*Unlocking the potential of innovative medicines*

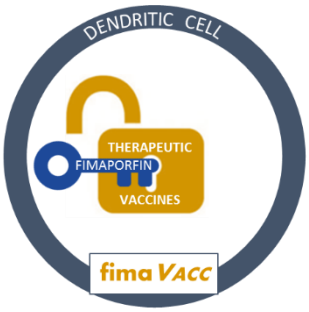
# FIRST QUARTER REPORT

# 2019

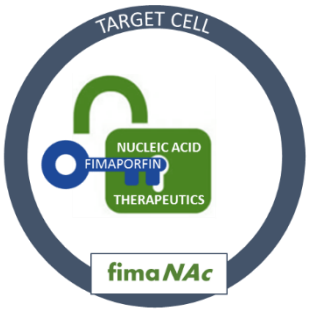
## LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS

### 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 fima*CHEM* 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 the company is about to start the pivotal RELEASE study in this high unmet need orphan indication. The second programme fima*VACC* is a vaccination technology in Phase I in healthy volunteers that applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic vaccines. The third programme fima*NAC* 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 of the first quarter

- fimaCHEM
  - **First sites for the pivotal RELEASE study open for enrolment**
  - **Successful safety read-out in the Phase I extension study confirmed** (subsequent event)
  - **Completion of the full Phase I study and formal closure of recruitment** (subsequent event)
  - **Presented Phase I dose-escalation results at the annual conference of the US Cholangiocarcinoma Foundation and at the 3rd Asia-Pacific Cholangiocarcinoma conference in Taiwan**
- fimaVACC
  - **Successful clinical translation** (subsequent event)
- **Corporate**
  - **Further strengthened the Scientific Advisory Committee**

## Key figures

| *(In NOK '000)* | **2019 Q1** | **2018 Q1** | **2018 FY** |
|---|---|---|---|
| Other income | 2 245 | 2 238 | 9 585 |
| Operating costs | 20 354 | 16 900 | 54 104 |
| Operating results | -17 929 | -14 663 | -44 519 |
| Financial items | -4 895 | 123 | 9 739 |
| **Comprehensive income** | **-22 824** | **-14 540** | **-34 780** |
| **Cash & cash equivalents** | **328 757** | **38 586** | **349 326** |
| **Net cash flow from operating activities** | **-21 407** | **-12 203** | **-30 297** |

# Operational review

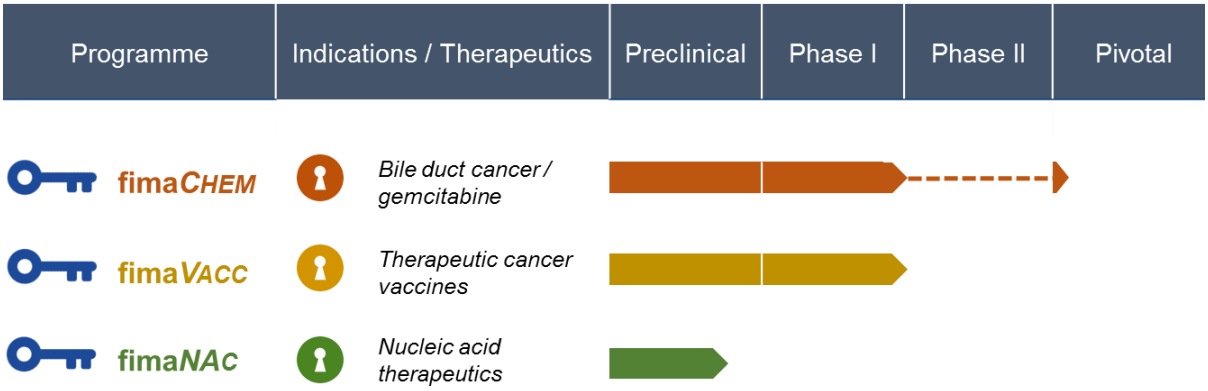
## First sites for the pivotal fimaCHEM "RELEASE" study open for enrolment and successful translation of fimaVACC into man

