



*Unlocking the potential of innovative medicines*



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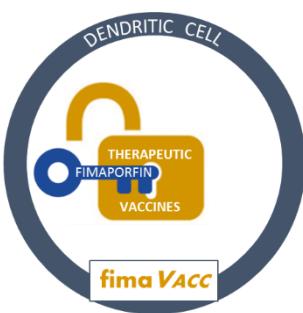
SECOND QUARTER AND  
FIRST HALF-YEAR REPORT  
2019

## 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 that is used to 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®). A first-in-man Phase I study of fimaporfin in cancer patients with encouraging early signs of tumour response has been published in the renowned medical journal the Lancet Oncology. This was followed by a Phase Ib study in bile duct cancer patients that delivered encouraging early signs of tumour response and survival, and in May 2019 the company initiated the pivotal RELEASE study in this high unmet need orphan indication. 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 in a Phase I study in healthy volunteers was achieved in May 2019. The third programme fimaNAc is a technology for intracellular delivery of nucleic acids that follows a collaborative development approach, with established collaborations with several key players in the field.

## Highlights

- **fimaCHEM**
  - First patient enrolled in the RELEASE study
  - Regulatory and ethics approvals for the RELEASE study achieved in two thirds of the planned countries, including USA
  - Almost half of the RELEASE study sites opened and actively screening for patients
  - Initiated feasibility study in Asia with the aim of including sites in 2020
  - Completion of the full Phase I study, with successful safety read-out for repeated treatment
  - Presented Phase I data at key conferences in Asia-Pacific and US
- **fimaVacc**
  - Successful clinical proof-of-concept with enhanced immune responses
  - Preclinical publication in high-impact immunology journal (subsequent event)
- **fimaNAC**
  - Promising response on patent application for mRNA delivery (subsequent event)
  - Final extension of the top-10 pharma research collaboration (subsequent event)
- **Corporate**
  - Further strengthened the Scientific Advisory Committee and the Board of Directors

## Key figures

(In NOK 1,000)	2019 1H	2018 1H	2019 Q2	2018 Q2	2018 FY
Other income	4 850	4 375	2 425	2 137	9 585
Operating expenses	49 829	26 230	29 475	9 330	54 104
Operating results	-44 979	-21 855	-27 050	-7 193	-44 519
Net financial result	-4 089	206	806	83	9 739
<b>Comprehensive income</b>	<b>-49 068</b>	<b>-21 649</b>	<b>-26 245</b>	<b>-7 110</b>	<b>-34 780</b>
<b>Cash &amp; cash equivalents</b>	<b>301 621</b>	<b>28 405</b>	<b>301 621</b>	<b>28 405</b>	<b>349 326</b>
<b>Net cash flow from operating activities</b>	<b>-41 969</b>	<b>-22 428</b>	<b>-25 489</b>	<b>-12 326</b>	<b>-30 297</b>

## Operational review

First patient enrolled into the pivotal **fimaCHEM** “RELEASE” study, successful clinical proof-of-concept of **fimaVACC** and extension of the **fimaNAC** collaboration with a large pharma company

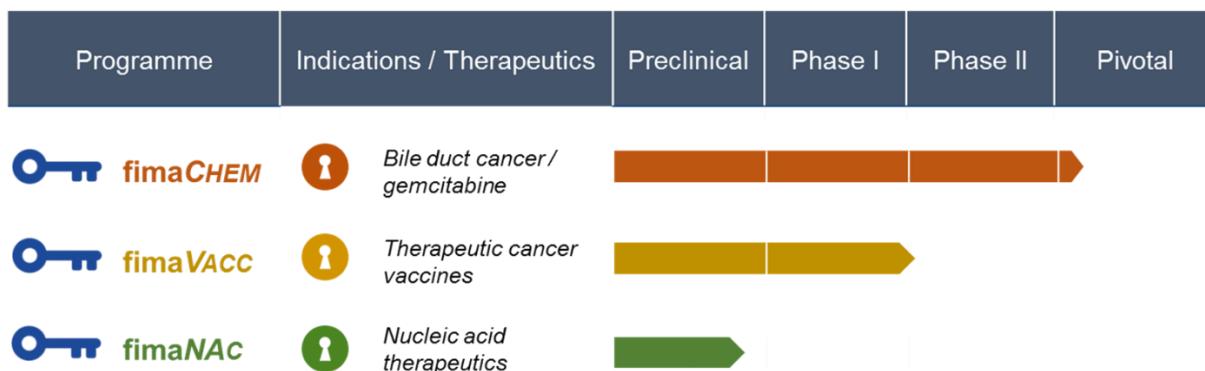
The pivotal RELEASE study in bile duct cancer enrolled its first patient in May 2019. The study is initiated with up to two **fimaCHEM** treatments, based on the final confirmation of safety that was reached in April 2019 in the Phase I extension study. The overall survival data for Phase I patients receiving the pivotal study dose are encouraging, suggesting a clear improvement over the best comparable published data in this high-unmet need orphan indication. By mid-August 2019, regulatory and ethics approvals have been achieved in 9 countries including USA, with 15 European RELEASE study sites open for enrolment. Bile duct cancer has a higher prevalence in Asia and a feasibility study for selection of Asian sites has been initiated, with the aim to include Asian sites in 2020. PCI Biotech’s focus is now to bring **fimaCHEM** to the market for the treatment of inoperable bile duct cancer through successful completion of the RELEASE study with potential accelerated approval at interim analysis.

