



# Unlocking the potential of innovative medicines

# FOURTH QUARTER AND PRELIMINARY FULL YEAR REPORT

2018

# LEVERAGING THE PCI TECHNOLOGY IN THREE DISTINCT AREAS



#### TRIGGERED ENDOSOMAL RELEASE

#### **ABOUT PCI BIOTECH**

PCI Biotech is an oncology-focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops novel therapies for the treatment of cancer through its proprietary photochemical internalisation (PCI) technology originating from the world-leading research at the Oslo University Hospital – the Norwegian Radium Hospital. The PCI technology works by inducing light-triggered endosomal release 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-inman 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 fourth quarter

- fima CHEM
  - Preparations for the pivotal RELEASE study progressing towards initiation in the first half of 2019
  - Continued positive early signs of efficacy from Phase I dose-escalation
  - Preliminary confirmation of safety read-out from the Phase I extension study
  - Presented Phase I dose-escalation results at the 2018 ESMO congress and at the annual conference of the US CCA Foundation in Jan 2019 (subsequent event)
- fima VACC
  - Phase I interim data suggest enhancement of several parameters of importance for vaccination
  - US patent granted for "band-aid-like" device for skin illumination/injection
- fimaNAc
  - Extension of preclinical research collaboration agreement with a top-10 large pharma company
- Corporate
  - Completed fully underwritten rights issue of NOK 360 million
  - Further strengthened the clinical organisation and the Scientific Advisory Committee

# **Key figures**

(In NOK '000)	2018 FY	2017 FY	2018 Q4	2017 Q4
Other income	9 585	10 250	2 972	3 067
Operating costs	54 104	53 681	17 250	18 991
Operating results	-44 519	-43 431	-14 278	-15 924
Financial items	9 739	590	9 484	20
Comprehensive income	-34 780	-42 841	-4 793	-15 904
Cash & cash equivalents	349 326	50 789	349 326	50 789
Net cash flow from operating activities	-30 297	-29 943	0	-2 966



# **Operational review**

Summary – solid performance through 2018, moving towards initiation of the pivotal "RELEASE" study

The fully underwritten rights issue of NOK 360 million completed in October 2018 provides PCI Biotech with the funds needed for the pivotal fima*CHEM* study, beyond interim read-out of results for potential accelerated/conditional marketing approval. The pivotal study, which for further communication purposes will be called "RELEASE", is expected to start in the first half of 2019.

The dose-escalation part of the Phase I study has provided positive early signs of efficacy, with a median overall survival of 21.7 months for the dose selected for the pivotal study. Although the data sample is small, the results with a single fima*CHEM* treatment indicate a clear improvement over the best comparable published data.

Preliminary confirmation of safety with two treatments was reached in Q4 in the 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. PCI Biotech's focus is now to bring fima CHEM to the market for the treatment of inoperable bile duct cancer through successful completion of the RELEASE study.

The translation of the vaccination technology, fima VACC, into humans by demonstrating improvement of immunogenicity of vaccines in a Phase 1 study in healthy volunteers is a main priority for PCI Biotech to establish the company in the immunotherapy field. The dose-finding part of the Phase I study identified a well-tolerated dosing regimen and the interim data suggest enhancement of several parameters of importance for vaccination. PCI Biotech is collaborating with international experts to finalise and publish the in-depth analysis and characterisation of the immune responses from Phase I.

The fima*NAC* programme continued positive development, with two new research collaborations established and the research collaboration with an undisclosed top-10 pharma company was extended twice during 2018.

On the corporate side, the clinical organisation and the Scientific Advisory Committee have both been reinforced to ensure continued progress in our key areas in 2019.



### **Overview of PCI Biotech's development pipeline**



# **Development programmes**

# fima *CHEM*

The **fima***CHEM* 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. fima*CHEM* is 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 about to start the RELEASE study, a pivotal study with the potential of accelerated/conditional marketing approval as a first-line treatment given the rare disease status and high unmet medical need.

