused solely on inoperable extrahepatic bile duct cancer.

## fimaVACC

The **fimaVACC** 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. The technology is versatile, as it can potentially be used with several modalities, including nucleic acid based technologies.

<sup>3</sup> Endosc Int Open 2020; DOI: 10.1055/a-1276-6366

## Successful clinical proof-of-concept in healthy volunteers

PCI Biotech has successfully translated **fimaVACC** 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 **fimaVACC**'s potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers. More than 90 subjects were included, and tolerability of intradermal treatment with **fimaVACC** 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 **fimaVACC** and exhibited increased functionality compared to control.

### **fimaVACC provides highly desired features for therapeutic vaccination technologies:**

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

## Proof-of-concept in healthy volunteers published

The full study results were published early January 2021 in *Frontiers in Immunology*<sup>4</sup>, 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 **fimaVACC** platform

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

The company 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 **fimaVACC** technology, such as intratumoural and intradermal vaccine delivery, initially focusing on the most apposite cancer indication before a potential broadening of the deployment of this versatile platform. The company was in Q1 2021 granted a patent related to therapeutic vaccines for melanoma, but this patent is not a decision driving factor in the ongoing development considerations.

The focus on RELEASE during the pandemic has unfortunately reduced available resources for the planning and progress of a clinical proof-of-concept trial in a disease setting for **fimaVACC**. The company has strong confidence in the commercial potential of both **fimaVACC** and **fimaNAC** and has further strengthened the organisation with a new Clinical Science Director that commenced 1<sup>st</sup> 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 exploit therapeutically, with the goal of developing novel anti-cancer therapies. Her R&D expertise and experience will further strengthen the team and she will play a key role in the development of both **fimaVACC** and **fimaNAC**.

## US patent in combination with checkpoint inhibitors

In June, a new patent was granted by the US Patent and Trademark Office (USPTO). The US patent covers the use of **fimaVACC** in combination with immune checkpoint inhibitors (ICIs). The use of ICIs has revolutionised cancer immunotherapy, as this class of drugs may induce long-lasting effects in those patients responding to treatment. Unfortunately, most patients do not respond to ICI therapy and different treatment combination strategies are explored with the aim to increase the number of patients responding. Combining ICIs with therapeutic cancer vaccines that induce relevant immune responses against the tumour cells is regarded as one of the most promising strategies. The patent granted in the

<sup>4</sup> doi.org/10.3389/fimmu.2020.576756

US covers the use of PCI Biotech's **fimaVACC** vaccination technology in combination with important classes of ICIs and an important type of immunological adjuvants (a class of so-called Toll like receptor agonists). This US patent secure protection until 2036 and this patent application is still pending in Europe and key Asian markets.

#### Research and development supported by a grant

The **fimaVACC** programme was supported by a government grant from the Research Council of Norway (BIA-programme) distributed over four years, ending first half of 2021, with an accumulated support of NOK 13.4 million.

#### Immunotherapy with the **fimaVACC** 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 **fimaVACC** 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 **fimaVACC** technology has the potential to effectively enhance intracellular delivery and vaccine presentation through these pathways.

## 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.

In February 2021 encouraging data on the delivery of RNA molecules and on the use of the **fimaNAC** delivery technology in the exciting field of RNA based therapies were presented at the 12<sup>th</sup> Annual RNA Therapeutics Virtual Conference, a UK based online event. The presented results suggest that the **fimaNAC** technology provides an appealing intracellular delivery solution for certain applications within this class of therapeutics. PCI Biotech see great potential for further development of our intracellular delivery technology, not least within the emerging field of immunotherapy. PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAC** programme.

In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics. OliX Pharmaceuticals and PCI Biotech will combine their know-how and technology platforms to explore synergies and further partnership. 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 companies will evaluate results achieved from this research collaboration to explore the potential for further development and partnership.

#### The **fimaNAC** 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 **fimaNAC** technology may resolve this issue through enhanced delivery of the majority of nucleic acid types.

## 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 deepening 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.

## 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 represents the end of the BIA grant. Other income for Q2 and 1H 2021 amounted to NOK 2.3 million (NOK 1.9 million) and NOK 3.9 million (NOK 3.8 million) respectively.