The translation of the vaccination technology, **fimaVACC**, into humans was successfully completed in May 2019. The results of the Phase I study provide proof-of-concept by demonstrating improvement of immunogenicity of vaccines in healthy volunteers. The overall clinical data covering more than 90 subjects provide clinical support of **fimaVACC**’s potential to enhance the cellular immune responses that are especially important for therapeutic effect of vaccines. A recent preclinical publication in the high-impact immunology journal, *Frontiers in Immunology*, further elucidates the mechanism of action and prerequisites for the efficacy of T-cell responses induced by **fimaVACC**.

The **fimaNAC** research collaboration with a large pharma company was recently extended with six months to the end of December 2019 and thereafter the companies have agreed to use the following six months (until end of June 2020) to evaluate the potential for a further partnership. A positive international search report has been received on a patent application within the field of mRNA, which may generate valuable IP for the **fimaNAC** programme.

On the corporate side, the Scientific Advisory Committee has been further strengthened to ensure adequate scientific support for continued progress of the **fimaVACC** programme. The Board of Directors has by the appointment of Mrs Hilde Furberg been further strengthened with commercial experience and expertise.

## Overview of PCI Biotech’s development pipeline



## Development programmes

### fimaCHEM

The **fimaCHEM** programme aims to fulfil unmet medical needs by providing localised targeted enhancement of approved chemotherapies for the benefit of the many patients currently left without effective treatment options. **fimaCHEM** is currently focused on localised enhancement of the chemotherapy gemcitabine in the rare disease inoperable extrahepatic bile duct cancer (cholangiocarcinoma), with **Amphinex®**, the intravenous formulation of fimaporfin. RELEASE is a pivotal clinical study of Amphinex with the potential of accelerated/conditional marketing approval as a first-line treatment given the rare disease status and high unmet medical need in bile duct cancer.

### First patient enrolled in RELEASE and start-up activities according to plan

The pivotal RELEASE study, with registration intent, enrolled the first patient in May 2019. The interim analysis of progression free survival (PFS) and objective response rate (ORR) for potential accelerated/conditional marketing approval is expected to be available in Q2 2022 (approximately 36 months from study initiation), while the final analysis is expected in Q3 2023 (approximately 50 months from initiation). The pivotal study will be executed in approximately 40 clinical sites that first are opened in 11 European countries, followed by a roll-out in the US from second half 2019. In addition, a feasibility study is ongoing in Asia with the aim to select the most appropriate RELEASE study sites for patient recruitment and market impact, and sites are expected to be opened in 2020.

Start-up activities are progressing according to plan with ongoing regulatory and ethics approvals and site contract negotiations. Regulatory and ethics approvals have been received for USA and 8 out of 11 planned European countries by mid-August (Norway, Germany, France, Spain, Belgium, Poland, Sweden and Denmark). The first site was opened in Norway in March 2019, while the first patient was enrolled into the study in May. A total of 15 sites in 7 different European countries were open for enrolment by mid-August 2019.

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

The pivotal RELEASE study design is 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). The study programme consists of a single open randomised two-arm study with 186 patients (93 patients per arm), having a control arm with the standard of care (SoC) treatment of up to eight cycles of the chemotherapies gemcitabine and cisplatin, and an experimental arm with up to two **fimaCHEM** treatments in addition to SoC. The study's primary endpoint is PFS, with overall survival (OS) as a key secondary endpoint. The study includes an interim analysis of PFS (after 60 events) followed by analysis of objective response rate (ORR), with the potential of accelerated/conditional marketing approval as a first-line treatment.

### 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. 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.

### Completion of the full Phase I study, with successful safety read-out for repeated treatment in the extension part

In April 2019 PCI Biotech announced final confirmation of successful safety read-out for the Phase I extension study in inoperable extrahepatic bile duct cancer patients evaluating the safety of two **fimaCHEM** treatments. A total of 23 patients were enrolled in Phase I, which provided safety results and encouraging early signs of efficacy that support further clinical development in this orphan indication, which is currently left without effective local treatment options. Based on the positive safety data, the pivotal RELEASE study with registration intent is initiated with up to two **fimaCHEM** treatments and will

include a seamless safety review by an Independent Data Monitoring Committee (IDMC) when eight patients have completed two treatments in the pivotal RELEASE study.