#### Positive overall survival data in Phase I

The ongoing Phase I study including the dose-escalation and extension part with fima *CHEM* for the treatment of inoperable extrahepatic bile duct cancer aims to demonstrate the candidate's safety and tolerability as well as finding the right dosing regimen for further clinical studies. Interim data per January 2019 continues to show encouraging initial results. The median overall survival from all dose cohorts in the dose-escalation part (sixteen patients in total) was 14.4 months, with one patient still being alive.

The selected dose (Cohort IV; six patients) for the upcoming pivotal study, included five patients with measurable tumours at baseline and tumour response was seen in three of these patients. The median overall survival for this group ended at 21.7 months in October 2018, with one patient still being alive. Although the data sample is small, the results suggest a clear improvement of survival over the best comparable published data (see information box on next page).

Professor Jörg Trojan, a key investigator of PCI Biotech's Phase I dose-escalation study, presented the study results in a poster session at the largest European oncology congress, ESMO, held in Munich, Germany, in October 2018. Dr. Hans Olivecrona, CMO, presented in January 2019 the same results at the U.S. Cholangiocarcinoma Foundation's annual conference. The conference attracts both bile duct cancer patients and key opinion leading clinicians in hepatobiliary cancers from all over US.

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

The pivotal RELEASE study 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 received in Norway (Feb, 2019).

#### Extension study to enable repeated fima CHEM treatment

The promising early signs of efficacy in the Phase I study described above were based on a single fima*CHEM* treatment when added to the current standard of care (SoC) as background treatment. A Phase I extension study was initiated with the objective to determine safety and tolerability of repeated treatments with fima*CHEM*, as this may well increase the encouraging signs of efficacy. In this study, the second fima*CHEM* treatment is administered approximately three to four months after the initial treatment.

Preliminary confirmation of achieved safety endpoint (at least five out of six patients without schedule limiting toxicity) in the Phase I extension study was reported in Q4 2018, supporting the proposed plan of including up to two fima *CHEM* treatments in the pivotal study. The final confirmation of successful safety read-out is pending completion of site monitoring and a formal review by the appointed Cohort

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Review Committee (CRC) in first half of 2019. The efficacy data from the Phase I extension study will be compiled in the same process. A total of 7 patients have been included and the first patient was treated in August 2017. All patients receiving two fima *CHEM* treatments were still alive at last censoring (December 2018), but the overall survival data is not yet mature enough for reporting. Recruitment of patients is not expected to formally close until the CRC has completed their review and confirmed that the safety endpoint has been reached.

Based on this positive safety data, the plan is now to initiate the pivotal RELEASE study with up to two fima *CHEM* treatments and 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 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 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 treated, 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 fime 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 is a main priority for PCI Biotech to establish the company in the immunotherapy field.

#### **Encouraging initial clinical results**

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 T-cell and antibody responses. The initial clinical translation of this preclinical efficacy is done through a Phase I study in healthy volunteers, designed to determine immune responses, safety and tolerability. The study is performed with two model vaccines; both a large immunogenic protein (KLH) and two smaller less immunogenic peptides (HPV). The interim clinical results reported so far have shown enhanced T-cell responses (CD3), with both earlier responses and higher response rates in groups treated with well tolerated fima *VACC* dosing regimens compared to the control group, which is treated with a state-of-the-art adjuvant technology (Hiltonol).

#### In-depth characterisation of T-cell responses – preliminary positive findings

The in-depth characterisation of the T-cells (CD4 and CD8) involved in the fima *VACC* immune response is done in collaboration with a renowned international expert institute; the laboratory of Experimental Cancer Immunology and Therapy of the department of Medical Oncology at Leiden University Medical Center in the Netherlands under the leadership of Professor Sjoerd van der Burg.

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 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. In the two dose groups analysed to date and which were demonstrated to be well tolerated, the numbers of volunteers showing CD8 responses upon completion of the vaccination schedule were higher in the two fima *VACC* treated groups (5 of 6 subjects) than in the control group (2 of 6 subjects). Analyses of further groups will be completed with the aim of confirming these preliminary positive findings prior to publication.

