



Unlocking the potential of innovative medicines

FIRST QUARTER 2020
INTERIM REPORT

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 applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic vaccines. Successful clinical proof of concept was achieved in a Phase I study in healthy volunteers in 2019. The third programme fimaNAC is a technology for intracellular delivery of nucleic acids, which is currently being evaluated in collaboration with key players in the field.

Highlights in the quarter

fima *CHEM*

- The main priorities during the COVID-19 pandemic has been identification and implementation of potential mitigating actions for the RELEASE study progress, as well as identification and removal of unnecessary recruitment hurdles in the study protocol. PCI Biotech has not yet a complete picture of the consequences for the RELEASE study, but delays in patient recruitment and increased costs are expected
- Several new initiatives to recoup long-term recruitment projections are being implemented, including potential modifications to screening parameters and further expansion into new countries. These new initiatives are being implemented to accelerate patient inclusion when the current restrictions of the COVID-19 pandemic are resolved, with the aim to reach interim analysis by Q2 2022. It is however currently not clear that the cash-position will suffice to reach interim read of the RELEASE trial, given the uncertainty surrounding long-term consequences of the unprecedented situation with the COVID-19 pandemic
- The majority of sites have halted or reduced patient screening and we are still awaiting enrolment of the first US patient. Site activations are delayed, but nonetheless 1 European and 3 US RELEASE study sites have opened since the Q4 2019 report. 34 of the 40 initially planned sites were open by end-April 2020
- Site preparations are ongoing for addition of Asian sites in 2020, to provide access to hospitals and KOL's in a region with higher prevalence of bile duct cancer and to enhance patient recruitment. So far progress has not been significantly impacted by the COVID-19 pandemic and regulatory approval has been achieved in Taiwan

fima *VACC*

- Two US patents granted in 2020 with broad coverage for the combination of fima *VACC* with various cytokines and a new important class of adjuvants
- A two-pronged development strategy is pursued, with Phase I results being used both in direct partnering efforts and planning for clinical proof of concept in a disease setting

Corporate

- The management team has been strengthened with appointment of CMO Dr Amir Snapir and CBO Mr Ludovic Robin

Key figures

(In NOK 1,000)	2020 Q1	2019 Q1	2019 FY
Other income	1 929	2 245	9 392
Operating expenses	17 893	20 354	98 195
Operating results	-15 974	-17 929	-88 804
Net financial result	20 401	-4 895	58
Comprehensive income	4 427	-22 824	-88 746
Cash & cash equivalents	258 080	328 757	261 103
Cash flow from operating activities	-22 866	-16 489	-83 471

Operational review and development programmes overview

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

Implications of the COVID-19 pandemic

PCI Biotech is closely monitoring potential implications on its short- and long-term operations following the development of the COVID-19 pandemic in 2020. PCI Biotech's overriding priority has been the safety of its staff, patients participating in the clinical trial and its collaborators. Other key priorities are now identification and implementation of potential mitigating actions for the **fimaCHEM** RELEASE study progress during the pandemic in collaboration with our contract research organisation, as well as identification and removal of unnecessary recruitment hurdles in the study protocol. PCI Biotech has not identified any major near-term shortage in supplies of investigational products or devices for the trial. PCI Biotech has per date of this report not a complete picture of consequences regarding timelines and costs for the RELEASE study, but delays and increased costs are expected.

PCI Biotech has a solid cash-position per Q1 2020, partly placed in EUR. It is however currently not clear that the cash-position will suffice to reach interim read of the RELEASE trial, given the uncertainty surrounding long-term consequences of the unprecedented situation with the COVID-19 pandemic.

For the **fimaVACC** and **fimaNAC** programmes the main identified implications are transient downturn in business development activities.

fimaCHEM

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

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

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

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

RELEASE start-up activities and new initiatives

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

By date of this report, the company had received regulatory and ethics approvals for USA and 10 out of 11 planned European countries; Norway, Germany, France, Spain, Italy, Belgium, Poland, Sweden, Denmark and Finland. The remaining country is UK. The study was initially planned to be executed in approximately 40 clinical sites, of which 34 sites had opened for recruitment by end-April 2020. 5 of these sites are in the US and we are awaiting enrolment of the first US patient. In addition, regulatory approval for Taiwan was achieved in March 2020.