Research and development (R&D) expenses for Q2 and 1H 2021 ended at NOK 15.5 million (NOK 18.6 million) and NOK 32.2 million (NOK 34.2 million) respectively. General and administrative (G&A) expense for Q2 and 1H 2021 ended at NOK 5.9 million (NOK 5.5 million) and NOK 12.0 million (NOK 7.8 million) respectively. The change in G&A for 1H 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 effects. Operating expenses for Q2 and 1H 2021 were NOK 21.4 million (NOK 24.2 million) and NOK 44.2 million (NOK 42.1 million) respectively. Operating expenses are mainly driven by the R&D activity level and the pivotal *fimaCHEM* 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 Q2 and 1H 2021 were NOK 0.9 million (NOK -6.7 million) and NOK -1.7 million (NOK 13.7 million) respectively.

Net loss for Q2 and 1H 2021 were NOK 18.1 million (NOK 29.0 million) and NOK 42.0 million (NOK 24.6 million) respectively. The main driver of the change for 1H 2021 compared to last year was a net positive financial result in 1H 2020, resulting from the above mentioned exchange rate fluctuations.

#### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 147.7 million at end of Q2 2021, compared to NOK 188.0 million per year-end 2020. Cash flow from operations is mainly dependent on R&D activities and cash flow from operating activities was NOK -15.0 million for Q2 2021 (NOK -16.6 million), and NOK -37.8 million (NOK -38.9 million) for 1H 2021. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency were NOK 0.8 million positive for Q2 2021, compared to NOK 7.2 million negative for Q2 2020. For the first half year, the effect was 1.9 million negative in 2021, compared to 12.8 million positive in 2020.

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 share price and 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 1<sup>st</sup> July. The company has also strengthened the team for **fimaVacc** with a new Clinical Science Director, Dr Nina Gustafsson, that commenced 1<sup>st</sup> August, who also will contribute to the further development of **fimaNAc**. For business development purposes a new position as Scientific Alliance and Business Development Manager is established, commencing 1<sup>st</sup> October. The full PCI Biotech team will by then be 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.

### 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 (**fimaVACC**) and nucleic acid therapeutics (**fimaNAC**).

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

The company is fully committed to advance the **fimaCHEM** 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, **fimaVACC** and **fimaNAC**, are proceeding in accordance with the established development strategy. The Phase I study in healthy volunteers provided affirmative results on translation of the **fimaVACC** technology into humans and key data to support the programme's further development. The **fimaNAC** programme continues to follow a collaborative approach, by pursuing out-licensing opportunities in the most attractive areas for the technology.

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

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

The Board of Directors and CEO  
PCI Biotech Holding ASA  
Oslo, 30 August 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)

## RESPONSIBILITY STATEMENT

We confirm that, to the best of our knowledge, the unaudited condensed set of financial statements for the first half of 2021 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Group's consolidated assets, liabilities, financial position and results of operations, and that the interim management report includes a fair view of the information required under the Norwegian Securities Trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO  
PCI Biotech Holding ASA  
Oslo, 30 August 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