#### New US patent granted

A patent application filed in 2013 for a "band-aid-like" illumination/injection device for fimaVACC vaccination, as well as other potential skin applications, has been granted in the US in October 2018.

#### 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.

#### Research collaboration with Ultimovacs ended based on strategic considerations

In January 2016, PCI Biotech announced the initiation of a preclinical research collaboration with the Norwegian privately held pharmaceutical company, Ultimovacs AS, developing novel immunotherapy against cancer. The purpose of the collaboration was to utilise the companies' complementary scientific platforms to explore potential compatibility and synergy based on preclinical *in vivo* studies. The research collaboration was supported by a grant from Innovation Norway of NOK 0.5 million in 2017.

The collaboration generated positive preclinical *in vivo* data, but based upon strategic considerations the companies agree that the potential for further partnership is limited and the collaboration is therefore ended. The generated positive data is planned to be published in a scientific journal.



#### 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 Tcells 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 **fime***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

The fima*NAc* programme generated two new research collaboration in 2018 and the research collaboration with an undisclosed top-10 pharma company was extended twice during 2018.

In August a research collaboration was signed with the Danish biotechnology company Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY), a key player in the emerging field of immunotherapy, with multiple clinical programmes within oncology and infectious diseases. In May a similar collaboration was signed with IMV Inc, a clinical stage Canadian biopharmaceutical corporation focused on developing immunotherapies.

The recently extended collaboration with an undisclosed top-10 pharma company, aiming to evaluate synergistic effects of fima*NAc* with their nucleic acid therapeutics. This agreement has been extended several times, most recently until the end of June 2019 with the possibility for further extension. In 2017, the collaboration was expanded to include evaluation of technological compatibility and synergy based on *in vivo* preclinical studies.

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 partners are working with the same purpose of exploring synergies between their proprietary nucleic acid technologies and the fima*NAc* technology. Thereafter, if successful, the intention is to explore the potential for further partnerships.

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

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



# Corporate

#### Strengthening organisation with clinical expertise

PCI Biotech is focused towards initiation of the pivotal study RELEASE with fima *CHEM* and has further strengthened the organisation by appointing Karin Staudacher, M.Sc. as Clinical Project Director, from November 2018. Staudacher will assume operational responsibility for PCI Biotech's pivotal study RELEASE. Staudacher brings extensive project management experience from multinational clinical research projects including Algeta's Phase III trial for Xofigo, a product marketed by Bayer and reached the market in 2013. Most recently, Staudacher held the position as Director Clinical Development at the biotechnology company Targovax ASA.

#### Updates on the Scientific Advisory Committee

PCI Biotech's Scientific Advisory Committee (SAC) has been reinforced 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 Clinical 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 cancer 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, ESCII), the Cancer Vaccine Consortium and the International Papillomavirus Society. He is an Associate Editor for Cancer Therapy.

# **Financial review**

#### Fully underwritten rights issue of NOK 360 million

The Company carried out a fully underwritten rights issue of NOK 360 million, resolved at an extraordinary general meeting held on the 14 September 2018 and completed on the 10 October 2018. The net proceeds, NOK 327.6 million, and the existing cash is expected to finance the Company well into 2022, which is beyond the anticipated interim read-out of the pivotal fima *CHEM* study in inoperable bile duct cancer. Further, a minor part of the net proceeds will be used to finance the completion of the ongoing clinical Phase I trial of fima *VACC* in healthy volunteers, selective preclinical and illumination device development for fima *VACC*, continue collaborations with external partners for fima *NAC* as well as general corporate purposes.

The rights issue was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received in October 2018 an underwriting fee equal to 3.5 per cent of their respective underwriting obligations. On the 4 October 2018, the day after the expiry of the subscription period, the board of directors of PCI Biotech approved the final allocation of the shares offered in the rights issue based on the allocation criteria set out in the prospectus dated 17 September 2018. The rights issue was subscribed with approximately 87% of the 12,000,000 new shares offered. New shares were allocated to underwriters in accordance with the underwriting commitment to the extent the underwriters had not fulfilled such commitments by subscribing for offer shares in the subscription period.