**Final confirmation of safety with two treatments was reached in April 2019 in the fimaCHEM Phase I extension study, without the report of any adverse reactions that would limit the delivery of up to two treatments in the RELEASE study. The pivotal RELEASE study will therefore be initiated with up to two treatments and it will also include a seamless safety review when eight patients have been given two treatments. The overall survival data for Phase I patients receiving the pivotal dose are encouraging, suggesting a clear improvement over the best comparable published data. All necessary approvals have been achieved in six countries and the first RELEASE study sites are open for enrolment of patients. 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.**

**The translation of the vaccination technology, fimaVACC, into humans has been successfully completed. 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. The results are now to be utilised to establish fimaVACC in the immunotherapy field.**

**On the corporate side, the Scientific Advisory Committee has been further strengthened to ensure adequate scientific support for continued progress of the fimaVACC programme in 2019.**

## 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), and is in clinical development with Amphinex, the intravenous formulation of fimaporfin. The lead project is initiating the RELEASE study, a pivotal clinical study with the potential of accelerated/conditional marketing approval as a first-line treatment given the rare disease status and high unmet medical need.**

### Successful safety read-out in the Phase I extension study confirmed

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 which currently are left without effective local treatment options. The appointed Cohort Review Committee (CRC) completed a formal review confirming PCI Biotech's preliminary report that no adverse reactions have been reported that would limit the delivery of up to two fimaCHEM treatments in the pivotal RELEASE study with registration intent.

### Completion of the full Phase I study and formal closure of recruitment

The full Phase I study, including the extension to explore safety of repeated treatments, is now completed and patient recruitment to this study has been formally closed. The results are planned to be published in scientific journals when the results database has been checked and cleaned.

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.

Tumour response data from the full Phase I study shows that approximately 50% of the patients with radiologically evaluable tumours had local tumour response according to RECIST criteria. It is encouraging to note that all the patients with tumour responses in this study had been given one of the two highest dose levels of fimaporfin, with approximately two thirds responding in each of these two groups. The local tumour response appeared to be somewhat less in the extension cohort with one fourth responding, but this may have been influenced by heterogeneity of patients between these small cohorts. Notably, the patient overall tumour burden in the extension cohort was on average about twice the overall tumour burden of the patients in the dose-escalation part of the study. In context of the importance of local control, it is also noteworthy that all progressive disease events were driven by the appearance of new lesions and not by further growth of fimaCHEM treated tumours.

A post-study follow-up of the patients from both the dose-escalation and extension part of the Phase I study is ongoing. The pivotal dosing regimen is up to two fimaCHEM treatments of the dose applied in the last ($4^{th}$) cohort in the dose-escalation part of Phase I. The median overall survival in the fourth dose cohort comprising six patients in the dose-escalation part ended at 21.7 months, with one patient still being alive more than three years after treatment. In the Phase I extension part a total of seven patients received the pivotal dose, and five out of the seven patients received two fimaCHEM treatments. Three of the seven patients in the extension part of Phase I were alive at last censoring (March – May 2019). Patient numbers are limited and it is too early to put significance to the emerging survival data, but currently this translates to an interim median overall survival of approximately 14 months including all seven patients.

The Phase I study including the dose-escalation and extension part with fima*CHEM* for the treatment of inoperable extrahepatic bile duct cancer aimed to demonstrate the candidate's safety and tolerability as well as finding the right dosing regimen for further clinical studies. 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. Based on the positive safety data, the pivotal RELEASE study is being initiated with up to two fima*CHEM* 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.

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

## Pivotal phase preparations underway for initiation in first half of 2019

The pivotal RELEASE study, with registration intent, is expected to start during the first half of 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 approximately 36 months after study initiation, while the final analysis is expected approximately 50 months from initiation. The pivotal study will be executed in clinical sites that first will open in Europe, followed by a roll-out in the U.S.