The RELEASE study has enthused investigators that are actively looking for patients, which is very important for clinical studies in rare patient groups such as cholangiocarcinoma. The opening of sites is however behind the original plan, and further impacted by the COVID-19 pandemic, which affects patient recruitment and study recruitment projections.

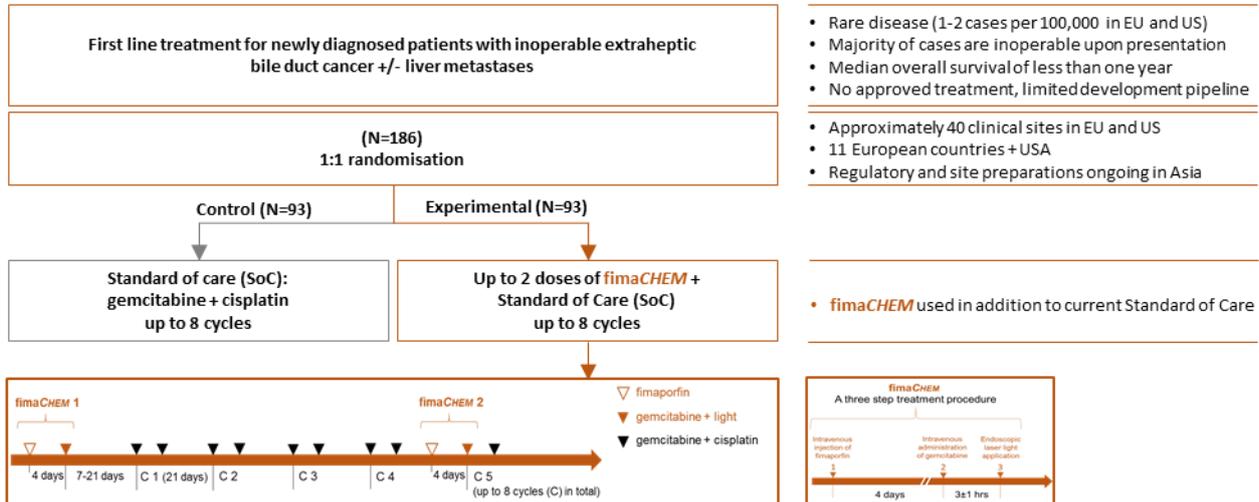
Several new initiatives to recoup long-term recruitment projections are being explored and implemented to accelerate patient inclusion when the current restrictions of the COVID-19 pandemic are resolved, with the aim to reach interim analysis by Q2 2022. These initiatives include potential modifications to screening parameters for removal of unnecessary recruitment hurdles, deployment of field-based personnel to understand patient flow and facilitate enrolment and expansion of the trial into new countries.

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

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

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

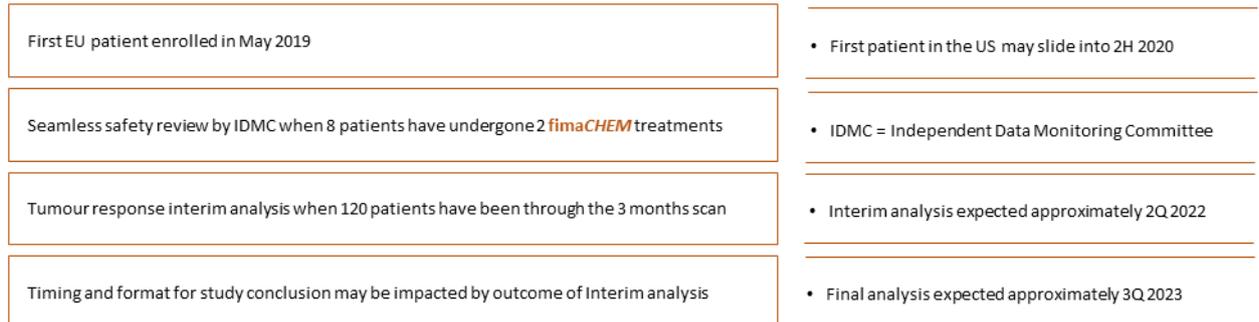
Study overview:



- Rare disease (1-2 cases per 100,000 in EU and US)
- Majority of cases are inoperable upon presentation
- Median overall survival of less than one year
- No approved treatment, limited development pipeline
- Approximately 40 clinical sites in EU and US
- 11 European countries + USA
- Regulatory and site preparations ongoing in Asia

