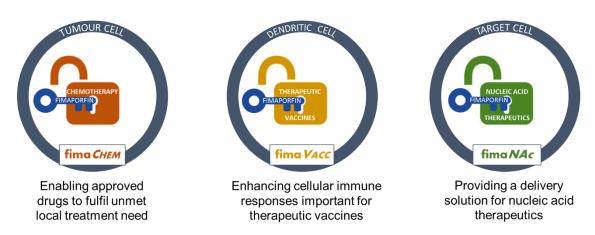




# Unlocking the potential of innovative medicines

FOURTH QUARTER AND PRELIMINARY FULL YEAR REPORT 2019

### LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS



### TRIGGERED ENDOSOMAL RELEASE

### **ABOUT PCI BIOTECH**

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

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



### Highlights in the quarter

### fima *CHEM*

- The encouraging early results on survival from the Phase I study in inoperable extrahepatic bile duct cancer have been quality checked and finally confirmed to a median overall survival (mOS) of 16.1 months for the full study; 22.8 months for the highest dose cohort (Cohort IV); and 16.6 months for the extension study
- Seven new RELEASE study sites have opened since the Q3 report and 30 out of the 40 initially planned sites were open for enrolment by mid-February 2020. This is 8 sites less than planned and patient recruitment and projections are currently behind the original start-up plan. Several new initiatives to recoup long-term recruitment projections are being implemented, with the aim to reach interim analysis by Q2 2022
- The two first US sites were open by mid-February 2020, with more sites lined up for activation during 1H 2020 and awaiting enrolment of the first US patient
- 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
- The primary endpoint of the interim analysis in the RELEASE study will be changed to objective response rate following a post-IND recommendation by the FDA. This modification is not expected to impact the estimated timelines

### fima VACC

- Phase I results were presented at the ESMO Immuno-Oncology Congress in December 2019. The results provide proof-of-concept of the fima VACC vaccination technology by demonstrating the improvement of immunogenicity in healthy volunteers
- 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
- US patent granted in January 2020 with broad coverage for the combination of fima VACC with various cytokines

### fima*NAc*

 The scope of the research collaboration with AstraZeneca was expanded to evaluate if synergies established in oncology are transferrable to additional disease areas – further collaboration to be evaluated during 1H 2020



(In NOK 1,000)	2019 FY	2018 FY	2019 Q4	2018 Q4
Other income	9 372	9 585	2 097	2 972
Operating expenses	98 195	54 104	27 446	17 250
Operating results	-88 824	-44 519	-25 350	-14 278
Net financial result	58	9 739	-78	9 484
Comprehensive income	-88 766	-34 780	-25 427	-4 793
Cash & cash equivalents	261 103	349 326	261 103	349 326
Cash flow from operating activities	-85 806	-40 170	-23 761	-9 042

### Key figures

### 2019 in review - focus on execution of the pivotal RELEASE study

The overall survival data for Phase I patients receiving the pivotal fimaCHEM study dose are encouraging. Although it is a small sample size the results suggest a clear improvement over the best comparable published data in the high unmet need orphan indication, bile duct cancer. During the year the results were presented at key conferences in Asia-Pacific and US. Final confirmation of the safety milestone of up to two fimaCHEM treatments was reached in the Phase I extension study in Q2 2019 and focus since then has been on start-up activities for the pivotal RELEASE study with registration intent. The first RELEASE study patient was enrolled in Europe in Q2 2019, but a delay in the opening of study sites was experienced during 2H 2019. The first US study site opened in Q4 2019, which pushed enrolment of the first US patient into 2020. Opening of sites is not yet back on track, and study recruitment and projections are currently behind the original plan. The company has therefore activated several additional initiatives to recoup long-term patient recruitment projections, with the aim to reach interim analysis by Q2 2022.

The translation of the fima VACC vaccination technology into humans was successfully completed in Q2 2019 and the results were presented at ESMO Immuno-Oncology in Q4 2019. The results of the Phase I study provide proof-of-concept by demonstrating improved immunogenicity of vaccines in healthy volunteers. The patent focused work initiated in 2013-2014 has started to generate results, providing additional IP protection for the development program. The development focus is two pronged; utilising the Phase I results in partnering efforts and planning for clinical proof-of-concept in a disease setting.

The collaborative fimaNAc programme continues its positive development, and the collaboration with AstraZeneca was extended and expanded during the year. The company received promising response on a patent application for mRNA delivery and a granted patent can provide valuable IP for fimaNAc.