Tumour response data from the full Phase I study (both the dose-escalation and extension part) shows that approximately 50% of the patients with radiologically evaluable tumours (N=15) had local tumour response according to RECIST criteria. Local tumour response in the bile duct is important to maintain biliary drainage and primary tumour response may therefore be more important for outcome than would be the case for many other cancers. The fimaCHEM treatment boosts the chemotherapy effect locally in the bile duct, thereby directly targeting this area. Appropriate biliary drainage may provide the opportunity for patients to receive the maximum cycles of standard of care (SoC) including a second fimaCHEM treatment and thereby improving patient outcome.

The dosing regimen in the pivotal RELEASE study is similar to the dosing regimen in the extension part of Phase I, i.e. up to two fimaCHEM treatments of the fimaporfin dose applied in the last (4<sup>th</sup>) cohort in the dose-escalation part of Phase I. All the 23 patients enrolled in the Phase I study have been followed-up post-study for survival. The fourth dose-escalation cohort comprised 6 patients and the extension part comprised 7 patients of which 5 received two treatments. These are both small patient groups with considerable heterogeneity and it is noteworthy that the average tumour burden in the extension group was approximately twice that in the fourth dose-escalation cohort. The median overall survival in the fourth dose cohort in the dose-escalation part ended at 21.7 months, with half of the patients exceeding 30 months survival including one patient still being alive more than three years after treatment. The survival data by end June 2019 for the extension part translates to an interim median overall survival of approximately 15 months (outcome range up to 15.6 months) including all 7 patients, with one patient still being alive. The emerging survival data by end June 2019 for all the patients that have received the pivotal study dose (N=13) showed an interim median survival of approximately 15 months (outcome range up to 15.6 months), with two patients still being alive.

### **Presented Phase I data at key conferences in Asia-Pacific and US**

The Phase I results and the pivotal study design and plans were in 1H 2019 presented at three key conferences to increase awareness about fimaCHEM among both clinicians and patients: the US Cholangiocarcinoma Foundation Annual Conference in Salt Lake City, USA, the 3<sup>rd</sup> Asia-Pacific Cholangiocarcinoma Conference in Taipei, Taiwan and the International Photodynamic Association (IPA) World Congress in Boston, USA.

#### **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 where the annual incidence rate is 1-2 cases per 100,000 in the Western world, but higher in most Asian countries. Currently, there is no approved treatment specifically for bile duct cancer and the development pipeline for new potential treatments is limited. Additionally, bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and the only possible curative treatment is surgery. As the majority of cases, however, present as inoperable, 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.

Today, the common treatment for inoperable extrahepatic bile duct cancer patients is stenting to keep the bile duct open, followed by chemotherapy, where a combination of the chemotherapies gemcitabine and cisplatin has become the SoC treatment. Gemcitabine is the most studied and used chemotherapy in the treatment of bile duct cancer, and its effect has been significantly enhanced by the fimaCHEM technology in preclinical studies. Additionally, 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 in the studies that established the chemotherapies gemcitabine in combination with cisplatin as SoC treatment 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). In the latter study, gallbladder cancer patients had a poorer outcome and the median overall survival was 13 months when these patients were excluded. These results represent the best available published comparator data, but are not directly comparable to the data in the fimaCHEM Phase I study. The published studies include a wide range of different inoperable bile duct cancer patients, while the fimaCHEM Phase I study focuses 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. This proprietary vaccination technology has entered clinical development after having demonstrated strong preclinical efficacy. The translation of this technology into humans by demonstrating improvement of immunogenicity of vaccines has been a main priority for PCI Biotech to establish the company in the immunotherapy field.

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

The fimaVACC technology has proven excellent preclinical efficacy with protein and peptide based vaccines, with particularly strong CD8 T-cell immune responses that are considered important for therapeutic vaccination, but also enhanced helper (CD4) T-cell and antibody responses.

The initial clinical translation of the fimaVACC technology was done through a Phase I study in healthy volunteers. The final data reported in May 2019, provide clinical proof-of-concept of fimaVACC's potential to enhance overall T-cell responses. The results show a substantial increase in number of T-cell responders to HPV peptides already after two vaccinations and a clear enhancement in the T-cell responses compared to the control group. The two HPV peptide antigens chosen for the Phase I study were derived from the E7 protein. A very high CD8 response hurdle was set by this choice, as it is notoriously difficult to induce CD8 T-cell responses in man with peptides from the HPV E7 protein. The important CD8 responses were both more robust with fimaVACC and exhibited increased functionality compared to control. These are all highly sought-after features of therapeutic vaccination technologies.

The overall clinical data covering more than 90 subjects provide clinical support of fimaVACC's potential to enhance the cellular immune responses that are important for therapeutic effect of vaccines. This enhancement of cellular immune responses was seen at well tolerated fimaVACC dose levels, with the tolerability of fimaVACC established across a wide range of doses.

The analysis of overall T-cell responses has been done in collaboration with Oslo University Hospital, The Radium Hospital, while the analysis of CD8 T-cell responses has been done at the Department of Medical Oncology at Leiden University Medical Centre (LUMC) under the leadership of Professor Sjoerd van der Burg. After reviewing the overall results of the Phase I study, Professor van der Burg said 'These encouraging results obtained by including fimaporfin during vaccination merit further exploration in a relevant clinical disease to assess if the enhanced immune responses translates into clinical benefit'.