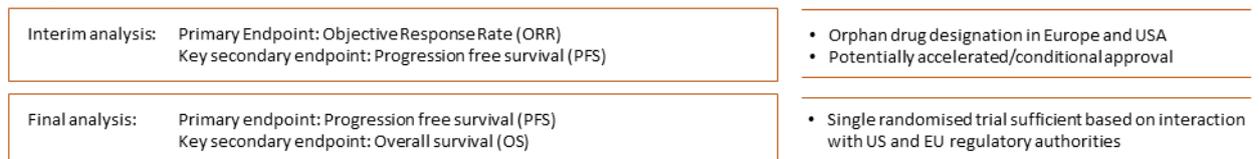
- **fimaCHEM** used in addition to current Standard of Care

Milestones and timelines:



- First patient in the US may slide into 2H 2020
- IDMC = Independent Data Monitoring Committee
- Interim analysis expected approximately 2Q 2022
- Final analysis expected approximately 3Q 2023

Endpoints:



- Orphan drug designation in Europe and USA
- Potentially accelerated/conditional approval
- Single randomised trial sufficient based on interaction with US and EU regulatory authorities

Regular communication milestones for the RELEASE study

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

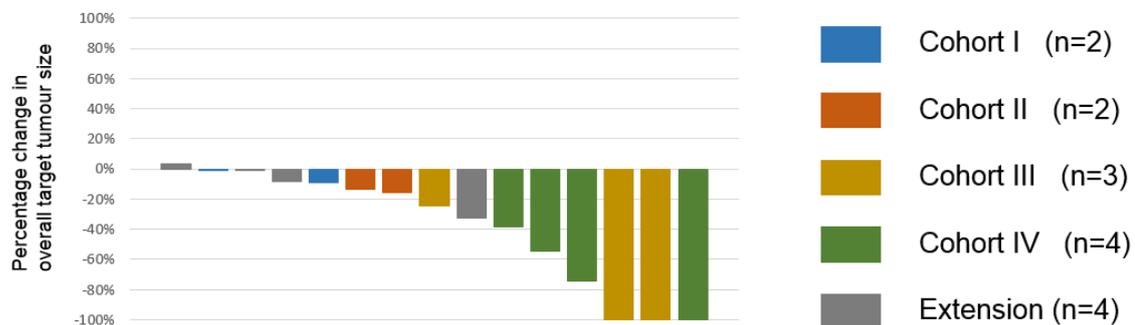
Phase I results paved the way for the pivotal RELEASE trial with registration intent

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

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

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

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



Tumour response translates into encouraging survival data

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

The group in the dose escalation study that received the RELEASE study dose (n=6, cohort IV) had a mOS of 22.8 months. Three of these patients exceeded 30 months survival, including one patient still alive more than four years after inclusion in the study. The mOS in the extension group (n=7), where patients received up to two **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, PCI Biotech is pleased to see that the positive signs of tumour response seem to translate into encouraging survival data.

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

Successful clinical proof-of-concept in healthy volunteers

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

fimaVACC provides highly desired features for therapeutic vaccination technologies:

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

The Phase I results showed a substantial increase in number of T-cell responders to HPV peptides already after two vaccinations, and a clear enhancement in the T-cell responses compared to the control

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

More than 90 subjects were included, and tolerability of intradermal treatment with **fimaVACC** is established across a wide range of doses. The study results were presented at the ESMO Immunology Congress in December 2019 and PCI Biotech aims for a publication in a relevant scientific journal in 2020.

Collaboration with international immunotherapy experts

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

Potential COVID-19 opportunities

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

New US patents granted

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

Research and development supported by a grant

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

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 vaccine presentation through these pathways.

fimaNAC

The **fimaNAC** programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage collaborative programme, with six research collaborations established with key players in the field.

The current collaboration partners include AstraZeneca and the five biotechnology companies Bavarian Nordic, BioNTech, eTheRNA immunotherapies, IMV and Phio Pharmaceuticals. All these collaboration partners are exploring synergies between their proprietary nucleic acid technologies and the **fimaNAC** technology, with potential for further deepening of the partnerships.

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

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.

Corporate

Management changes

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

Dr. Hans Olivecrona has been CMO since autumn 2017 and has provided instrumental drive and competence to PCI Biotech's clinical projects, including design and start-up of the pivotal RELEASE study. From July 2019, the current CMO Dr. Olivecrona has operated via a consultancy agreement, and he will continue to be available for PCI Biotech on a consultancy basis to secure a smooth transition.