<b>PROFIT AND LOSS</b> (in NOK '000)	<b>Note</b>	<b>Q2 2021</b>	<b>Q2 2020</b>	<b>1H 2021</b>	<b>1H 2020</b>	<b>FY 2020</b>
<b>Other income</b>	6	2 310	1 919	3 898	3 838	7 368
Research and development	7,8	15 527	18 640	32 179	34 220	75 571
General and administrative		5 866	5 530	11 973	7 843	13 917
<b>Operating expenses</b>		<b>21 393</b>	<b>24 171</b>	<b>44 152</b>	<b>42 064</b>	<b>89 488</b>
<b>Operating results</b>		<b>-19 083</b>	<b>-22 252</b>	<b>-40 254</b>	<b>-38 226</b>	<b>-82 121</b>
<b>Financial income and expenses</b>						
Financial income		999	732	1 205	21 432	10 796
Financial expenses		63	7 477	2 869	7 776	915
<b>Net financial result</b>	7	<b>937</b>	<b>-6 745</b>	<b>-1 665</b>	<b>13 656</b>	<b>9 881</b>
<b>Profit/Loss before income tax</b>		<b>-18 146</b>	<b>-28 997</b>	<b>-41 919</b>	<b>-24 570</b>	<b>-72 239</b>
Income tax	9	0	0	0	0	0
<b>Net profit/loss</b>		<b>-18 146</b>	<b>-28 997</b>	<b>-41 919</b>	<b>-24 570</b>	<b>-72 239</b>
Other comprehensive income		0	0	0	0	0
<b>Total comprehensive income</b>	5	<b>-18 146</b>	<b>-28 997</b>	<b>-41 919</b>	<b>-24 570</b>	<b>-72 239</b>
<b>Balance sheet</b> (in NOK '000)						
	<b>Note</b>	<b>30.06 2021</b>	<b>30.06 2020</b>	<b>31.12 2020</b>		
<b>Non-current assets</b>						
Property, plant and equipment	16	6 774	7 562	7 388		
Right to use asset	15	2 116	908	605		
<b>Total non-current assets</b>		<b>8 891</b>	<b>8 470</b>	<b>7 994</b>		
<b>Current assets</b>						
Short term receivables	7	15 259	17 353	13 162		
Cash & cash equivalents	7	147 732	231 370	187 967		
<b>Total current assets</b>	14	<b>162 991</b>	<b>248 723</b>	<b>201 129</b>		
<b>Total assets</b>		<b>171 881</b>	<b>257 194</b>	<b>209 123</b>		
<b>Equity and liabilities</b>						
<b>Equity</b>						
Paid in capital	10,11	562 443	562 126	562 443		
Other reserves		-408 482	-329 631	-373 199		
<b>Total equity</b>		<b>153 961</b>	<b>232 495</b>	<b>189 244</b>		
<b>Long-term liabilities</b>						
Other long-term liabilities	13	19	2 102	32		
Lease liabilities	15	1 541	232	0		
<b>Total long-term liabilities</b>		<b>1 560</b>	<b>2 334</b>	<b>32</b>		
<b>Short term liabilities</b>						
Trade debtors		4 095	7 022	5 191		
Lease liabilities	15	627	668	673		
Other short-term liabilities	7,12	11 639	14 675	13 983		
<b>Total short-term liabilities</b>		<b>16 361</b>	<b>22 365</b>	<b>19 847</b>		
<b>Total liabilities</b>	14	<b>17 920</b>	<b>24 699</b>	<b>19 879</b>		
<b>Total equity and liabilities</b>		<b>171 881</b>	<b>257 194</b>	<b>209 123</b>		

## CHANGE IN EQUITY

<i>(in NOK '000)</i>	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
<b>Equity at beginning of period</b>	<b>168 741</b>	<b>260 452</b>	<b>189 244</b>	<b>254 828</b>	<b>254 828</b>
Capital increase	0	0	0	0	316
Share option scheme	3 366	1 041	6 636	2 236	6 339
Comprehensive income in the period	-18 146	-28 997	-41 919	-24 570	-72 239
<b>Equity at end of period</b>	<b>153 961</b>	<b>232 495</b>	<b>153 961</b>	<b>232 495</b>	<b>189 244</b>

## CASH FLOW

<i>(in NOK '000)</i>	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
Ordinary profit before taxes	-18 146	-28 997	-41 919	-24 570	-72 239
Depreciation, amortisation and write off	630	580	1 257	1 009	2 208
Leasing interest cost	19	19	19	37	75
Share options	3 366	1 041	6 636	2 236	6 339
Currency gain (-)/ loss (+) not related to operations	-826	7 191	1 883	-12 726	-8 526
Changes in working capital and other non-cash adjustments	0	3 610	-5 719	-4 914	-5 248
<b>Cash flow from operating activities</b>	<b>-14 958</b>	<b>-16 556</b>	<b>-37 843</b>	<b>-38 927</b>	<b>-77 391</b>
Acquisition of non-current assets	-171	-2 796	-341	-3 196	-3 919
<b>Net cash flow from investing activities</b>	<b>-171</b>	<b>-2 796</b>	<b>-341</b>	<b>-3 196</b>	<b>-3 919</b>
<b>Cash flow from financial activities</b>					
Payment principal portion of lease liabilities	0	-166	-168	-334	-668
Net proceeds from share issues	0	0	0	0	316
<b>Net cash flow from financial activities</b>	<b>0</b>	<b>-166</b>	<b>-168</b>	<b>-334</b>	<b>-352</b>
<b>Net change in cash during the period</b>	<b>-17 392</b>	<b>-19 518</b>	<b>-38 352</b>	<b>-42 458</b>	<b>-81 662</b>
Exchange rate effect on bank deposits in foreign currency	826	-7 191	-1 883	12 726	8 526
Cash and cash equivalents at the beginning of the period	164 298	258 080	187 967	261 103	261 103
<b>Cash and cash equivalents at the end of the period</b>	<b>147 732</b>	<b>231 370</b>	<b>147 732</b>	<b>231 370</b>	<b>187 967</b>