On the corporate side, the Scientific Advisory Committee has been further strengthened to ensure adequate scientific support for continued progress of the fima VACC programme.



### Operational review and development programmes overview

Programme	Indica	tions / Therapeutics	Preclinical	Phase I	Phase II	Pivotal
fimaCHEM	1	Bile duct cancer / gemcitabine				
<b>G</b> fima <i>V</i> ACC	0	Therapeutic cancer vaccines				
<b>fimaNAc</b>	1	Nucleic acid therapeutics				

### fima *CHEM*

The **fima***CHEM* 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 fima *CHEM* treatments in the Phase I extension study in April.

RELEASE will evaluate PCI Biotech's Amphinex<sup>®</sup> -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 ongoing

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 mid-February, 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 30 sites had opened for recruitment by mid-February 2020. Two of these are in the US, with more sites lined up for activation during 1H 2020 and awaiting enrolment of the first US patient.

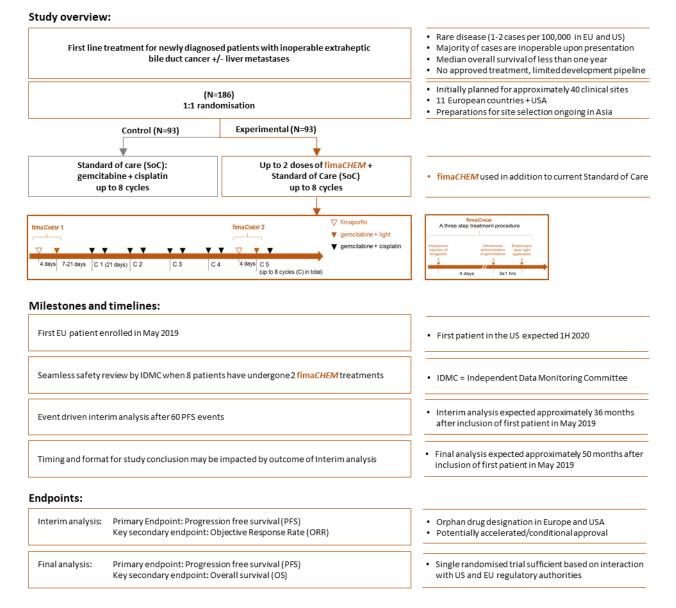
The RELEASE study has enthused investigators that are actively looking for patients, which is very important for clinical studies in rare patient groups such as cholangiocarcinoma. The opening of sites are however 8 sites behind the original plan, which affects patient recruitment and study recruitment projections. PCI Biotech is therefore currently exploring and implementing several initiatives to recoup long-term patient recruitment projections, with the aim to reach interim analysis by Q2 2022. These initiatives include opening of more sites to increase capacity, deployment of field-based personnel to understand patient flow and facilitate enrolment, and close scrutiny of eligibility failures to clearly understand and remove unnecessary recruitment hurdles.

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 there is a planned change of the interim analysis primary endpoint from progression free survival (PFS) to objective response rate (ORR). Currently ORR is a key secondary endpoint. The change is motivated by a post-investigational new drug (IND) recommendation by the FDA and the planned modification will change 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. The planned change for the interim analysis is not yet included in the overview below, as the protocol amendment is still in process.

# Bile Duct Cancer - RELEASE pivotal study with fimaCHEM



### Regular communication milestones

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.

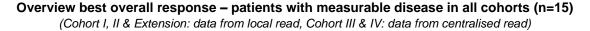
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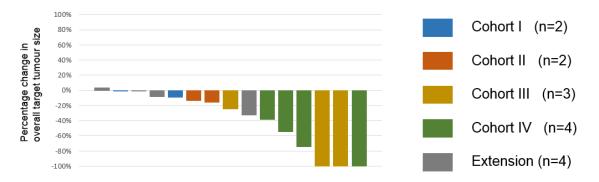


### Phase I results paved the way for the pivotal RELEASE trial with registration intent

The RELEASE study builds on the favourable safety results and encouraging early signs of efficacy in the Phase I study. The results database for this study is now closed, with all data quality checked and finally confirmed. Tumour response data from the full Phase I study (n=23) showed that more than 40% of the patients with radiologically evaluable tumours (n=15) had local target tumour response according to RECIST criteria.

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





The dose-escalation part (Cohort I to IV) of the study showed increasing tumour response rates with increasing dose levels of fimaporfin, and the encouraging results from the highest dose levels (Cohorts III & IV) were sent for independent centralised expert assessment. This confirmed the encouraging results, reporting that more than 20% tumour reduction was observed in 17 out of 19 identified target lesions and that 12 of these lesions became undetectable. The Cohort IV dose was taken forward into the RELEASE study. The extension part with two **fima***CHEM* treatments provided less tumour response, but the average tumour burden was higher in this group.