In April 2020, PCI Biotech announced the appointment of Mr Ludovic Robin, PharmD, MBA, as Chief Business Officer (CBO), commencing from May 2020. Mr Robin will also serve as a member of PCI Biotech's executive management team. He will lead all business and commercial development activities

and be a key contributor to the strategic decision making for the existing pipeline and to capture new opportunities. Over the last twenty-five years, Ludovic has held numerous international managerial positions providing leadership in the pharmaceutical industry in the areas of international research and development, business development, as well as marketing and sales. In particular, he has participated in the launch of more than fifteen original orphan drugs or specialty pharmaceuticals. Mr Robin joined Shire in 2004 serving as Marketing Manager, Business Unit Director, Marketing Director and Commercial Operations Head of France/Benelux. In 2016 he joined Advicenne, a French biotech listed on Euronext as CBO, deputy CEO, responsible for commercial strategy of the drug candidates under development/registration in EU and US. Mr Robin holds a Doctorate of Pharmacy (PharmD) from Lyon I University, a Master's in Industrial Pharmacy from Lyon Institute of Industrial Pharmacy, and an MBA from HEC Paris.

Financial review

Income Statement

(Figures in brackets = same period 2019 unless stated otherwise)

The Group has not recorded revenues for the financial year 2020 nor 2019. Grants received from public sources as the Norwegian Research Council "BIA" and "SkatteFUNN" are recorded as other income. Other income for Q1 amounted to NOK 1.9 million (NOK 2.4 million). The SkatteFUNN tax scheme has been modified by the authorities with effect from 2020, reducing the maximum benefit level. Timelines for PCI Biotech's BIA supported project has been extended with one year, until end of 2021. These changes cause reduction in other income for the quarter compared to 2019.

Research and development (R&D) expenses for Q1 ended at NOK 15.6 million (NOK 16.7 million). Operating expenses for the quarter were NOK 17.9 million (NOK 20.4 million). Operating expenses are mainly driven by the R&D activity level. The pivotal fimaCHEM trial is the main cost driver, in both Q1 2020 and Q1 2019. For Q1 2020 the operating expenses are positively impacted by the change in estimated social security liabilities (recognised as long- and short-term liabilities) in connection with the share option scheme for employees. The net positive non-cash P&L effect for the share option scheme is NOK 2.0 million in Q1 2020 compared to Q1 2019.

Net financial results for Q1 2020 were NOK 20.4 million positive, compared to NOK 4.9 million negative in Q1 2019. The 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, and interest on bank deposits.

For the first time PCI Biotech presents a net positive result in the quarter, solely driven by the positive net financial result, which is due to positive exchange rate effects on bank deposits. Net profit for the quarter was NOK 4.4 million (net loss NOK 22.8 million).

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 258.1 million at the end of the quarter, compared to NOK 261.1 million per year-end 2019. Cash flow from operations is mainly dependent on R&D activities. Cash flow from operating activities was NOK -22.9 million in the quarter, compared to NOK -16.5 million Q1 2019, reflecting timing differences in settlement of liabilities from operational activities. All cash and cash equivalents are placed as bank deposits. Exchange rate effects on bank deposits in foreign currency was NOK 19.9 million positive in the quarter, compared to NOK 5.4 million negative in Q1 2019.

The increase in short term receivables per end of Q1 2020 compared to Q1 2019 is mainly due to advance payments during 2019 in connection with initiation of the RELEASE trial. Other long-term

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

Other

Risks and uncertainty factors for 2020

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

Related party transactions

PCI Biotech is relying on services provided by third parties, including related parties, as a result of its organisational set-up. PCI Biotech considers its business relationship with The Norwegian Radium Hospital Research Foundation as the only material ordinary related party transactions per year end of March 2020. Please see note 7 Related party transactions for further details.

Post-closing events

In April 2020, PCI Biotech announced the appointment of Mr Ludovic Robin, PharmD, MBA, as Chief Business Officer (CBO), commencing from May 2020. Mr Robin will also serve as a member of PCI Biotech's executive management team. He will lead all business and corporate development activities and be a key contributor to the strategic decision making for the existing pipeline and to capture new opportunities.