## 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 (fimaCHEM), and as a platform that may both potentiate the effect of vaccines (fimaVACC) and delivery of nucleic acids (fimaNAC). PCI Biotech has two active clinical development programmes; one project in the fimaCHEM programme and the other in the fimaVACC programme. The fimaCHEM 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 fimaVACC project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fimaNAC 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 30 August 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 31<sup>st</sup>, 2020.

#### 5. Earnings per share

	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
Result allocated to shareholders (in NOK '000)	(18 146)	(28 997)	(41 919)	(24 570)	(72 239)
Weighted average of outstanding shares (in NOK '000)	37 326	37 266	37 326	37 266	37 285
Earnings per share (NOK per share)	-0,49	-0,78	-1,12	-0,66	-1,94

Weighted average of outstanding diluted shares is the 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. The weighted average number of outstanding shares for Q2 2021 and 1H 2021, that are in the money, are 610 thousand share options, but as the result is negative in both periods there are no impact of dilution effects for the earnings per share calculation.

#### 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	7 055	459	5 369	2 375	15 259
Total receivables	7 055	459	5 369	2 375	15 259

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.

Per end of Q2 2021 a negative accounting effect of NOK 1.9 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 was NOK 12.8 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

	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
Clinical studies	11 821	14 225	24 728	26 655	57 761
Pre-clinical studies	2 047	1 367	3 452	2 871	6 607
CMC and equipment	747	2 252	2 074	3 301	6 637
Patents	911	797	1 925	1 394	4 566
Other costs	0	0	0	0	0
<b>Total</b>	<b>15 527</b>	<b>18 640</b>	<b>32 179</b>	<b>34 220</b>	<b>75 571</b>

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 133.8 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:

Expiry date	Exercise price in NOK per share option	Number of share options	
		31.12.2020	30.06.2021
2022 - Q3	21.48	325 000	310 000
2024 - Q3	25.78	320 000	300 000
2025 - Q3	50.36	540 000	540 000
<b>Total</b>		<b>1 185 000</b>	<b>1 130 000</b>

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 1,130,000 have been granted by the Board of Directors per end of the quarter.

Overview share options, Senior executives	Total holdings					Total holdings 30.06.2021
	31.12.2020	Allocated	Lapsed	Exercised	Expired	
Per Walday, CEO	225 000	0	0	0	0	225 000
Ronny Skuggedal, CFO	140 000	0	0	0	0	140 000
Anders Høgset, CSO	150 000	0	0	0	0	150 000
Kristin Eivindvik, CDO	60 000	0	0	0	0	60 000
Lucy Wabakken, CDO (acting)	120 000	0	0	0	0	120 000
Ludovic Robin, CBO	90 000	0	0	0	0	90 000
Amir Snapir, CMO	90 000	0	0	0	0	90 000
<b>Total</b>	<b>875 000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>875 000</b>

## 11. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
<b>31.12.2020</b>	<b>37 326 390</b>	<b>3.00</b>	<b>111 979 170</b>
Transactions	-	-	-
<b>30.06.2021</b>	<b>37 326 390</b>	<b>3.00</b>	<b>111 979 170</b>

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 close to 6,400 shareholders at end of the quarter.