#### 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 treatments of the RELEASE dose, was 16.6 months and one patient is still alive. Five of the seven extension patients received two fima*CHEM* 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.



During Q1 2019 the Phase I results and the pivotal study design and plans were presented at two key conferences to increase awareness about **fima***CHEM* among both clinicians and patients: the US Cholangiocarcinoma Foundation Annual Conference in Salt Lake City, USA and the 3rd Asia-Pacific Cholangiocarcinoma conference in Taipei, Taiwan.

### Bile duct cancer and the fima CHEM technology

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

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

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

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

#### Comparator data for inoperable bile duct cancer

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

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

### fima VACC

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

PCI Biotech successfully translated the vaccination technology into humans through a Phase I study in healthy volunteers that was completed in May 2019. The study covered more than 90 subjects and established the tolerability of fima VACC across a wide range of doses. The immune results provided Proof-of-Concept and clinical support of fima VACC's potential to enhance overall T-cell responses, by demonstrating improvement of the immunogenicity of vaccines in healthy volunteers.

The mechanism of action and impact of **fimaVACC** on T-cell responses was further described in a preclinical publication in the high-impact immunology journal 'Frontiers in Immunology' (Varypataki *et al.* 2019 10:1548).



The U.S. Patent and Trademark Office (USPTO) granted PCI Biotech, in January 2020, a US patent providing a broad coverage for the combination of various cytokines with the fima VACC technology. There are many vaccines under development utilising cytokines to elicit immune responses and the patent is therefore important for PCI Biotech's development strategy, as it supplements our ability to potentially generate an internal future vaccine pipeline, in addition to bringing value for the fima VACC technology in partnering efforts. The US patent secures protection until 2035 while the patent application is still pending in Europe and key Asian markets.

PCI Biotech pursues several development strategies in parallel for **fima VACC**, utilising the Phase I results both in direct partnering efforts and planning for clinical Proof-of-Concept in a disease setting.

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

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

The important CD8 responses were more robust with **fima***VACC* and also exhibited increased functionality compared to control.

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

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

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

The more detailed study results were presented at the ESMO Immuno-Oncology Congress in December and PCI Biotech aims for a publication in a relevant scientific journal in 2020. A general presentation of the technology and its capabilities was given at the World Vaccine Congress Europe, Spain, in October.

### Research and development supported by a grant

The **fima VACC** programme is supported by a government grant from the Research Council of Norway (BIA-programme) of up to NOK 13.8 million, distributed over the course of four years until December 2020.

#### Immunotherapy with the fima VACC technology

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

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

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



### fima*NAc*

The **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 was earlier this year extended for an additional six months until the end of December 2019. The scope of the agreement 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 fima*NAC* technology may resolve this issue through enhanced delivery of the majority of nucleic acid types.

### Corporate

### **Management changes**

Dr. Hans Olivecrona was appointed CMO in August 2017. From July 2019 Dr. Olivecrona has functioned as a CMO via a consultancy agreement. PCI Biotech has initiated a process to recruit a new in-house CMO. The company is also actively working on recruitment to the vacant chief business development officer (CBDO) position after Mr L'Heveder resigned from his position end March 2019.

### Further strengthened the Scientific Advisory Committee (SAC)

SAC was further strengthened by the appointment of Professor Sjoerd van der Burg as committee member from 2019. Professor van der Burg is the Head of laboratory at the Department of Medical Oncology, Leiden University Medical Center (LUMC), The Netherlands. Professor van der Burg's research focus is on immunotherapy in oncology, including cancer vaccines, aiming at developing new treatments of solid tumours.

### Updates on the Board of Directors

Board Member Dr. Hilde H. Steineger notified PCI Biotech Holding ASA's nomination committee that she was not a candidate for re-election and ended her term at the Annual General Meeting in May 2019. Dr. Steineger has made strong contributions to the company with her solid industry and scientific knowledge and experience during her service as a Board Member since May 2014.

Hilde Furberg was appointed as Board Member in May 2019. Hilde Furberg holds a Master of Science from the University of Oslo, Norway. She is an independent consultant and a professional board member. She has broad senior leadership experience, coming from her 35 years in sales, marketing, strategy and general management in Pharma/Biotech. Her experience is in different areas of specialty

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care, and from small to large global companies. Hilde Furberg has worked in companies like Baxter and Genzyme, she was most recently European Head of Rare Diseases for Sanofi Genzyme. In addition to working for Genzyme/Sanofi Genzyme, she has since 2005 been a non-executive director, and board member of BerGenBio, Probi, Pronova, Clavis, Algeta and chair of the board for Blueprint Gentics. She is currently an industrial advisor to Investinor and board member of Calliditas and Tappin.