The study was designed as an open-label, antigen-adjuvant controlled study with the objectives to determine immune responses, safety and tolerability of fimaVACC in healthy volunteers. Two model vaccines were used; a large immunogenic protein called keyhole limpet hemocyanin (KLH) and two less immunogenic peptides from human papillomavirus (HPV). The T-cell response to vaccination was most strongly enhanced with the HPV peptides, which are much less immunogenic than the KLH protein.

Based on the successful clinical translation, PCI Biotech is now assessing the format and potential conferences for publication and presentation of the more detailed study results. The overall development strategy for fimaVACC is two-pronged, both utilising the current Phase I results in direct partnering efforts and plan for clinical proof-of-concept in a disease setting.

### Preclinical publication in high-impact immunology journal

Preclinical results were recently published in the high-impact immunology journal "Frontiers in Immunology" (Combined Photosensitization and vaccination enable CD8 T-Cell Immunity and Tumor Suppression independent of CD4 T-Cell help, Varypataki et al. Front.Immunol. 10:1548). The study provided evidence of strong activation of CD8 T-cells and tumour regression after vaccination with fimaVACC in melanoma bearing mice, including mice with impaired T-helper cell function. The study thereby demonstrate that therapeutic cancer vaccination with fimaVACC can be effective independent of T-helper cell functionality.

### 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 three and a half years, 2017-2020.

#### 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. Whilst several companies have reported failed clinical studies in the past years, the potential of combining vaccination with immune checkpoint inhibitors has triggered a renewed interest in therapeutic cancer vaccines. Nevertheless, there are still key issues to solve of which improving the immunogenicity of vaccine candidates is a main priority within immunotherapy. PCI Biotech believes the fimaVAcc technology may play a key role in solving this key challenge.

In order to realise the huge potential of therapeutic cancer vaccines, effective induction of cytotoxic T-cells is critical. Unfortunately, today's vaccines often fail to generate such responses. Most likely, one of the main reasons behind this failure is insufficient delivery of vaccine antigens to the appropriate presentation pathway in the immune cells. The fimaVAcc technology has the potential to solve this challenge by effectively enhancing the vaccine presentation through this pathway.

### 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.

#### Final extension of large pharma research collaboration agreement

The ongoing collaboration with an undisclosed large pharma company has been extended several times, most recently with additional six months until the end of December 2019. The aim of the extension is to complete the agreed *in vivo* research. Thereafter the companies have agreed to use the following six months (until end of June 2020) to evaluate the potential for a further partnership.

PCI Biotech employs a collaborative strategy for fimaNAc. All the collaborators have the same purpose of exploring synergies between the partner's proprietary nucleic acid technologies and the fimaNAc technology. Thereafter, the intention is to explore the potential for further partnerships.

The current collaboration partners span from an undisclosed big pharma company to five mid-/small-size biotechnology companies: Bavarian Nordic, BioNTech, eTheRNA immunotherapies, IMV and Phio Pharmaceuticals.

#### Promising response on patent application for mRNA delivery

Initial positive feedback on a patent application for intracellular delivery of mRNA was received in Q3 2019 and the application may generate valuable intellectual property (IP) for the fimaNAc programme. The broad therapeutic potential of mRNA is widely recognised, but sufficient intracellular delivery of these large molecules remains a major hurdle. This patent application may provide important competitive advantage, as several of the ongoing research collaborations are within mRNA delivery.

#### 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 such compounds is challenged by the obstacles to achieve adequate intracellular access, which the fimaNAc technology may resolve through enhancing the delivery of the majority of nucleic acid types.

## Corporate

### 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 2019 Annual General Meeting. 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 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 and Algeta. She is currently an industrial advisor to Investinor and board member of Calliditas, Tappin, Combigene and Chairman of the Board for Blueprint Genetics.

### Updates on the Scientific Advisory Committee

PCI Biotech's Scientific Advisory Committee (SAC) has been 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. With a translational approach, Professor van der Burg's research spans from preclinical studies and methodological development to clinical trials and collaborative initiatives with special focus on human T-cell response against tumour-specific and associated antigens. Professor van der Burg is a member of numerous international advisory committees and societies including American and European societies for immunology and cancer (AACR, C-IMT, ESMO) and the International Papillomavirus Society.

### Resignation of the Chief Business Development Officer (CBDO)

Gaël L'Hévéder resigned as CBDO and left PCI Biotech per end of March 2019 to pursue other career opportunities. The 10,000 share options Mr L'Hévéder held per his resignation are terminated. The business development responsibilities are shared between the executive management members in the interim and a replacement process is initiated.

### Update on the Chief Medical Officer (CMO) position

Dr. Hans Olivecrona was appointed CMO in August 2017. From July 2019 Dr. Olivecrona will be functioning as a CMO via a consultancy agreement and the 60,000 unexercised share options held by Dr Olivecrona were terminated by the end of June 2019. PCI Biotech has initiated a process to evaluate opportunities for a new in-house CMO position.