#### 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 170,000 share options on 17 October 2018. Out of these share options 85,000 were exercised by the primary insider Gaël L'Hévéder (CBDO).

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 510,000 by issuing 170,000 new shares, each share with a nominal value of

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NOK 3.00 and each giving one vote at the Company's general meeting. The transaction was completed 24 October 2018 and resulted in net proceeds of NOK 1.2 million.

In addition participants of the Company's share option program for employees exercised a total number of 8,000 share options on 12 April 2018. 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 2017, decided to increase the Company's share capital with NOK 24,000 by issuing 8,000 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 17 April 2018. The capital increase resulted in net proceeds of NOK 44 thousand.

#### **Income Statement**

(Figures in brackets = same period 2017 unless stated otherwise).

The Group did not record revenues for financial year (FY) 2018 nor 2017. Grants received from various public sources such as the Norwegian Research Council and "SkatteFUNN" were recorded as other income. Other income for Q4 and FY 2018 amounted to NOK 3.0 million (NOK 3.1 million) and 9.6 million (NOK 10.3 million) respectively.

Research and development (R&D) costs for Q4 and FY 2018 totalled to NOK 11.9 million (NOK 14.5 million) and 40.3 million (NOK 41.0 million) respectively. Operating costs for Q4 and FY 2018 ended at NOK 17.3 million (NOK 19.0 million) and 54.1 million (NOK 53.7 million) respectively. Operating expenses are mainly driven by the R&D activity level and for 2018 there are two clinical phase I trials running, in addition to preparation for the pivotal trial.

Net financial result for Q4 was NOK 9.5 million (NOK 0 million) and for FY 2018 NOK 9.7 million (NOK 0.6 million), The increased net result compared to last year is mainly driven by a financial income on funds, from the recently completed rights issue, placed as Euro deposits as a hedge of the foreign currency risk for the pivotal study to be initiated in 2019.

Net loss for the quarter was NOK 4.8 million (NOK 15.9 million). Net loss for FY 2018 was NOK 34.8 million (NOK 42.8 million). The decreased net loss for the quarter and the full year is mainly due to increased financial income.

#### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 349.3 million at the end of the year, compared to NOK 50.8 million at year-end 2017, reflecting net negative cash flow from operating activities of NOK 30.3 million and total net proceeds of NOK 328.8 million from share issues. All cash and cash equivalents were placed as bank deposits at the end of the guarter.

Cash flow from operations is mainly dependent on R&D activities. Net cash flow from operating activities was NOK 0 million (NOK -3.0 million) in the quarter and NOK -40.0 million (NOK -30.6 million) for the full year 2018.

#### Share capital

Following completion of the rights issue of NOK 360 million and two capital increases following exercise of share options during 2018 the Company's share capital is NOK 111,494,670 divided into 37,164,890 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 2018**

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 2017, the most important risks the company is exposed to in 2018 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 2017.

#### **Related party transactions**

PCI Biotech is relying on services provided by third parties, including related parties, as a result of its organisational set-up. PCI Biotech considers its business relationship with The Norwegian Radium Hospital Research Foundation as the only material ordinary related party transactions per year end 2018. In addition, The Norwegian Radium Hospital Research Foundation and other major shareholders had entered into the underwriting agreement for the fully underwritten rights issue of NOK 360 million completed in October 2018. The underwriters received an underwriting fee equal to 3.5 per cent of their respective underwriting obligations. Stocken Invest AS, a company wholly owned by Lars Viksmoen, a board member of PCI Biotech, had entered into the underwriting agreement for the underwriting agreement for the details.