### **Financial review**

### **Income Statement**

(Figures in brackets = same period 2018 unless stated otherwise)

The Group has not recorded revenues for the financial year 2019 nor 2018. Grants received from public sources as the Norwegian Research Council and "SkatteFUNN" are recorded as other income. Other income for Q4 and FY 2019 amounted to NOK 2.1 million (NOK 3.0 million) and NOK 9.4 million (NOK 9.6 million) respectively.

Research and development (R&D) expenses for Q4 and FY 2019 totalled NOK 21.8 million (NOK 11.9 million) and NOK 83.3 million (NOK 40.3 million) respectively. Operating expenses for Q4 and FY 2019 were NOK 5.7 million (NOK 5.3 million) and NOK 14.9 million (NOK 13.8 million) respectively. Operating expenses are mainly driven by the R&D activity level. Preparations for and initiation of the pivotal fima *CHEM* trial are the main cost driver, compared to last year.

Net financial results for Q4 and FY 2019 were NOK -0.1 million (NOK 9.5 million) and NOK 0.1 million (NOK 9.7 million), respectively. The net financial results are mainly driven by exchange rate fluctuation on bank deposits placed in Euro, as a hedge of the foreign currency risk for the pivotal study initiated in 2019, and interest on bank deposits. Since inception in October 2018, the hedging effects on expenses have been beneficial, but the Euro bank deposits have had a net negative effect for 2019.

Net loss for the quarter was NOK 25.4 million (NOK 4.8 million). Net loss for FY 2019 was NOK 88.8 million (NOK 34.8 million). The increased net loss compared to last year is mainly driven by increased R&D activities and lower net financial result.

### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 261.1 million at the end of 2019, compared to NOK 349.3 million per end of 2018, reflecting net negative cash flow of NOK 86.6 million (NOK 40.1 million) in 2019 and NOK 1.6 million net negative (NOK 9.1 net positive) exchange rate effect on bank deposits in foreign currency. Cash flow from operating activities was NOK -23.8 million in Q4 2019 (NOK -9.0 million) and NOK -85.8 million (NOK -40.2 million) for the full year. Cash flow from operations is mainly dependent on R&D activities. All cash and cash equivalents were placed as bank deposits at the end of the year.

During 2019 PCI Biotech acquired the first lots of lasers to be used in the pivotal RELEASE study, impacting non-current assets compared to last year. In addition, PCI Biotech adopted IFRS 16 Leases for the first time in 2019, applying the modified retrospective method. The implementation effects for 2019 are disclosed under note 16 Right of use assets and lease liabilities.

Short term receivables per end of 2019 increased by NOK 6.9 million compared to end of 2018, mainly due to advance payments in connection with initiation of the RELEASE study and timing effects. Current liabilities were generally higher per the end of 2019 compared to the end of 2018, due to the increased R&D activities. 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 current share price and



number of outstanding 'in-the-money' share options. Social security liabilities for share options that are vested, or may be vested during 2020, are disclosed as short-term liabilities.

### Share capital

After completion of a share issue of 40,000 shares in September 2019 and 61,000 shares in February 2019, following exercise of share options and with net proceeds of NOK 1.2 million, the Company's share capital is NOK 111,797,670 divided into 37,265,890 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 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.

### The employee share option program

The primary insider Ronny Skuggedal (CFO) exercised on 4 September 2019 a total number of 40,000 share options received from the Company's share option program for employees. Pursuant to an authorisation granted by the company's Annual General Meeting on 29 May 2019, the board of directors decided to increase the Company's share capital with NOK 120,000 by issuing 40,000 new shares, each share with a nominal value of NOK 3.00 and each giving one vote at the company's general meeting. The transaction was completed 9 September 2019 and resulted in net proceeds of NOK 0.3 million.

Participants of the Company's share option program for employees exercised a total number of 61,000 share options on 20 February 2019. Out of these share options 11,000 were exercised by the primary insider Gaël L'Hévéder (CBDO at that time) and 30,000 were exercised by the primary insider Hans Olivecrona (CMO). Following the exercise of share options the Company's board of directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 29 May 2018, decided to increase the Company's share capital with NOK 183,000 by issuing 61,000 new shares, each share with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The transaction was completed 25 February 2019 and resulted in net proceeds of NOK 0.8 million.