Ongoing regulatory and ethics approvals and site contract negotiations are progressing well. Regulatory and ethics approvals have been received for 6 countries by April 2019 (Norway, Germany, France, Spain, Sweden and Denmark). The first site was opened in Norway in March 2019 and a total of 2 sites in 2 different countries are open for enrolment by date of this report.

**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 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 SoC treatment of up to eight cycles of the chemotherapies gemcitabine and cisplatin, and an experimental arm with up to two fima*CHEM* treatments in addition to SoC. The second fima*CHEM* treatment is administered approximately three to four months after the initial treatment. The study's primary endpoint is PFS, with overall survival (OS) as a key secondary endpoint. The study includes an interim analysis of PFS followed by analysis of objective response rate (ORR), with the potential of accelerated/conditional marketing approval. In addition, the study contains several other secondary endpoints that provide the opportunity to generate robust comparative data of importance for market acceptance of fima*CHEM* as a first-line treatment for inoperable bile duct cancer.

**Regular communication milestones**
The planned communication milestones for the pivotal RELEASE study will be the initiation of the study, meaning first patient enrolled, and thereafter quarterly updates on the number of countries and clinical sites open for recruitment. Other milestones will be communicated as appropriate, including outcome of the IDMC reviews, as well as further details regarding timing and plan for interim analysis. In addition, the company will continue with quarterly updates on survival data from the Phase I study.

**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 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 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 fima*CHEM* 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 fima*CHEM* Phase I study. The published studies include a wide range of different inoperable bile duct cancer patients, while the fima*CHEM* Phase I study focuses 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. 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 translation

The fima*VACC* 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 this preclinical efficacy was done through a Phase I study in healthy volunteers. The study was designed as an open-label, antigen-adjuvant controlled study with the objectives to determine immune responses, safety and tolerability of fima*VACC* in healthy volunteers. The study was performed with two model vaccines; a large immunogenic protein (KLH) and two less immunogenic peptides (HPV). The two HPV peptide antigens chosen for the Phase I study were derived from the E7 protein of the human papillomavirus (HPV). 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 interim clinical results previously reported that fima*VACC* may enhance overall T-cell responses, especially to the HPV peptide, which is much less immunogenic than the KLH protein. The final data, reported in May 2019, confirms these results, showing a substantial increase in number of T-cell responders to the HPV peptides already after two vaccinations and a clear enhancement in the T-cell responses compared to the control group. The important CD8 responses are also more robust with fima*VACC* and exhibit 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 fima*VACC*'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 fima*VACC* dose levels, with the tolerability of fima*VACC* also 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'.

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 planned immune analysis of the Phase I study samples is now completed and recruitment is stopped. The overall development strategy for fima*VACC* is under assessment.

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

**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. 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 fima*VACC* 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 fima*VACC* technology may solve this challenge by effectively enhancing the vaccine presentation through this pathway.

## fima*NAc*

**The fima*NAc* 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.**

### Focus on preclinical research collaborations

PCI Biotech employs a collaborative strategy for fima*NAc*. Currently, the delivery technology is used in six preclinical research collaborations in the area of nucleic acid therapeutics. All the collaborators have the same purpose of exploring synergies between the partner's proprietary nucleic acid technologies and the fima*NAc* 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.

The ongoing collaboration with an undisclosed big pharma company has been extended several times, most recently until the end of June 2019 with the possibility for further extension.

**The fima*NAc* 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 fima*NAc* technology may resolve through enhancing the delivery of the majority of nucleic acid types.

# Corporate

**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 or 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 will be shared between the management members in the interim.

# Financial review

## Exercise of share options under 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.

## 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 various public sources such as the Norwegian Research Council and "SkatteFUNN" were recorded as other income. Other income for Q1 2019 amounted to NOK 2.4 million (NOK 2.2 million).

Research and development (R&D) costs for Q1 2019 totalled to NOK 16.7 million (NOK 13.3 million). Operating costs for Q1 2019 ended at NOK 20.4 million (NOK 16.9 million). Operating costs are mainly driven by the R&D activity level. For Q1 2019 the preparations for initiation of the pivotal fima*CHEM* trial was driving the costs, while for Q1 2018 the Phase I fima*CHEM* trial and the Phase I fima*VACC* study were the cost drivers.