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

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 now 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 and the Phase I study in healthy volunteers will provide results on clinical translation of the technology into humans. The initial results are encouraging, and the study is expected to provide key data to support decisions of the programme's further development strategy. The fima NAC programme continues to follow a collaborative approach, by pursuing outlicensing 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
- Complete the clinical translation of the fima VACC technology
- 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, 12 February 2019

Hans Peter Bøhn Chairman (sign) Christina Herder Director (sign) Hilde H. Steineger 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	2018	2017	2018	2017
		Q4	Q4	FY	FY
Other income	5	2 972	3 067	9 585	10 250
Research and development	8	11 924	14 494	40 337	40 988
General and administrative		5 326	4 497	13 767	12 693
Operating costs		17 250	18 991	54 104	53 681
Operating results		-14 278	-15 924	-44 519	-43 431
Financial income and costs					
Financial income		9 625	107	9 890	677
Financial expenses		141	87	151	87
Net financial result		9 484	20	9 739	590
Profit/loss before income tax		-4 793	-15 904	-34 780	-42 841
Income tax	9	0	0	0	0
Net profit/loss	4	-4 793	-15 904	-34 780	-42 841
Other comprehensive income		0	0	0	0
Comprehensive income		-4 793	-15 904	-34 780	-42 841

### **BALANCE SHEET**

(In NOK 1,000) Note	2018	2017
	31.12	31.12
Fixed and intangible assets		
Operating assets	17	22
Total fixed and intangible assets	17	22
Current assets		
Short term receivables 7	7 713	7 625
Cash & cash equivalents 7	349 326	50 789
Total current assets	357 039	58 414
Total assets	357 056	58 436
Shareholders' equity and liabilities		
Shareholders' equity		
Paid in capital	563 135	232 109
Other reserves	-223 180	-190 266
Total equity 10	339 955	41 842
Other long term liabilities 14	107	2 009
Total long term liabilities	107	2 009
Trade debtors	1 889	1 497
Other short term liabilities	15 105	13 088
Total short term liabilities	16 994	14 585
Total liabilities	17 101	16 594
Total shareholders' equity and liabilities	357 056	58 436

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### **CHANGE IN SHAREHOLDERS EQUITY**

(In NOK '000)	2018 Q4	2017 Q4	2018 FY	2017 FY
Equity at beginning of period	14 910	55 937	41 842	13 086
Capital increase	328 790	-	328 834	66 729
Share option scheme	1 048	1 808	4 059	4 867
Comprehensive income in the period	-4 793	-15 904	-34 780	-42 841
Equity at end of period	339 955	41 842	339 955	41 842

#### **CASH FLOW**

(In NOK '000)	2018	2017	2018	2017
	Q4	Q4	FY	FY
Ordinary profit before taxes	-4 793	-15 904	-34 780	-42 841
Depreciation, amortisation and write off	1	1	5	6
Share options	1 048	1 806	4 059	4 867
Net financials	-9 484	-180	-9 739	-677
Changes in working capital	3 744	11 132	420	8 025
Cash flow from operating activities	-9 484	-3 073	-40 035	-30 620
Net financials	9 484	108	9 739	677
Taxes paid	-	-	-	-
Net cash flow from operating activities	0	-2 966	-30 297	-29 943
Cash flow from financial activities				
Net proceeds from share issues	328 790	-	328 834	66 730
Net cash flow from financial activities	328 790	-	328 834	66 730
Not always in each dealers the mode d	000 700	0.000	000 007	00 707
Net change in cash during the period	328 790	-2 966	298 837	36787
cash and cash equivalents at the beginning of	20 536	53 755	50 780	14 002
Cash and cash equivalents at the end of the	20 000	33733	50769	14 002
period	349 326	50 789	349 326	50 789



# 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 the Oslo Axess since 18 June 2008 under the ticker PCIB. On 27 April 2018 the listing was transferred from Oslo Axess to Oslo Børs. 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 ready to enter 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, for 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 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 2017 (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 12 February 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 2017.



The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2018 or later and that could affect PCI Biotech are discussed in accounting principles, part 4, to the consolidated financial statements for 2017. In the 2017 financial statements, PCI Biotech made evaluations that at current stage *IFRS 9 Financial Instruments, IFRS 15 Revenue from contract with customers* and *IFRS 16 Leases* are not expected to have a significant impact on PCI Biotech's financial position, performance and/or disclosure.