In accordance with the authorisation granted by the Annual General Meeting in May 2019, the Board of Directors awarded in June 2019 a total of 320,000 share options under the employee share option program. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 25.78, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The share options are lapsing in Q3 2024.

### Other

### **Risks and uncertainty factors for 2019**

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 2018, the most important risks the company is exposed to in 2019 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 2018.



### **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 2019. Please see note 7 Related party transactions for further details.

#### **Post-closing events**

In January 2020, a US patent were granted providing a broad coverage for the combination of various cytokines with the **fima VACC** technology. The US patent secure protection until 2035 while the patent application is still pending in Europe and key Asian markets.

PCI Biotech is not aware of any 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 (fima VACC) and nucleic acid therapeutics (fima NAC).

Although the company's focus is divided over the three programmes, most resources are currently spent on progressing the lead project of **fima***CHEM*, which is the clinical development programme of fimaporfin with gemcitabine for the treatment of inoperable extrahepatic bile duct cancer; a rare disease with high unmet medical need. Based on the encouraging early signs of efficacy in Phase I, the company worked with 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 funding expected to finance the study to interim read-out is in place. The first patient was enrolled in May 2019. During this next step, the company maintains its full commitment 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, **fima VACC** and **fimaNAC**, are proceeding in accordance with the established development strategy. The clinical validation of the **fima VACC** technology is essential for PCI Biotech's role within the immunotherapy space. 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 **fima***CHEM* clinical development programme in inoperable extrahepatic bile duct cancer towards the market
- Implement the strategy for the next phase of development for fima VACC
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

The Board of Directors and CEO PCI Biotech Holding ASA Oslo, 25 February 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

(In NOK 1,000)	Note	2019	2018	2019	2018
		Q4	Q4	FY	FY
Other income	6	2 097	2 972	9 372	9 585
Research and development	7,9	21 767	11 924	83 312	40 337
General and administrative		5 679	5 326	14 883	13 767
Operating expenses		27 446	17 250	98 195	54 104
Operating results		-25 350	-14 278	-88 824	-44 519
Financial income and expenses					
Financial income		3 677	9 625	2 737	9 890
Financial expenses		3 599	141	2 680	151
Net financial result	8	-78	9 484	58	9 739
Profit/Loss before income tax		-25 427	-4 793	-88 766	-34 780
Income tax	10	0	0	0	0
Net profit/loss		-25 427	-4 793	-88 766	-34 780
Other comprehensive income		0	0	0	0
Total comprehensive income	5	-25 427	-4 793	-88 766	-34 780

### **BALANCE SHEET**

(In NOK 1,000)	Note	2019	2018
		31.12	31.12
Non-current assets			
Property, plant and equipment	17	5 072	17
Right to use asset	16	1 211	0
Total non-current assets		6 283	17
Current assets			
Short term receivables	8	14 631	7 713
Cash & cash equivalents	8	261 103	349 326
Total current assets		275 733	357 039
Total assets		282 016	357 056
Equity and liabilities			
Equity			
Paid in capital	11,12	562 125	560 942
Other reserves		-307 318	-220 988
Total equity		254 808	339 954
Liabilities			
Other long term liabilities	14	2 037	107
Lease liabilities	16	539	0
Total long term liabilities	-	2 576	107
C			
Trade debtors		8 601	1 889
Lease liabilities	16	657	0
Other short term liabilities	7,13,17	15 374	15 106
Total short term liabilities		24 632	16 995
Total liabilities		27 208	17 102
Total equity and liabilities		282 016	357 056

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### **CHANGE IN EQUITY**

(In NOK '000)	2019 Q4	2018 Q4	2019 FY	2018 FY
Equity at beginning of period	278 926	14 910	339 954	41 842
Capital increase	-	328 790	1 183	328 833
Share option scheme	1 309	1 048	2 436	4 059
Comprehensive income in the period	-25 427	-4 793	-88 766	-34 780
Equity at end of period	254 808	339 954	254 808	339 954