## Financial review

### The employee share option program

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) 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.

## Income Statement

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

The Group did not record revenues for financial year (FY) 2019 nor 2018. Grants received from public sources as the Norwegian Research Council and "SkatteFUNN" are recorded as other income. Other income for Q2 and 1H 2019 amounted to NOK 2.4 million (NOK 2.1 million) and NOK NOK 4.9 million (NOK 4.4 million) respectively.

Research and development (R&D) expenses for Q2 and 1H 2019 totalled to NOK 26.8 million (NOK 6.4 million) and NOK 43.5 million (NOK 19.7 million) respectively. Operating expenses for Q2 and 1H 2019 ended at NOK 29.5 million (NOK 9.3 million) and NOK 49.8 million (NOK 26.2 million) respectively. Operating expenses are mainly driven by the R&D activity level. Preparations for initiation of the pivotal fimaCHEM trial are the main cost driver, compared to last year.

Net financial results for Q2 and 1H 2019 were NOK 0.8 million (NOK 0.1 million) and NOK -4.1 million (NOK 0.2 million) respectively. The net negative financial result in 1H 2019 is 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. Since inception in October 2018, the hedging effects on expenses have been beneficial and the Euro bank deposits have a net positive effect per end of first half 2019.

Net loss for the quarter was NOK 26.2 million (NOK 7.1 million). The net loss for first half year was NOK 49.1 million (NOK 21.6 million). The increased net loss for the first half year compared to last year is due to increased R&D activities and the net negative financial result driven by exchange rate fluctuation on bank deposits in Euro.

## Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 301.6 million at the end of first half 2019, compared to NOK 349.3 million per end of 2018, reflecting net negative cash flow of NOK 42.9 million in the period and NOK 4.8 million net negative exchange rate effect on bank deposits in foreign currency per 30 June 2019. Cash flow from operating activities was NOK -25.5 million in Q2 2019 (NOK -12.3 million) and NOK -42.0 million (NOK -22.6 million) in 1H 2019. 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 quarter.

PCI Biotech acquired in Q2 2019 the first lot of lasers to be used in the pivotal RELEASE study, impacting both non-current assets and current liabilities. Short term receivables per end of 1H 2019 is increased by NOK 8.8 million compared to end of 2018, mainly due to advance payments in connection with initiation of the RELEASE study. Current liabilities are generally increased per end of 1H 2019 compared to end of 2018 due to the increased R&D activities by initiation of the RELEASE study.

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.

## Share capital

After completion of a share issue, with net proceeds of NOK 0.8 million, following exercise of share options in February 2019 the Company's share capital is NOK 111,677,670 divided into 37,225,890 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.

## 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 1H 2019. Please see note 7 Related party transactions for further details.

### Post-closing events

Initial positive feedback on a patent application for intracellular delivery of mRNA was received in Q3 2019 and the application may generate valuable intellectual property (IP) for the fimaNAc programme.

Preclinical results were in Q3 2019 published in the high-impact immunology journal "Frontiers in Immunology" (Combined Photosensitization and vaccination enable CD8 T-Cell Immunity and Tumor Suppression independent of CD4 T-Cell help, Varypataki et al. Front.Immunol. 10:1548).

The ongoing collaboration with an undisclosed large pharma company has been extended several times, most recently in Q3 2019 with additional six months until the end of December 2019. The aim of the extension is to complete of the agreed *in vivo* research. Thereafter the companies have agreed to use the following six months (until end of June 2020) to evaluate the potential for a further partnership.

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 of playing 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 three-pronged, divided over the three programmes, most resources are currently spent on progressing the lead project of fimaCHEM, 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 the key regulators in Europe and the U.S. receiving important guidance which informs the design for 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, and the first patient was enrolled in May 2019. During this next step, the company will maintain its full commitment of advancing the programme with the ambition of helping the patients currently left without effective treatment options 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
- Define and execute 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, 27 August 2019

Hans Peter Bøhn  
Chairman (sign)

Christina Herder  
Director (sign)

Hilde Furberg  
Director (sign)

Andrew Hughes  
Director (sign)

Lars Viksmoen  
Director (sign)

Per Walday  
CEO (sign)

## RESPONSIBILITY STATEMENT

We confirm that, to the best of our knowledge, the unaudited condensed set of financial statements for the first half of 2019 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Group's consolidated assets, liabilities, financial position and results of operations, and that the interim management report includes a fair view of the information required under the Norwegian Securities Trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO  
PCI Biotech Holding ASA  
Oslo, 27 August 2019