Net financial result for Q1 2019 was NOK -4.9 million (NOK 0 million). The net negative financial result in first quarter 2019 is mainly driven by exchange rate effects on bank deposits placed in Euro in October 2018, as a hedge of the foreign currency risk for the pivotal study to be initiated in 2019. Since inception the foreign currency hedge has a net positive effect per end of first quarter 2019.

Net loss for the quarter was NOK 22.8 million (NOK 14.5 million). The higher net loss for the quarter compared to last year is due to increased R&D activities and the net negative financial result.

### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 328.8 million at the end of first quarter 2019, compared to NOK 349.3 million per end of 2018, reflecting net negative cash flow from operating activities of NOK 21.4 million in Q1 2019 (NOK 12.2 million) and net proceeds of NOK 0.8 million from a share issue in February 2019 in connection with the employee incentive program. 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 adopted IFRS 16 Leases for the first time in 2019, applying the modified retrospective method. The implementation effects for Q1 2019 are disclosed under note 16 Right of use assets and lease liabilities.

### Share capital

Following completion of the share issue 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.

## 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 Q1 2019. Please see note 7 Related party transactions for further details.

### Post-closing events

Final confirmation of successful safety read-out in the fima*CHEM* Phase I extension study was reported in April 2019, including a summary of efficacy results and interim overall survival for patients receiving the pivotal fima*CHEM* dosing regimen. Final results from successful clinical translation of the fima*VACC* vaccination technology was reported in May 2019. 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 (fima*VACC*) and nucleic acid therapeutics (fima*NAc*).

Although the company's focus is three-pronged, 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 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 beyond interim read-out is in place. 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, fima*VACC* and fima*NAc*, 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 decisions of the programme's further development strategy. The fima*NAc* 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
- Define and execute 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, 7 May 2019

| | | |
|---|---|---|
| Hans Peter Bøhn<br>Chairman (sign) | Christina Herder<br>Director (sign) | Hilde H. Steineger<br>Director (sign) |
| Andrew Hughes<br>Director (sign) | Lars Viksmoen<br>Director (sign) | Per Walday<br>CEO (sign) |

# CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

## PROFIT AND LOSS

| *(In NOK 1,000)* | Note | 2019 Q1 | 2018 Q1 | 2018 FY |
|---|---|---|---|---|
| **Other income** | *6* | **2 425** | **2 238** | **9 585** |
| Research and development | *7,8,9* | 16 739 | 13 335 | 40 337 |
| General and administrative | *16* | 3 615 | 3 565 | 13 767 |
| **Operating costs** | | **20 354** | **16 900** | **54 104** |
| **Operating results** | | **-17 929** | **-14 663** | **-44 519** |
| **Financial income and costs** | | | | |
| Financial income | | 659 | 123 | 9 890 |
| Financial expenses | *16* | 5 554 | 0 | 151 |
| **Net financial result** | *8* | **-4 895** | **123** | **9 739** |
| **Profit/loss before income tax** | | **-22 824** | **-14 540** | **-34 780** |
| Income tax | *9* | 0 | 0 | 0 |
| **Net profit/loss** | | **-22 824** | **-14 540** | **-34 780** |
| Other comprehensive income | | 0 | 0 | 0 |
| **Comprehensive income** | *5* | **-22 824** | **-14 540** | **-34 780** |