### 10 largest shareholders per 30 June 2021:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,07 %
MYRLID AS	2 500 000	6,70 %
MP PENJON PK	1 650 729	4,42 %
RADFORSK INVESTERINGSSTIFTELSE	1 082 415	2,90 %
NORDNET LIVSFORSIKRING AS	808 170	2,17 %
GRESSLIEN, ODD R.	780 000	2,09 %
NORDNET BANK AB	714 586	1,91 %
BERG-LARSEN, ALEXANDER	481 200	1,29 %
JANDERSEN KAPITAL AS	460 000	1,23 %
FORENEDE FORVALTNING AS	335 000	0,90 %
<b>Total 10 largest shareholders</b>	<b>12 572 543</b>	<b>33,68 %</b>
<i>Others</i>	<i>24 753 847</i>	<i>66,32 %</i>
<i>Total</i>	<i>37 326 390</i>	<i>100,00 %</i>

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

Name	Position	No. of shares	
		31.12.2020	30.06.2021
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
<b>Total</b>		<b>378 336</b>	<b>378 336</b>

\* 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. 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 in PCI Biotech's employee share option scheme and lease payments

for right-to-use assets due in more than 12 months per end of the quarter.

#### 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 0.3 million (non-discounted contractual payments) for the second half 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

<b>Right to use asset - office lease</b>	
Initial recognition 01.01.2019	1 815
Acquisitions FY 2020	0
Acquisitions Q1 2021	1 813
Acquisitions Q2 2021	0
<b>Acquisition costs 30.06.2021</b>	<b>3 628</b>
Depreciation FY 2019	604
Depreciation FY 2020	605
Depreciation Q1 2021	151
Depreciation Q2 2021	151
<b>Accumulated depreciation and impairment as of 30.06.2021</b>	<b>1 512</b>
<b>Total right to use assets - office lease as of 30.06.2021</b>	<b>2 116</b>
Lower of remaining lease term or economic life	3.5 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
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
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
<b>Total lease liabilities for office as of 30.06.2021</b>	<b>2 168</b>
Whereof:	
Short term lease liabilities < 1 year	627
Long term lease liabilities > 1 year	1 541

<b>Income statement effects – office lease</b>	<b>Q2 2021</b>	<b>Q2 2020</b>	<b>1H 2021</b>	<b>1H 2020</b>	<b>FY 2020</b>
Depreciation of right to use asset	-151	-151	-302	-302	-605
Operating expenses for short-term leases	0	0	0	0	-170
<b>Effect on Operating results net of tax</b>	<b>-151</b>	<b>-151</b>	<b>-302</b>	<b>-302</b>	<b>-775</b>
Interest expenses on the lease liabilities	-10	-18	-20	-36	-144
<b>Effect on Net financial result net of tax</b>	<b>-161</b>	<b>-169</b>	<b>-322</b>	<b>-338</b>	<b>-920</b>
<b>Comprehensive income effect net of tax</b>	<b>-161</b>	<b>-169</b>	<b>-322</b>	<b>-338</b>	<b>-920</b>

### 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.

<b>Equipment</b>	<b>30.06 2021</b>	<b>30.06 2020</b>	<b>31.12 2020</b>
<b>Carrying value at the beginning of the period</b>	<b>7 388</b>	<b>5 072</b>	<b>5 072</b>
Acquisitions	341	3 196	3 919
Depreciation	955	706	1 603
<b>Carrying value at the end of the period</b>	<b>6 774</b>	<b>7 562</b>	<b>7 388</b>

### 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
fimaCHEM:	PCI Biotech's development program for enhancement of generic chemotherapies
fimaNAC:	PCI Biotech's development program for delivery of nucleic acids
fimaVACC:	PCI Biotech's development program for a vaccination technology
HPV:	Human papillomavirus
IDMC:	Independent Data Monitoring Committee
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 (1 <sup>st</sup> January – 31 <sup>st</sup> December)
1H:	First half year (1 <sup>st</sup> January – 30 <sup>th</sup> June)
2H:	Second half year (1 <sup>st</sup> July – 31 <sup>st</sup> December)
Q1:	First quarter (1 <sup>st</sup> January – 31 <sup>st</sup> March)
Q2:	Second quarter (1 <sup>st</sup> April – 30 <sup>th</sup> June)
Q3:	Third quarter (1 <sup>st</sup> July – 30 <sup>th</sup> September)
Q4:	Fourth quarter (1 <sup>st</sup> October – 31 <sup>st</sup> December)
YTD:	Year to date

## FINANCIAL CALENDAR

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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