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

Outlook

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

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

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

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

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

- Effectively drive the **fimaCHEM** clinical 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, 5 May 2020

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 <i>(in NOK 1,000)</i>	Note	Q1 2020	Q1 2019	FY 2019
Other income	6	1 919	2 425	9 392
Research and development	7,9	15 580	16 739	83 312
General and administrative		2 313	3 615	14 883
Operating expenses		17 893	20 354	98 195
Operating results		-15 974	-17 929	-88 804
Financial income and expenses				
Financial income		20 700	659	2 737
Financial expenses		299	5 554	2 680
Net financial result	8	20 401	-4 895	58
Profit/Loss before income tax		4 427	-22 824	-88 746
Income tax	10	0	0	0
Net profit/loss		4 427	-22 824	-88 746
Other comprehensive income		0	0	0
Total comprehensive income	5	4 427	-22 824	-88 746

BALANCE SHEET <i>(in NOK 1,000)</i>	Note	31.03 2020	31.03 2019	31.12 2019
Non-current assets				
Property, plant and equipment	17	5 194	39	5 072
Right to use asset	16	1 060	1 665	1 211
Total non-current assets		6 254	1 704	6 283
Current assets				
Short term receivables	8	16 594	9 968	14 646
Cash & cash equivalents	8	258 080	328 757	261 103
Total current assets		274 673	338 725	275 749
Total assets		280 927	340 429	282 032
Equity and liabilities				
Equity				
Paid in capital	11,12	562 126	562 119	562 126
Other reserves		-301 674	-243 812	-307 297
Total equity		260 452	318 308	254 828
Long term liabilities				
Other long term liabilities	14	738	96	2 037
Lease liabilities	16	380	1 169	539
Total long term liabilities		1 119	1 265	2 576
Short term liabilities				
Trade debtors		2 828	5 391	8 601
Lease liabilities	16	668	657	657
Other short term liabilities	7,13	15 862	14 808	15 370
Total short term liabilities		19 357	20 856	24 628
Total liabilities		20 476	22 121	27 204
Total equity and liabilities		280 927	340 429	282 032

CHANGE IN EQUITY

<i>(in NOK '000)</i>	31.03 2020	31.03 2019	31.12 2019
Equity at beginning of period	254 828	339 954	339 954
Capital increase	0	839	1 183
Share option scheme	1 195	339	2 436
Comprehensive income in the period	4 427	-22 824	-88 746
Equity at end of period	260 452	318 308	254 828

CASH FLOW

<i>(in NOK '000)</i>	Q1 2020	Q1 2019	FY 2019
Ordinary profit before taxes	4 427	-22 824	-88 746
Depreciation, amortisation and write off	429	153	955
Leasing interest cost	19	9	37
Share options	1 195	339	2 436
Currency gain(-)/ loss(+) not related to operations	-19 917	5 445	1 649
Net interest paid/received	-495	-527	-1 776
Changes in working capital and other non-cash adjustments	-8 525	915	1 973
Cash flow from operating activities	-22 866	-16 489	-83 471
Net interest paid/received	495	527	1 776
Acquisition of non-current assets	-400	-	-5 405
Net cash flow from investing activities	95	527	-3 629
Cash flow from financial activities			
Payment principal portion of lease liabilities	-168	-	-657
Net proceeds from share issues	-	838	1 183
Net cash flow from financial activities	-168	838	526
Net change in cash during the period	-22 940	-15 124	-86 574
Exchange rate effect on bank deposits in foreign currency	19 917	-5 445	-1 649
Cash and cash equivalents at the beginning of the period	261 103	349 326	349 326
Cash and cash equivalents at the end of the period	258 080	328 757	261 103

SELECTED EXPLANATORY NOTES:

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA, the fully owned subsidiary PCI Biotech AS and the dormant Icelandic Branch PCI Biotech Utibu. 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 substantial 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 has initiated the pivotal clinical RELEASE study with registration intent for the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agents 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 2019 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 5 May 2020.

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

3. Summary of significant accounting policies

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

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

4. Important accounting valuations, estimates and assumptions

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

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

5. Earnings per share

Earnings per share

	Q1 2020	Q1 2019	FY 2019
Result allocated to shareholders (in NOK '000)	4 427	(22 824)	(88 746)
Weighted average of outstanding shares (in '000)	37 266	37 185	37 229
Earnings per share (NOK per share)	0,12	-0,61	-2,38

Diluted earnings per share:

	Q1 2020	Q1 2019	FY 2019
Result allocated to shareholders (in NOK '000)	4 427	(22 824)	(88 746)
Weighted average of outstanding shares (in '000)	37 971	37 671	37 935
Earnings per share (NOK per share)	0,12	-0,61	-2,38

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

6. Segment information and Other income

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

7. Related party transactions

PCI Biotech is relying on services provided by third parties, included related parties, as a result of its organisational set-up. PCI Biotech considers that its business relationship with The Norwegian Radium Hospital Research Foundation regarding research and overall PCI technology development represent related party transactions.