## BALANCE SHEET

| *(In NOK 1,000)* | Note | 2019 31.03 | 2018 31.03 | 2018 31.12 |
|---|---|---|---|---|
| **Fixed and intangible assets** | | | | |
| Operating assets | | 39 | 21 | 17 |
| Right to use asset | *16* | 1 665 | 0 | 0 |
| **Total fixed and intangible assets** | | **1 704** | **21** | **17** |
| **Current assets** | | | | |
| Short term receivables | *7* | 9 968 | 8 838 | 7 713 |
| Cash & cash equivalents | *7* | 328 757 | 38 586 | 349 326 |
| **Total current assets** | | **338 725** | **47 424** | **357 039** |
| **Total assets** | | **340 429** | **47 445** | **357 056** |
| **Shareholders' equity and liabilities** | | | | |
| **Shareholders' equity** | | | | |
| Paid in capital | *11,12* | 562 119 | 232 109 | 560 942 |
| Other reserves | | -243 812 | -203 551 | -220 988 |
| **Total equity** | | **318 308** | **28 558** | **339 954** |
| Other long term liabilities | | 96 | 2 260 | 107 |
| Lease liabilites | *16* | 1 169 | 0 | 0 |
| **Total long term liabilities** | *14* | **1 265** | **2 260** | **107** |
| Trade debtors | | 5 391 | 2 109 | 1 889 |
| Lease liabilities | *16* | 657 | 0 | 0 |
| Other short term liabilities | *7* | 14 808 | 14 519 | 15 106 |
| **Total short term liabilities** | *13* | **20 856** | **16 627** | **16 995** |
| **Total liabilities** | | **22 121** | **18 887** | **17 102** |
| **Total shareholders' equity and liabilities** | | **340 429** | **47 445** | **357 056** |

## CHANGE IN SHAREHOLDERS EQUITY

| *(In NOK '000)* | **2019 Q1** | **2018 Q1** | **2018 FY** |
|---|---|---|---|
| **Equity at beginning of period** | **339 954** | **41 842** | **41 842** |
| Capital increase | 839 | - | 328 833 |
| Share option scheme | 339 | 1 256 | 4 059 |
| Comprehensive income in the period | -22 824 | -14 540 | -34 780 |
| **Equity at end of period** | **318 308** | **28 558** | **339 954** |

## CASH FLOW

| *(In NOK '000)* | **2019 Q1** | **2018 Q1** | **2018 FY** |
|---|---|---|---|
| Ordinary profit before taxes | -22 824 | -14 540 | -34 780 |
| Depreciation, amortisation and write off | 153 | 1 | 5 |
| Share options | 339 | 1 256 | 4 059 |
| Net financials | -527 | -123 | -782 |
| Changes in working capital | 924 | 1 080 | 420 |
| Cash flow from operating activities | -21 934 | -12 326 | -31 079 |
| | | | |
| Net financials | 527 | 123 | 782 |
| Taxes paid | - | - | - |
| Net cash flow from operating and investing activities | -21 407 | -12 203 | -30 297 |
| | | | |
| **Cash flow from financial activities** | | | |
| Net proceeds from share issues | 838 | - | 328 834 |
| Net cash flow from financial activities | 838 | - | 328 834 |
| | | | |
| **Net change in cash during the period** | -20 569 | -12 203 | 298 537 |
| Cash and cash equivalents at the beginning of the period | 349 326 | 50 789 | 50 789 |
| **Cash and cash equivalents at the end of the period** | **328 757** | **38 586** | **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. PCI Biotech AS was a subsidiary of Photocure ASA until June 2008. 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 is about to initiate pivotal clinical development with the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agent gemcitabine for treatment of inoperable extrahepatic bile duct cancer. The fima*VACC* project is 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 7 May 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 31st, 2018.

## 5. Earnings per share

Earnings per share

| | 2019 Q1 | 2018 Q1 | 2018 FY |
|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -22 824 | -14 540 | -34 780 |
| Weighted average of outstanding shares ('000) | 37 185 | 24 988 | 27 797 |
| Earnings per share (NOK per share) | -0.61 | -0. 58 | -1.25 |

Diluted earnings per share:

| | 2019 Q1 | 2018 Q1 | 2018 FY |
|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -22 824 | -14 540 | -34 780 |
| Weighted average of outstanding shares ('000) | 37 671 | 25 727 | 28 353 |
| Earnings per share (NOK per share) | -0.61 | -0.58 | -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 recognised at the value of the contribution at the transaction date. 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 costs, and are disclosed as other income. The Company has recognised Norwegian grants and 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 Q1 | 2018 Q1 | 2018 FY |
|---|---|---|---|
| The Norwegian Radium Hospital Research Foundation | 639 | 459 | 1 806 |

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

## 8. Credit risk, foreign currency risk and interest risk

**Credit risk**
PCI Biotech has no sales for 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 | 704 | 417 | 7 422 | 1 425 | 9 968 |
| Total receivables | **704** | **417** | **7 422** | **1 425** | **9 968** |

A majority of the short-term receivables relates to accrued, not received grants (BIA) and tax incentive scheme (SkatteFUNN).