### **CASH FLOW**

(In NOK '000)	2019 Q4	2018 Q4	2019 FY	2018 FY
Ordinary profit before taxes	-25 427	-4 793	-88 766	-34 780
Depreciation, amortisation and write off	345	1	955	5
Share options	1 309	1 048	2 436	4 059
Currency gain(-)/ loss(+) not related to operations	644	-9 092	1 649	-9 092
Net interest paid/received	-1 372	50	-1 776	-782
Changes in working capital and other non-cash				
adjustments	739	3 744	-305	420
Cash flow from operating activities	-23 761	-9 042	-85 806	-40 170
Net interest paid/received	1 372	-50	1 776	782
Acquisition of non-current assets	-32	-	-3 069	-
Net cash flow from investing activities	1 339	-50	-1 293	782
Cash flow from financial activities	101		057	
Leasing liability payment	-164	-	-657	-
Net proceeds from share issues	0	328 790	1 183	328 834
Net cash flow from financial activities	-164	328 790	526	328 834
<b>Net change in cash during the period</b> Exchange rate effect on bank deposits in foreign	-22 585	319 698	-86 573	289 445
currency Cash and cash equivalents at the beginning of	-644	9 092	-1 649	9 092
the period	284 332	20 536	349 326	50 789
Cash and cash equivalents at the end of the period	261 103	349 326	261 103	349 326



## 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 (fima*CHEM*), and as a platform that may both potentiate the effect of vaccines (fima *VAcc*) and delivery of nucleic acids (fima*NAc*). PCI Biotech has two active clinical development programmes; one project in the fima*CHEM* programme and the other in the fima *VAcc* programme. The fima*CHEM* project 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 fima *VAcc* project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fima *VAcc* 's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fima*NAc* programme is in preclinical stage.

### 2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2018 (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 25 February 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 2019 is consistent with the consolidated financial statements for the year ended 31 December 2018.



The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2019 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the consolidated financial statements for 2018. In the 2018 financial statements, PCI Biotech made evaluations that *IFRS 16 Leases* will impact PCI Biotech's balance sheet, operating profit and financial expenses, without any expected significant effect on the net total comprehensive income for 2019. Please see note 16 Rights of 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 31<sup>st</sup>, 2018.

### 5. Earnings per share

#### Earnings per share

	2019	2018	2019	2018
	Q4	Q4	FY	FY
Result allocated to shareholders (NOK'000)	-25 427	-4 793	-88 766	-34 780
Weighted average of outstanding shares ('000)	37 266	36 203	37 229	27 797
Earnings per share (NOK per share)	-0.68	-0.13	-2.38	-1.25

Diluted earnings per share:

	2019	2018	2019	2018
	Q4	Q4	FY	FY
Result allocated to shareholders (NOK'000)	-25 427	-4 793	-88 766	-34 780
Weighted average of outstanding shares ('000)	37 971	36 759	37 935	28 353
Earnings per share (NOK per share)	-0.68	-0.13	-2.38	-1.25

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	2019	2018	2019	2018
	Q4	Q4	FY	FY
The Norwegian Radium Hospital Research Foundation	451	423	2 091	1 806

At the end of the quarter PCI Biotech had NOK 0.5 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 2018 and 2019 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
Trade receivables	-	-	-	-	-
Other receivables	7 439	1 203	5 989	-	14 631
Total receivables	7 439	1 203	5 989	-	14 631

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 negative accounting effect of NOK 0.6 million and NOK 1.6 million for the full year. From inception in October 2018 the Euro deposits have a net positive accounting effect of NOK 7.4 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

	2019 Q4	2018 Q4	2019 FY	2018 FY
Clinical studies	13 127	8 686	62 971	27 499
Pre-clinical studies	1 380	1 430	6 198	5 943
CMC and equipment	6 418	920	10 716	3 846
Patents	842	888	3 427	3 049
Other expenses	0	0	0	0
Total	21 767	11 924	83 312	40 337

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 109.7 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:

	Exercise price in NOK	Number of sha	are options
Expiry date	per share option	31.12.2018	31.12.2019
2020 - Q3	7.84	41 000	26 000
2020 - Q3	3.26	45 500	34 500
2022 - Q3	21.48	340 000	325 000
2022 - Q3	19.24	90 000	0
2024 - Q3	25.78	0	320 000
Total		516 500	705 500

Participants in the Company's share option program have on 20 February 2019 exercised a total number of 61,000 share options. Out of these share options 30,000 were exercised at a strike price of NOK 19.24, 15,000 share options were exercised at a strike price of NOK 7.84, 11,000 share options were exercised at a strike price of NOK 3.26 and 5,000 share options were exercised at a strike price of NOK 21.48.

Out of the total number of exercised share options, 5,000 share options at a strike price of NOK 21.48 and 6,000 share options at a strike price of NOK 3.26 were exercised by the primary insider Gaël L'Hévéder (CBDO at that time), who sold 5,300 shares in the market at an average price of NOK 25.75 per share in order to finance the cash and tax impact of the share option exercise. After the transaction Mr. L'Hévéder held 67,700 shares and 10,000 share options in the Company. The 10,000 share options were terminated upon Mr L'Hévéder's resignation in March 2019.



Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 were exercised by the primary insider Hans Olivecrona (CMO), who has sold 30,000 shares in the market

at an average price of NOK 25.75 per share. After the transaction Mr. Olivecrona held 0 shares and 60,000 share options in the Company. The 60,000 share options were terminated in June 2019 upon Dr. Olivercona's transition from an employee to an external consultant.

The primary insider Ronny Skuggedal (CFO), exercised a total number of 40,000 share options at a strike price of NOK 8.63. Mr Skuggedal sold at the same time 25,300 shares in the market at an average price of NOK 27.08 per share in order to finance the cash and tax impact of the share option exercise. After the transaction Mr. Skuggedal holds 43,000 shares and 116,000 share options in the Company.

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 the 40,000 share options exercised in Q3 2019.

Overview share options,	Total holdings					Total holdings
Senior executives	31.12.2018	Allocated	Lapsed	Exercised	Expired	31.12.2019
Per Walday, CEO	104 000	60 000	0	0	0	164 000
Ronny Skuggedal, CFO	116 000	40 000	0	40 000	0	116 000
Anders Høgset, CSO	66 000	40 000	0	0	0	106 000
Gaël L'Hévéder, CBDO*	21 000	0	0	11 000	10 000	0
Kristin Eivindvik, PD	33 500	40 000	0	0	0	73 500
Hans Olivecrona, CMO**	90 000	0	0	30 000	60 000	0
Sum	430 500	180 000	0	81 000	70 000	459 500

\* Resigned by end of March 2019 and all unexercised share options were terminated.

\*\* 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
31.12.2018	37 164 890	3.00	111 494 670
Exercise of share options	101 000	3.00	303 000
31.12.2019	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.

In Q1 2019 participants of the Company's share option program for employees exercised a total number of 61,000 share options on 20 February 2019. Following the exercise of share options the Company's board of directors, pursuant to an authorisation granted by the Company's Annual General Meeting on 29 May 2018, decided to increase the Company's share capital with NOK 183,000 by issuing 61,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the



Company's general meeting. The transaction was completed 25 February 2019. The capital increase resulted in net proceeds of NOK 0.8 million.

In Q3 2019 participants of the company's share option program for employees exercised a total number of 40,000 share options. Following the exercise of share options the company's board of directors, pursuant to an authorisation granted by the company's annual general meeting on 29 May 2019, decided to increase the company's share capital with NOK 120,000 by issuing 40,000 new shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the company's general meeting. The transaction was completed 9 September 2019. The capital increase resulted in net proceeds of NOK 0.3 million.

Subsequent to the transactions the company's share capital is NOK 111,797,670 divided into 37,265,890 shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the company's general meeting.

PCI Biotech has more than 4,200 shareholders at the end of December 2019.

#### 10 largest shareholders per 31 December 2019:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,09 %
Myrlid AS	2 415 000	6,48 %
MP PENSJON PK	2 258 206	6,06 %
RADIUMHOSPITALETS FORSKNINGSSTIFT.	1 281 415	3,44 %
NORDNET LIVSFORSIKRING AS	1 065 216	2,86 %
GRESSLIEN	665 320	1,79 %
Nordnet Bank AB	554 231	1,49 %
Jandersen Kapital AS	540 200	1,45 %
BERG-LARSEN	462 400	1,24 %
ESTI AS	391 000	1,05 %
Total 10 largest shareholders	<u>13 393 431</u>	<u>35,94 %</u>
Others	23 872 459	64,06 %
Total	37 265 890	100,00 %



		No. of s	shares
Name	Position	31.12.2018	31.12.2019
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen (Stocken Invest AS)	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)	Board member*	NA	4 000
Andrew Hughes	Board member	0	0
Hilde H. Steineger	Board member**	0	NA
Per Walday	CEO	68 300	68 300
Anders Høgset	CSO	63 300	63 300
Ronny Skuggedal	CFO	28 300	43 000
Kristin Eivindvik	CDO	18 800	18 800
Gaël L'Hévéder	CBDO***	62 000	NA
Hans Olivecrona	CMO****	0	NA
Total		387 328	344 028

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties per end of December 2019:

\* Hilde Furberg was elected as board member in the annual general meeting in May 2019 and holdings are reported from that date. The shares are owned via Borkenholm AS, which is a related party to Hilde Furberg.