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

Purchase of services	Q1 2020	Q1 2019	FY 2019
The Norwegian Radium Hospital Research Foundation	423	639	2 091

At the end of the quarter PCI Biotech had NOK 0.4 million in short-term liability to The Norwegian Radium Hospital Research Foundation.

8. Credit risk, foreign currency risk and interest risk

Credit risk

PCI Biotech has no sales for 2019 and 2020 and faces therefore no credit risk.

Maturity profile on short-term 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	7 521	1 261	6 625	1 188	16 594
Total receivables	7 521	1 261	6 625	1 188	16 594

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

Foreign currency risk

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

In the quarter exchange rate fluctuation on cash deposits placed in Euro generated a positive accounting effect of NOK 19.9 million. From inception in October 2018 the Euro deposits have had a net positive accounting effect of NOK 27.4 million.

Interest risk

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

9. Research and Development

All figures in '000 NOK

	Q1 2020	Q1 2019	FY 2019
Clinical studies	12 430	12 818	62 971
Pre-clinical studies	1 504	1 990	6 198
CMC and equipment	1 049	1 279	10 716
Patents	597	651	3 427
Other costs	0	0	0
Total	15 580	16 739	83 312

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

10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 109 million in non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

11. 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	
		31.12.2019	31.03.2020
2020 - Q3	7.84	26 000	26 000
2020 - Q3	3.26	34 500	34 500
2022 - Q3	21.48	325 000	325 000
2024 - Q3	25.78	320 000	320 000
Total		705 500	705 500

The current authorisation, granted by the Annual General Meeting in May 2019, for the employee share option program allows for a total of 2,790,000 share options, of which 745,500 have been granted by the Board of Directors, including 40,000 share options exercised in Q3 2019.

Overview share options, Senior executives	Total holdings 31.12.2019		Total holdings 31.03.2020		
	Allocated	Lapsed	Exercised	Expired	
Per Walday, CEO	164 000	0	0	0	164 000
Ronny Skuggedal, CFO	116 000	0	0	0	116 000
Anders Høgset, CSO	106 000	0	0	0	106 000
Kristin Eivindvik, PD	73 500	0	0	0	73 500
Hans Olivecrona, CMO*	0	0	0	0	0
Total	459 500	0	0	0	459 500

* Transitioned from an employee to a consultant position by 30 June 2019 and all unexercised share options were terminated.

12. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2019	37 265 890	3.00	111 797 670
Transactions			
31.03.2020	37 265 890	3.00	111 797 670

The annual general meeting in May 2019 authorised the board of directors to execute share capital increases by issuing up to 2,790,000 shares with a nominal value of NOK 3.00 in connection with the company's employee share option program. The authorisation is valid for one year. In addition the board of directors were authorised to execute share capital increases with up to NOK 12,004,700 in connection with private placements. The authorisation shall not be used to increase share capital by an amount in excess of 10% of the share capital, based on the share capital per date of the authorisation and potential share capital increases in relation to the employee share option program. The authorisation may be used for general corporate purposes and is valid for one year.

PCI Biotech has more than 5,100 shareholders at the end of March 2020.

10 largest shareholders per 31 March 2020:

Name	No. of shares	Ownership
FONDSVANSE AS	3 760 443	10,09 %
Myrlid AS	2 465 000	6,61 %
MP PENSJON PK	2 258 206	6,06 %
RADIUMHOSPITALET'S FORSKNINGSSSTIFT.	1 281 415	3,44 %
NORDNET LIVSFORSIKRING AS	1 107 063	2,97 %
GRESSLIEN	721 000	1,93 %
Nordnet Bank AB	610 271	1,64 %
Jandersen Kapital AS	500 000	1,34 %
BERG-LARSEN	477 400	1,28 %
ESTI AS	386 000	1,04 %
Total 10 largest shareholders	13 566 798	36,41 %
<i>Others</i>	<i>23 699 092</i>	<i>63,59 %</i>
<i>Total</i>	<i>37 265 890</i>	<i>100,00 %</i>