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 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
<b>Other income</b>	6	<b>2 425</b>	<b>2 137</b>	<b>4 850</b>	<b>4 375</b>	<b>9 585</b>
Research and development	7,9	26 767	6 359	43 506	19 694	40 337
General and administrative		2 708	2 971	6 323	6 536	13 767
<b>Operating expenses</b>		<b>29 475</b>	<b>9 330</b>	<b>49 829</b>	<b>26 230</b>	<b>54 104</b>
<b>Operating results</b>		<b>-27 050</b>	<b>-7 193</b>	<b>-44 979</b>	<b>-21 855</b>	<b>-44 519</b>
<b>Financial income and expenses</b>						
Financial income		1 106	85	1 766	208	9 890
Financial expenses		300	2	5 855	2	151
<b>Net financial result</b>	8	<b>806</b>	<b>83</b>	<b>-4 089</b>	<b>206</b>	<b>9 739</b>
<b>Profit/Loss before income tax</b>		<b>-26 245</b>	<b>-7 110</b>	<b>-49 068</b>	<b>-21 649</b>	<b>-34 780</b>
Income tax	10	0	0	0	0	0
<b>Net profit/loss</b>		<b>-26 245</b>	<b>-7 110</b>	<b>-49 068</b>	<b>-21 649</b>	<b>-34 780</b>
Other comprehensive income		0	0	0	0	0
<b>Total comprehensive income</b>	5	<b>-26 245</b>	<b>-7 110</b>	<b>-49 068</b>	<b>-21 649</b>	<b>-34 780</b>

## BALANCE SHEET

(In NOK 1,000)	Note	2019 30.06	2018 30.06	2018 31.12
<b>Non-current assets</b>				
Property, plant and equipment	17	2 136	20	17
Right to use asset	16	1 514	0	0
<b>Total non-current assets</b>		<b>3 650</b>	<b>20</b>	<b>17</b>
<b>Current assets</b>				
Short term receivables	8	16 450	9 445	7 713
Cash & cash equivalents	8	301 621	28 405	349 326
<b>Total current assets</b>		<b>318 071</b>	<b>37 850</b>	<b>357 039</b>
<b>Total assets</b>		<b>321 721</b>	<b>37 870</b>	<b>357 056</b>
<b>Equity and liabilities</b>				
<b>Equity</b>				
Paid in capital	11,12	561 597	234 346	560 942
Other reserves		-270 056	-211 917	-220 988
<b>Total equity</b>		<b>291 541</b>	<b>22 429</b>	<b>339 954</b>
<b>Liabilities</b>				
Other long term liabilities		94	2 280	107
Lease liabilities	16	1 178	0	0
<b>Total long term liabilities</b>	14	<b>1 272</b>	<b>2 280</b>	<b>107</b>
Trade debtors		9 621	626	1 889
Lease liabilities	16	329	0	0
Other short term liabilities	7,13,17	18 959	12 534	15 106
<b>Total short term liabilities</b>		<b>28 908</b>	<b>13 161</b>	<b>16 995</b>
<b>Total liabilities</b>		<b>30 180</b>	<b>15 441</b>	<b>17 102</b>
<b>Total equity and liabilities</b>		<b>321 721</b>	<b>37 870</b>	<b>357 056</b>

## CHANGE IN EQUITY

(In NOK '000)	2019 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
<b>Equity at beginning of period</b>	<b>318 308</b>	<b>28 558</b>	<b>339 954</b>	<b>41 842</b>	<b>41 842</b>
Capital increase	-	44	838	44	328 833
Share option scheme	-523	938	-183	2 193	4 059
Comprehensive income in the period	-26 245	-7 110	-49 068	-21 649	-34 780
<b>Equity at end of period</b>	<b>291 541</b>	<b>22 429</b>	<b>291 541</b>	<b>22 429</b>	<b>339 954</b>

## CASH FLOW

(In NOK '000)	2019 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
Ordinary profit before taxes	-26 245	-7 110	-49 068	-21 649	-34 780
Depreciation, amortisation and write off	154	1	307	2	5
Share options	-522	938	-182	2 192	4 059
Currency gain(-)/ loss(+) not related to operations	-595	0	4 850	0	-9 092
Net interest paid/received	-186	83	-727	-206	-782
Changes in working capital and other non-cash adjustements	1 904	-4 054	2 852	-2 973	420
<b>Cash flow from operating activities</b>	<b>-25 489</b>	<b>-10 142</b>	<b>-41 969</b>	<b>-22 633</b>	<b>-40 170</b>
Net interest paid/received	186	-83	727	206	782
Acquisition of non-current assets	-2 100	-	-2 123	-	-
<b>Net cash flow from investing activities</b>	<b>-1 914</b>	<b>-83</b>	<b>-1 396</b>	<b>206</b>	<b>782</b>
<b>Cash flow from financial activities</b>					
Leasing liability payment	-329	-	-329	-	-
Net proceeds from share issues	-	-	838	44	328 834
<b>Net cash flow from financial activities</b>	<b>-329</b>	<b>-</b>	<b>509</b>	<b>44</b>	<b>328 834</b>
<b>Net change in cash during the period</b>	<b>-27 732</b>	<b>-10 181</b>	<b>-42 855</b>	<b>-22 384</b>	<b>289 445</b>
Exchange rate effect on bank deposits in foreign currency	595	0	-4 850	0	9 092
Cash and cash equivalents at the beginning of the period	328 757	38 586	349 326	50 789	50 789
<b>Cash and cash equivalents at the end of the period</b>	<b>301 621</b>	<b>28 405</b>	<b>301 621</b>	<b>28 405</b>	<b>349 326</b>

## 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 Utibú. 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 agent gemcitabine for treatment of inoperable extrahepatic bile duct cancer. The fimaVacc project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fimaVacc's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fimaNAc programme is in preclinical stage.