\*\* Hilde H. Steineger ended her term as board member in May 2019 and holdings are reported up to that date. \*\*\* Gaël L'Hévéder resigned by end of March 2019 and holdings are reported to that date.

\*\*\*\* 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 1-5 years for potential future exercises of "inthe-money" share options per year-end in PCI Biotech's employee share option scheme and lease liabilities due in 1-3 years according to IFRS 16. See note 16 for further details regarding IFRS 16 implementation in 2019 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)

As of year-end 2018 PCI Biotech had no agreements that classified as financial lease under IAS 17. Under the new standard for leases, IFRS 16, PCI Biotech identified office lease as the only applicable right-to-use asset. IFRS 16 was implemented by PCI Biotech with effects as of 1 January 2019, applying the modified retrospective method and 2018 figures have therefore not been restated. 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.

On transition to IFRS 16, PCI Biotech recognised NOK 1.8 million in right of 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 lease payments. Accounting principles applied are described in the annual financial statement for the year ended 31 December 2018, under accounting principles section 4.

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

All figures in '000 NOK

#### Right of use asset - office

Initial recognition 01.01.2019	1,815
Acquisition costs 31.12.2019	<u>1,815</u>
Depreciation Q1 2019	151
Depreciation Q2 2019	151
Depreciation Q3 2019	151
Depreciation Q4 2019	151
Accumulated depreciation and impairment 30.09.2019	<u>604</u>
Total right of use assets 31.12.2019	<u>1,211</u>
Lower of remaining lease term or economic life	2.0 years
Depreciation method	Linear

#### Lease liabilities - office

Initial recognition 01.01.2019	1,815
Payments for the principal portion of the lease liability	-657
Interest expenses on the lease liability	38
Total lease liabilities as of 31.12.2019	<u>1,196</u>
Whereof:	
Short term lease liabilities < 1 year	657
Long term lease liabilities > 1 year	539

#### Income statement FY 2019 – office lease

Depreciation	-604
Effect on Operating results	<u>-604</u>
Interest expenses on the lease liabilities	-38
Effect on Net financial result	<u>-38</u>
Net Comprehensive income effect	-642

The net comprehensive income effect from implementation of IFRS 16 in 2019 will not impact cash flow. Payments for the principal portion of the lease liabilities (kNOK 657) for FY 2019 are not charged to profit and loss under IFRS 16 and will only have cash flow effects for 2019, while for 2018 these payments were charged directly to profit and loss under IAS 17.



The impact of IFRS 16 adoption on net comprehensive income for FY 2019 compared to IAS 17, where the only income statement effect were payments for the principal portion of the lease liability, is kNOK 15 positive (kNOK -657 income effect under IAS 17 versus kNOK -642 income effect under IFRS 16).

#### 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 life-time of five years for the equipment is applied.

Equipment	Q4 2019	Q4 2018	FY 2019	FY 2018
Carrying value at the beginning of the period	4 797	18	17	22
Additions	469	-	5 405	-
Depreciation in the period	194	1	350	5
Carrying value at the end of the period	5 072	17	5 072	17

### 18. Subsequent events

In January 2020, a US patent were granted providing a broad coverage for the combination of various cytokines with the **fima VACC** technology. The US patent secure protection until 2035 while the patent application is still pending in Europe and key Asian markets.

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
fima <i>CHEM</i> :	PCI Biotech's development program for enhancement of generic chemotherapies
fima <i>VAC</i> :	PCI Biotech's development program for delivery of nucleic acids
fima <i>VAC</i> :	PCI Biotech's development program for a vaccination technology
fima <i>VAC</i> :	Human papillomavirus
HPV:	Independent Data Monitoring Committee
IDMC:	Investigational New Drug
IND	Studies performed with cells or biological molecules studied outside their normal
In vitro:	biological context; for example proteins are examined in solution, or cells in
In vivo: KLH ODD: ORR: OS: PCI: PCIB: PFS: RELEASE:	artificial culture medium. Studies in which the effects of various biological entities are tested on whole, living organisms usually animals. Keyhole limpet hemocyanin Orphan Drug Designation Overall Response Rate Overall Survival Photochemical internalisation PCI Biotech's ticker at Oslo Børs Progression Free Survival 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 <sup>st</sup> January – 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)



### FINANCIAL CALENDAR

Annual Report	22 April	2020
Q1 Report 2020	6 May	2020
Q2 Report 2020	26 August	2020
Q3 Report 2020	11 November	2020

### **INVESTOR CONTACT**

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### FORWARD LOOKING STATEMENTS

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

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