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

Name	Position	No. of shares	
		31.12.2019	31.03.2020
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)*	Board member	4 000	4 000
Andrew Hughes	Board member	0	0
Per Walday	CEO	68 300	68 300
Anders Høgset	CSO	63 300	63 300
Ronny Skuggedal	CFO	43 000	43 000
Kristin Eivindvik	CDO	18 800	18 800
Hans Olivecrona**	CMO*	NA	NA
Total		344 028	344 028

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

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

13. Other short-term liabilities

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

14. Other long-term liabilities

Long term liabilities include public duties payables due in 1-4 years for potential future exercises of "in-the-money" share options per end of the quarter in PCI Biotech's employee share option scheme and lease liabilities due in 1-2 years according to IFRS 16. See note 16 for further details regarding IFRS 16 and the related long-term lease liability.

15. Financial assets and liabilities

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

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

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

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

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

All figures in '000 NOK

Right to use asset - office lease	
Initial recognition 01.01.2019	1 815
Acquisition costs 31.12.2019	1 815
Acquisitions Q1 2020	0
Acquisition costs 31.03.2020	1 815
Depreciation FY 2019	604
Depreciation Q1 2020	151
Accumulated depreciation and impairment as of 31.03.2020	755
Total right to use assets - office lease as of 31.03.2020	1 060
Lower of remaining lease term or economic life	1.75 years
Depreciation method	Linear
Lease liabilities - office	
Initial recognition 01.01.2019	1 815
Payments principal portion of the lease liability 2019	-657
Payments principal portion of the lease liability Q1 2020	-167
Interest expenses on the lease liability 2019	38
Interest expenses on the lease liability Q1 2020	18
Total lease liabilities for office as of year-end	1 048
Whereof:	
Short term lease liabilities < 1 year	668
Long term lease liabilities > 1 year	380
Income statement effects Q1 2020 – office lease	
Depreciation of right to use asset	-151
Effect on Operating results net of tax	-151
Interest expenses on the lease liabilities	-18
Effect on Net financial result net of tax	-18
Comprehensive income effect net of tax	-169
Cash flow effects Q1 2020 - office lease	
Payments principal portion of the lease liability Q1 2020	-167

Payments of principal portion of the lease liabilities are not charged to profit and loss under IFRS 16 and will only have cash flow effects.

17. Property, plant and equipment

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

Equipment	31.03 2020	31.03 2019	31.12 2019
Carrying value at the beginning of the period	5 072	17	17
Acquisitions	400	23	5 405
Depreciation	278	1	350
Carrying value at the end of the period	5 194	39	5 072

18. Subsequent events

In April 2020, PCI Biotech announced the appointment of Mr Ludovic Robin, PharmD, MBA, as Chief Business Officer (CBO), commencing from May 2020. Mr Robin will also serve as a member of PCI Biotech's executive management team. He will lead all business and corporate development activities and be a key contributor to the strategic decision making for the existing pipeline and to capture new opportunities.

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

DEFINITIONS AND GLOSSARY

Amphinex:	Trade name of the clinical intravenous formulation of fimaporfin
BIA:	User-driven research-based innovation program by the Research Council of Norway
CCA:	Cholangiocarcinoma – Bile duct cancer
CRC:	Cohort Review Committee
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
IND	Investigational New Drug
<i>In vitro</i> :	Studies performed with cells or biological molecules studied outside their normal biological context; for example proteins are examined in solution, or cells in artificial culture medium.
<i>In vivo</i> :	Studies in which the effects of various biological entities are tested on whole, living organisms usually animals.
KLH	Keyhole limpet hemocyanin
ODD:	Orphan Drug Designation
ORR:	Overall Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PCIB:	PCI Biotech's ticker at Oslo Børs
PFS:	Progression Free Survival
RELEASE:	Name of PCI Biotech's pivotal study for inoperable extrahepatic bile duct cancer
R&D:	Research and Development
SAC:	Scientific Advisory Committee
SoC:	Standard of Care
NOK:	Norwegian kroner
FY:	Financial year (1 st January – 31 st December)
Q1:	First quarter (1 st January – 31 st March)
Q2:	Second quarter (1 st April – 30 th June)
Q3:	Third quarter (1 st July – 30 th September)
Q4:	Fourth quarter (1 st October – 31 st December)

FINANCIAL CALENDAR

Q2 Report 2020	26 August	2020
Q3 Report 2020	11 November	2020

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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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