### 2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 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 27 August 2019.

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 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 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
Result allocated to shareholders (NOK'000)	-26 245	-7 110	-49 068	-21 649	-34 780
Weighted average of outstanding shares ('000)	37 226	24 933	37 206	24 990	27 797
Earnings per share (NOK per share)	-0.71	-0.28	-1.32	-0.87	-1.25

Diluted earnings per share:

	2019 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
Result allocated to shareholders (NOK'000)	-26 245	-7 110	-49 068	-21 649	-34 780
Weighted average of outstanding shares ('000)	37 971	25 720	37 951	25 717	28 353
Earnings per share (NOK per share)	-0.71	-0.28	-1.25	-0.87	-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 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
The Norwegian Radium Hospital Research Foundation	673	568	1 312	1 035	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	6 090	333	7 176	2 850	16 450
<b>Total receivables</b>	<b>6 090</b>	<b>333</b>	<b>7 176</b>	<b>2 850</b>	<b>16 450</b>

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.

For the first half of 2019 exchange rate fluctuation on cash deposits placed in Euro generated a negative accounting effect of NOK 4.9 million. From inception in October 2018 the Euro deposits have a net positive accounting effect of NOK 4.2 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 Q2	2018 Q2	2019 1H	2018 1H	2018 FY
Clinical studies	23 423	3 625	36 241	13 618	27 499
Pre-clinical studies	1 296	1 671	3 286	3 202	5 943
CMC and equipment	1 429	577	2 708	1 816	3 846
Patents	620	487	1 271	1 058	3 049
Other expenses	0	0	0	0	0
<b>Total</b>	<b>26 767</b>	<b>6 359</b>	<b>43 506</b>	<b>19 694</b>	<b>40 337</b>

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

## 10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 100.9 million in non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

## 11. Share options

Share options outstanding at the end of the period have the following expiry date and exercise prices:

Expiry date	Exercise price in NOK per share option	Number of share options	
		31.12.2018	30.06.2019
2019 - Q3	8.63	40 000	40 000
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
<b>Total</b>		<b>556 500</b>	<b>745 500</b>

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 are exercised by the primary insider Gaël L'Hévéder (CBDO), 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. Mr. L'Hévéder left the Company per 31 March 2019 and all unvested share options (a total of 10,000) were terminated upon resignation.

Out of the total number of exercised share options, 30,000 share options at a strike price of NOK 19.24 are 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. Mr. Olivecrona transitioned from an employee to a consultant position per end June 2019 and all unvested share options (a total of 60,000) were terminated upon the transition.

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.

The share options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after three years. To ensure long term ownership by executive management, shares shall be held for at least three years after exercise, except shares to be sold immediately to cover transaction costs and tax under a so called cash less exercise. The share options are subject to other customary terms and conditions for employee incentive programs and the share options are lapsing in Q3 2024.

The Black-Scholes method is used for fair value assessment of the share options at grant date and the fair value is assessed to NOK 6.8 million which will be charged to the profit and loss statement over the vesting period for the share options. During 1H 2019 a total number of 70,000 non-vested share options were terminated due to cease of employment. Expenses for these share options charged through profit and loss in previous periods have been reversed in 1H 2019, with a net positive effect of NOK 1.0 million.

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 now have been granted by the Board of Directors.

Overview share options 2019, Senior executives	Total holdings 31.12 2018	Allocated	Lapsed	Exercised	Expired	Total holdings 30.06 2019
Per Walday, CEO	104 000	60 000	0	0	0	104 000
Ronny Skuggedal, CFO	116 000	40 000	0	0	0	116 000
Anders Høgset, CSO	66 000	40 000	0	0	0	66 000
Gaël L'Hévéder*, CBDO	21 000	0	0	11 000	10 000	0
Kristin Eivindvik, CDO	33 500	0	0	0	0	33 500
Hans Olivecrona**, CMO	90 000	0	0	30 000	60 000	0
<b>Sum</b>	<b>430 500</b>	<b>140 000</b>	<b>0</b>	<b>41 000</b>	<b>70 000</b>	<b>459 500</b>

\* Left the Company 31 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	<b>37 164 890</b>	<b>3.00</b>	<b>111 494 670</b>
Exercise of share options	61 000	3.00	183 000
<b>30.06.2019</b>	<b>37 225 890</b>	<b>3.00</b>	<b>111 677 670</b>

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 and subsequent to the transactions the Company's share capital is NOK 111,667,670 divided into 37,225,890 shares, each share with a nominal value of NOK 3.00 and each share 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.

PCI Biotech has more than 3,700 shareholders at the end of first half 2019.