**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 study, which is planned to be initiated in 2019. PCI Biotech has not implemented any other hedging strategy to reduce foreign currency risk.

For the quarter the cash deposits placed in Euro generated a negative accounting effect of NOK 5.4 million. From inception in October 2018 the Euro deposits have a net positive accounting effect of NOK 3.7 million.

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

## 9. Research and Development costs

All figures in '000 NOK

| | 2019 Q1 | 2018 Q1 | 2018 FY |
|---|---|---|---|
| Clinical studies | 12 818 | 9 993 | 27 499 |
| Pre-clinical studies | 1 990 | 1 531 | 5 943 |
| CMC and equipment | 1 279 | 1 239 | 3 846 |
| Patents | 651 | 572 | 3 049 |
| Other costs | 0 | 0 | 0 |
| **Total** | **16 739** | **13 335** | **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 94.7 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 | 31.03.2019 |
|---|---|---|---|
| 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 | 60 000 |
| **Total** | | **556 500** | **485 500** |

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 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. After the transaction Mr. L'Hévéder held 67,700 shares and 10,000 share options in the Company.

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. After the transaction Mr. Olivecrona hold 0 shares and 60,000 share options in the Company.

| Overview options 2019, Senior executives | Total holdings 31.12 2018 | Allocated | Lapsed | Exercised | Expired | Total holdings 31.03 2019 |
|---|---|---|---|---|---|---|
| Per Walday, CEO | 104 000 | 0 | 0 | 0 | 0 | 104 000 |
| Ronny Skuggedal, CFO | 116 000 | 0 | 0 | 0 | 0 | 116 000 |
| Anders Høgset, CSO | 66 000 | 0 | 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 | 0 | 60 000 |
| **Sum** | **430 500** | **0** | **0** | **41 000** | **10 000** | **379 500** |

* Left the Company 31 March 2019 and all unexercised share options expired upon resignation.

## 12. Share capital

The Company's share capital is NOK 111,677,670 divided into 37,164,890 shares, each share with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

| | 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 | 61 000 | 3.00 | 183 000 |
| **31.03.2019** | **37 225 890** | **3.00** | **111 677 670** |

The Annual General Meeting held 29 May 2018 authorised the Board of Directors to execute share capital increases by issuing up to 1,865,000 shares with a nominal value of NOK 3.00 in connection with the company's employee incentive program. The authorisation is valid for one year.

The Annual General Meeting held 29 May 2018 authorised the Board of Directors to execute share capital increases with up to NOK 8,029,600 in connection with private placements. The authorisation shall not be used to increase the share capital by an amount in excess of 10% of the share capital, based on the share capital per 29 May 2018 and potential share capital increases in relation to the employee incentive programme. The authorisation may be used for general corporate purposes. The authorisation is valid for one year.

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.

Subsequent to the capital increase transactions in February 2019 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.

PCI Biotech has more than 3,700 shareholders at the end of the quarter.

**10 largest shareholders per 31 March 2019:**

| Name | No. of shares | Ownership |
|---|---|---|
| FONDSAVANSE AS | 3 760 443 | 10,10 % |
| MP PENSJON PK | 2 676 305 | 7,19 % |
| MYRLID AS | 2 415 000 | 6,49 % |
| RADIUMHOSPITALETS FORSKNINGSSTIFT. | 1 321 415 | 3,55 % |
| NORDNET LIVSFORSIKRING AS | 760 239 | 2,04 % |
| GRESSLIEN ODD ROAR | 618 100 | 1,66 % |
| NORDNET BANK AB | 560 114 | 1,50 % |
| JANDERSEN KAPITAL AS | 535 000 | 1,44 % |
| BERG-LARSEN ALEXANDER | 490 232 | 1,32 % |
| VESLIK AS | 419 540 | 1,13 % |
| **Total 10 largest shareholders** | **13 556 388** | ***36,42 %*** |
| *Others* | *23 669 502* | *63,58 %* |
| *Total* | *37 225 890* | *100,00 %* |