#### 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>, 2017.

#### 5. Earnings per share

#### Earnings per share

	2018	2017	2018	2017
	Q4	Q4	FY	FY
Result allocated to shareholders (NOK'000)	-4 793	-15 904	-34 780	-42 841
Weighted average of outstanding shares ('000)	36 203	24 987	27 797	24 348
Earnings per share (NOK per share)	-0.13	-0.64	-1.25	-1.76

Diluted earnings per share:

	2018	2017	2018	2017
	Q4	Q4	FY	FY
Result allocated to shareholders (NOK'000)	-4 793	-15 904	-34 780	-42 841
Weighted average of outstanding shares ('000)	36 759	25 465	28 353	24 348
Earnings per share (NOK per share)	-0.13	-0.64	-1.25	-1.76

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	2018	2017	2018	2017
	Q4	Q4	FY	FY
The Norwegian Radium Hospital Research Foundation	423	758	1 806	2 600

At the end of the quarter PCI Biotech had NOK 0.3 million in short-term liability to The Norwegian Radium Hospital Research Foundation. In addition, The Norwegian Radium Hospital Research Foundation and other major shareholders had entered into the underwriting agreement for the fully underwritten rights issue of NOK 360 million completed in October 2018. The underwriters received an underwriting fee equal to 3.5 per cent of their respective underwriting obligations. Stocken Invest AS, a company wholly owned by Lars Viksmoen, a member of the board, had entered into the underwriting agreement with a commitment of NOK 1.0 million of the rights issue. The corresponding underwriting fee has been settled in October 2018.

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

#### Credit risk

PCI Biotech has no sales for 2017 and 2018 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	239	462	7 012	-	7 713
Total receivables	239	462	7 012	-	7 713

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.

#### Interest risk

PCI Biotech has no interest bearing debt.



#### 9. Research and Development costs

All figures in '000 NOK

	2018 Q4	2017 Q4	2018 FY	2017 FY
Clinical studies	8 686	8 447	27 499	23 886
Pre-clinical studies	1 430	4 434	5 943	12 539
CMC and equipment	920	626	3 846	1 770
Patents	888	988	3 049	2 793
Other costs	0	0	0	0
Total	11 924	14 494	40 337	40 988

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.

PCI Biotech reviewed in 2017 the internal allocation of operating expenses for disclosure of the sub categories in the statement of comprehensive income; research and development expenses versus general and administrative expenses. The review was made based on the current operational set-up of the organisation which has changed and developed over the years, from an early stage clinical company towards a pivotal stage ready company. The outcome of the review has led to reallocation of expenses, for the interim figures previously reported for 2017, between these two relevant P&L sub categories with no net change in the disclosed total operating expenses. In the statement of comprehensive income 2017 for the Company the new allocation routines are applied prospectively, as this reflects the underlying operations.

#### 10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 89.4 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:

	Exercise price in NOK	Number of	shares
Expiry date	per share	31.12.2017	31.12.2018
2019 - Q3	9.08	85 000	0
2019 - Q3	8.63	40 000	40 000
2020 - Q3	7.84	73 500	41 000
2020 - Q3	3.26	110 000	45 500
2022 - Q3	21.48	340 000	340 000
2022 - Q3	19.24	90 000	90 000
Total		738 500	556 500



The exercise price of the outstanding share options are adjusted based upon standard terms for dilution effects for specific company transactions and the rights issue of NOK 360 million completed 10<sup>th</sup> October 2018 is a transaction of this kind. The total P&L effect of the adjustment, based on calculation using the Black- Scholes valuation method, is NOK -0.6 million where NOK 0.3 million is charged to the P&L in 2018. The residual value will be charged over the remaining lifetime of the outstanding share options.

The lifetime of 125,000 share options originally expiring in Q3 2018, during the rights issue process, were extended with one year in August 2018 and are now expiring in Q3 2019. The total P&L effect of the change, based on calculation using the Black- Scholes valuation method, is NOK -0.1 million and is charged to the P&L in 2018.

One participant in the Company's share option program exercised 12 April 2018 a total number of 5,000 share options at a strike price of NOK 9.11 and a total number of 3,000 share options at a strike price of NOK 3.79, corresponding to a total number of 8,000 shares. At the same time another 4,000 share options lapsed.