### 10 largest shareholders per 30 June 2019:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,10 %
MP PENSJON PK	2 658 805	7,14 %
MYRLID AS	2 415 000	6,49 %
RADIUMHOSPITALET FORSKNINGSSSTIFT.	1 281 415	3,44 %
NORDNET LIVSFORSIKRING AS	1 068 770	2,87 %
GRESSLIEN	627 000	1,68 %
NORDNET BANK AB	573 543	1,54 %
JANDERSEN KAPITAL AS	535 000	1,44 %
BERG-LARSEN	490 504	1,32 %
VESLIK AS	417 570	1,12 %
<b>Total 10 largest shareholders</b>	<b>13 828 050</b>	<b>37,15 %</b>
Others	23 397 840	62,85 %
<b>Total</b>	<b>37 225 890</b>	<b>100,00 %</b>

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

Name	Position	No. of shares	
		31.12.2018	30.06.2019
Hans Peter Bøhn	Chairman	123 662	123 662
Christina Herder	Board member	10 000	10 000
Lars Viksmoen (Stocken Invest AS)	Board member	12 966	12 966
Hilde H. Steinenger	Board member*	0	NA
Andrew Hughes	Board member	0	0
Hilde Furberg	Board member**	NA	0
Per Walday	CEO	68 300	68 300
Anders Høgset	CSO	63 300	63 300
Ronny Skuggedal	CFO	28 300	28 300
Gaël L'Hévéder	CBDO***	62 000	NA
Kristin Eivindvik	CDO	18 800	18 800
Hans Olivecrona	CMO	0	0
<b>Total</b>		<b>387 328</b>	<b>325 328</b>

\* Hilde H. Steinenger ended her term as board member in May 2019 and holdings are reported up to that date.

\*\* Hilde Furberg was elected as board member in the annual general meeting in May 2019 and holdings are reported from that date.

\*\*\* Gaël L'Hévéder resigned and left PCI Biotech by end of March 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. Long term liabilities

Long term liabilities include public duties payables due in 1-5 years for potential future exercises of share options 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.

### 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 first half 2019 are presented below:

All figures in '000 NOK

#### **Right of use asset – office**

Initial recognition 01.01.2019	1,816
<b><u>Acquisition costs 30.06.2019</u></b>	<b><u>1,816</u></b>
Depreciation Q1 2019	151
Depreciation Q2 2019	151
<b><u>Accumulated depreciation and impairment 30.06.2019</u></b>	<b><u>302</u></b>
<b><u>Total right of use assets 30.06.2019</u></b>	<b><u>1,514</u></b>
Lower of remaining lease term or economic life	2.5 years
Depreciation method	Linear

#### **Lease liabilities - office**

Initial recognition 01.01.2019	1,816
Payments for the principal portion of the lease liability	-327
Interest expenses on the lease liability	18
<b><u>Total lease liabilities as of 30.06.2019</u></b>	<b><u>1,507</u></b>
Whereof:	
Short term lease liabilities < 1 year	329
Long term lease liabilities > 1 year	1,178

#### **Income statement 1H 2019 – office lease**

Depreciation	-302
<b><u>Effect on Operating results</u></b>	<b><u>-302</u></b>
Interest expenses on the lease liabilities	-18
<b><u>Effect on Net financial result</u></b>	<b><u>-18</u></b>
<b><u>Net Comprehensive income effect</u></b>	<b><u>-320</u></b>

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 327) for first half of 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 first half 2019 compared to IAS 17, where the only income statement effect were payments for the principal portion of the lease liability, is kNOK 7 positive (kNOK -327 income effect under IAS 17 versus kNOK -320 income effect under IFRS 16).

## 17. Property, plant and equipment

PCI Biotech acquired the first lot of lasers to be used in the RELEASE study in Q2 2019. A linear depreciation method over the expected life-time of five years for the equipment will be applied.

## 18. Subsequent events

Initial positive feedback on an international patent application examination for intracellular delivery of mRNA was received in Q3 2019 and the application may generate valuable intellectual property (IP) for the fimaNAc programme.

Preclinical results were in Q3 2019 published in the high-impact immunology journal “Frontiers in Immunology” (Combined Photosensitization and vaccination enable CD8 T-Cell Immunity and Tumor Suppression independent of CD4 T-Cell help, Varypataki et al. Front.Immunol. 10:1548).

The ongoing collaboration with an undisclosed large pharma company has been extended several times, most recently in Q3 2019 with additional six months until the end of December 2019. The aim of the extension is to complete of the agreed *in vivo* research. Thereafter the companies have agreed to use the following six months (until end of June 2020) to evaluate the potential for a further partnership.

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 <sup>st</sup> January – 31 <sup>st</sup> December)
1H:	First half (1 <sup>st</sup> January – 30 <sup>th</sup> June)
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

Q3 Report 2019	27 November	2019
Q4 Report 2019	26 February	2020
Annual Report	22 April	2020
Q1 Report 2020	6 May	2020
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.



*Unlocking the potential of innovative medicines*

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