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

| | | No. of shares | |
|---|---|---|---|
| **Name** | **Position** | **31.12.2018** | **31.03.2019** |
| 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. Steineger | Board member | 0 | 0 |
| Andrew Hughes | Board member* | 0 | 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 | 67 700 |
| Kristin Eivindvik | CDO | 18 800 | 18 800 |
| Hans Olivecrona | CMO | 0 | 0 |
| **Total** | | **387 328** | **393 028** |

* Andrew Hughes was elected as board member in the annual general meeting in May 2018 and holdings are reported from that date.
** Gaël L'Hévéder resigned and left PCI Biotech by end of March 2019.

## 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

Other long term liabilities include public duties payables due in 1-4 years for potential future exercise 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.

## 15. Financial assets and liabilities

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

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

IFRS 16 Leases was implemented by PCI Biotech with effects as of 1 January 2019. PCI Biotech leases offices and on transition to IFRS 16, PCI Biotech recognised NOK 1.8 million in right of use assets and a corresponding lease liability which is 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 Q1 2019 are presented below:

All figures in '000 NOK

**Right of use asset – office**

| | |
|---|---|
| Initial recognition 01.01.2019 | 1,816 |
| **Acquisition costs 31.03.2019** | **1,816** |
| | |
| Depreciation Q1 2019 | 151 |
| **Accumulated depreciation and impairment 31.03.2019** | **151** |
| | |
| Lower of remaining lease term or economic life | 3 years |
| Depreciation method | Linear |

**Lease liabilities - office**

| | |
|---|---|
| Initial recognition 01.01.2019 | 1,816 |
| Payments for the principal portion of the lease liabilities | 0 |
| Interest expenses on the lease liabilities | 9 |
| **Total lease liabilities as of 31.03.2019** | **1,825** |
| | |
| Whereof: | |
| Short term lease liabilities < 1 year | 657 |
| Long term lease liabilities > 1 year | 1,168 |

**Income statement Q1 2019 - office**

| | |
|---|---|
| Depreciation | -151 |
| **Effect on Operating results** | **-151** |
| | |
| Interest expenses on the lease liabilities | -9 |
| **Effect on Net financial result** | **-9** |
| | |
| **Net effect Comprehensive income** | **-160** |

Payments for the principal portion of the lease liabilities (NOK 0 in Q1 2019) is not charged to profit and loss under IFRS 16 and will only have cash flow effects for 2019, while for 2018 these payments are charged directly to profit and loss.

## 17. Subsequent events

Final confirmation of successful safety read-out in the fima*CHEM* Phase I extension study was reported in April 2019, including a summary of efficacy results and interim overall survival for patients receiving the pivotal fima*CHEM* dosing regimen. Final results from successful clinical translation of the fima*VACC* vaccination technology was reported in May 2019. 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*CHEM*: | PCI Biotech's development program for enhancement of generic chemotherapies |
| fima*NAC*: | PCI Biotech's development program for delivery of nucleic acids |
| fima*VACC*: | PCI Biotech's development program for a vaccination technology |
| HPV: | Human papillomavirus |
| IDMC: | Independent Data Monitoring Committee |
| IND | Investigational New Drug |
| *In vitro*: | 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. |
| *In vivo*: | 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 (1st January – 31st December) |
| Q1: | Fourth quarter (1st January – 31st March) |

## FINANCIAL CALENDAR

| | | |
|---|---|---|
| Q2 Report 2019 | 28 August | 2019 |
| Q3 Report 2019 | 13 November | 2019 |

## INVESTOR CONTACT

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## FORWARD LOOKING STATEMENTS

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

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