Participants of the Company's share option program for employees exercised a total number of 170,000 share options on 17 October 2018. Out of these share options 85,000 were exercised at a strike price of NOK 9.08, 60,000 share options were exercised at a strike price of NOK 3.26 and 25,000 share options were exercised at a strike price of NOK 7.84.

Out of the total number of exercised share options, 70,000 share options at a strike price of NOK 9.08 and 15,000 share options at a strike price of NOK 7.84 were exercised by the primary insider Gaël L'Hévéder (CBDO), who sold 33,000 shares in the market at an average price of NOK 27.58 per share in order to finance the cash and tax impact of the share option exercise.

Overview options 2018, Senior executives	Total holdings 31.12 2017	Allocated	Lapsed	Exercised	Expired	Total holdings 31.12 2018
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	106 000	0	0	85 000	0	21 000
Kristin Eivindvik, PD	33 500	0	0	0	0	33 500
Hans Olivecrona, CMO	90 000	0	0	0	0	90 000
Sum	515 500	0	0	85 000	0	430 500

#### 12. Share capital

The Company's share capital is NOK 111,494,670 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
31.12.2017	24 986 890	3.00	74 960 670
Exercise of share options	178 000	3.00	534 000
Rights Issue	12 000 000	3.00	36 000 000
31.12.2018	37 164 890	3.00	111 494 670



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 8,000 share options on 12 April 2018. 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 2017, decided to increase the Company's share capital with NOK 24,000 by issuing 8,000 new shares, each share of par value NOK 3.00 and each share giving one vote at the Company's general meeting. The transaction was completed 17 April 2018. The capital increase resulted in net proceeds of NOK 40 thousand.

The Company carried out a fully underwritten rights issue of NOK 360 million, resolved at an extraordinary general meeting held on 14 September 2018, by a share capital increase of NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting. The rights issue was completed 10 October 2018.

The rights issue was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received an underwriting fee equal to 3.5 per cent of their respective underwriting obligations.

On the 4 October 2018, the day after expiry of the subscription period, the board of directors of PCI Biotech approved the final allocation of the shares offered in the rights issue based on the allocation criteria set out in the prospectus dated 17 September 2018. A total of 12,000,000 new shares were allocated and the rights issue was subscribed with 87 per cent of the shares offered. Approximately 9.2 million new shares were allocated to subscribers on the basis of exercised subscription rights. Approximately 0.9 million new shares were allocated to holders of subscription rights as a result of oversubscription. Approximately 0.3 million new shares were allocated to subscribers without subscription rights. Approximately 1.6 million new shares were allocated to the underwriters in accordance with the underwriting commitments of the respective underwriters to the extent the underwriters have not fulfilled such commitments by subscribing for offer shares in the subscription period. The capital increase resulted in net proceeds of NOK 327.6

Participants of the Company's share option program for employees exercised a total number of 170,000 share options on 17 October 2018. 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 510,000 by issuing 170,000 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 24 October 2018. The capital increase resulted in net proceeds of NOK 1.2 million.

Subsequent to the three capital increase transactions in 2018 the Company's share capital is NOK 111,494,670 divided into 37,164,890 shares, each share with a nominal value of NOK 3.00 and each share giving one vote at the Company's general meeting.

The Company has more than 3,700 shareholders at the end of the quarter.



#### 10 largest shareholders per 31 December 2018:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,12 %
MP PENSJON PK	2 726 305	7,34 %
MYRLID AS	2 415 000	6,50 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 321 415	3,56 %
NORDNET LIVSFORSIKRING AS	739 314	1,99 %
GRESSLIEN ODD ROAR	620 850	1,67 %
ABN AMRO Global Custody Services N	586 537	1,58 %
NORDNET BANK AB	565 669	1,52 %
JANDERSEN KAPITAL AS	535 000	1,44 %
BERG-LARSEN ALEXANDER	494 697	1,33 %
Total 10 largest shareholders	<u>13 765 230</u>	<u>37,04 %</u>
Others	23 399 660	62,96 %
Total	37 164 890	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	31.12.2017	31.12.2018
Hans Peter Bøhn	Chairman	83 556	123 662
Christina Herder	Board member	8 355	10 000
Kjetil Taskén (Kjetil Taskén AS)	Board member*	4 000	NA
Lars Viksmoen (Stocken Invest AS)	Board member	4 000	12 966
Hilde H. Steineger	Board member	0	0
Andrew Hughes	Board member**	NA	0
Per Walday	CEO	65 133	68 300
Anders Høgset	CSO	62 456	63 300
Ronny Skuggedal	CFO	25 066	28 300
Gaël L'Hévéder	CBDO	10 000	62 000
Kristin Eivindvik	CDO	17 948	18 800
Total		280 514	387 328

\* Kjetil Taskén, board member, ended his term at the annual general meeting in May 2018 and holdings are reported up to that date.

\*\* Andrew Hughes was elected as board member in the annual general meeting in May 2018 and holdings are reported from that date.

The board of directors and management (primary insiders) made the following exercise of subscription rights in the fully underwritten rights issue of NOK 360 million completed in October 2018 and are part of their shareholding portfolio after completion of the rights issue in October 2018:

The chairman of the board, Hans Peter Bøhn, exercised all 40,106 subscription rights allocated in the rights issue. Stocken Invest AS, a company wholly owned by Lars Viksmoen, a member of the board, bought and exercised 1,580 subscription rights, in addition to all the 1,920 subscription rights allocated in the rights issue. In addition, Stocken Invest AS had entered into the underwriting agreement with a commitment of NOK 1.0 million of the rights issue. The corresponding underwriting fee was settled in

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October 2018. The rights issue was subscribed with approximately 87% of the shares offered and new shares were allocated to underwriters in accordance with the underwriting commitment to the extent the underwriters had not fulfilled such commitments by subscribing for offer shares in the subscription period. Stocken Invest AS was allocated 5,466 shares and these shares are part of the shareholding portfolio pursuant of completion of the rights issue on 10 October 2018.

The board member Christina Herder exercised 1,645 out of the 4,010 subscription rights allocated in the rights issue. The allocated subscription rights that were not exercised were sold to an average sales price of NOK 4.40 per subscription right. The board members, Hilde H. Steineger and Andrew Hughes, held no shares in the Company and hence were not allocated any subscription rights in the rights issue.

Per Walday, CEO, exercised 3,167 out of the 31,263 subscription rights allocated in the rights issue. Ronny Skuggedal, CFO, exercised 3,234 out of the 12,031 subscription rights allocated in the rights issue. Gaël L'Hévéder, CBDO, exercised none of the 4,800 subscription rights allocated in the rights issue. Kristin Eivindvik, PD, exercised 852 out of the 8,615 subscription rights allocated in the rights issue. Anders Høgset, CSO, exercised 844 out of the 29,978 subscription rights allocated in the rights issue. The allocated subscription rights that were not exercised by management were sold to an average sales price of NOK 4.71 per subscription right.

#### 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 relates to public duties payables due in 1-4 years for potential future exercise of share options in PCI Biotech's employee share option scheme.

#### 15. Subsequent events

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



### **DEFINITIONS AND GLOSSARY**

Amphinex: CRC: EMA: FDA:	Trade name of the clinical intravenous formulation of fimaporfin Cohort Review Committee European Medicines Agency U.S. Food and Drug Administration
Fimaporfin:	Generic name of the photosensitiser active ingredient TPCS2a
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.
ODD:	Orphan Drug Designation
ORR:	Objective Response Rate
OS:	Overall Survival
PCI:	Photochemical internalisation
PFS:	Progression Free Survival
R&D:	Research and Development
SoC:	Standard of Care
NOK: FY: Q4:	Norwegian kroner Financial year (1 <sup>st</sup> January – 31 <sup>st</sup> December) Fourth quarter (1 <sup>st</sup> October – 31 <sup>st</sup> December)

#### FINANCIAL CALENDAR

Q1 Report 2019	08 May	2019
Q2 Report 2019	28 August	2019
Q3 Report 2019	13 November	2019

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#### FORWARD LOOKING STATEMENTS

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

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