



Unlocking the potential of innovative medicines

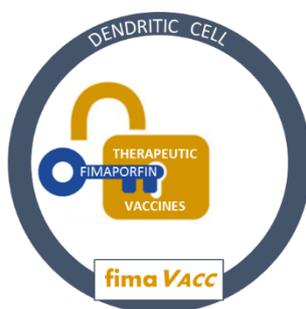
THIRD QUARTER REPORT
2019

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 fimaCHEM with the photosensitiser fimaporfin (Amphinex®), which entered the pivotal RELEASE study in May 2019. The second programme fimaVACC is a vaccination technology that applies a unique mode of action to enhance the essential cytotoxic effect of therapeutic vaccines. Successful clinical proof of concept was achieved in a Phase I study in healthy volunteers in 2019. The third programme fimaNAC is a technology for intracellular delivery of nucleic acids is currently evaluated in collaboration with key players in the field.

Highlights

fimaCHEM

- Start-up activities for the RELEASE study are progressing well after the study commenced with enrolment of the first patient in May 2019
- 23 out of 40 planned clinical sites had opened for enrolment by mid-November. While this is 10 sites less than planned and causes a temporary effect on patient recruitment projections, the company expects site activations to be back on track early 2020. The overall RELEASE study timelines are maintained
- The first US site was activated only recently and enrolment of the first US patient may therefore slide into 1H 2020
- Site selection is ongoing for addition of sites in Asia in 2020, to provide access to hospitals and key opinion leaders in a region with higher prevalence of bile duct cancer and to enhance patient recruitment

fimaVACC

- Phase I results have been accepted for presentation at ESMO Immuno-Oncology Congress in December 2019. The results provide proof-of-concept of the fimaVACC vaccination technology by demonstrating the improvement of immunogenicity in healthy volunteers
- Development strategies are being pursued in parallel, with Phase I results being used both in direct partnering efforts and planning for clinical proof of concept in a disease setting
- Preclinical study published in high-impact immunology journal Frontiers of Immunology, demonstrating that therapeutic cancer vaccination with fimaVACC can be effective independent of T-helper cell functionality

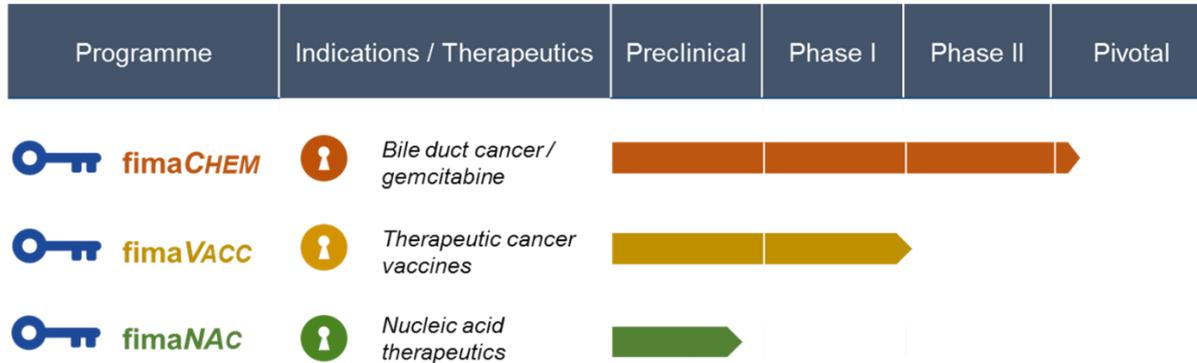
fimaNAC

- Research collaboration with AstraZeneca was extended by six months until end of 2019. The scope has been expanded to evaluate if synergies established in oncology are transferrable to additional disease areas – further collaboration to be evaluated in 1H 2020
- Promising response on patent application for mRNA delivery, which may generate valuable intellectual property

Key figures

(In NOK 1,000)	2019 YTD	2018 YTD	2019 Q3	2018 Q3	2018 FY
Other income	7 275	6 613	2 425	2 238	9 585
Operating expenses	70 749	36 854	20 920	10 624	54 104
Operating results	-63 474	-30 241	-18 495	-8 386	-44 519
Net financial result	135	255	4 224	50	9 739
Comprehensive income	-63 339	-29 986	-14 271	-8 336	-34 780
Cash & cash equivalents	284 332	20 536	284 332	20 536	349 326
Net cash flow from operating activities	-62 016	-30 296	-18 763	-7 869	-30 297

Operational review and development programmes overview



fimaCHEM

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

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

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

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

RELEASE start-up activities progressing well

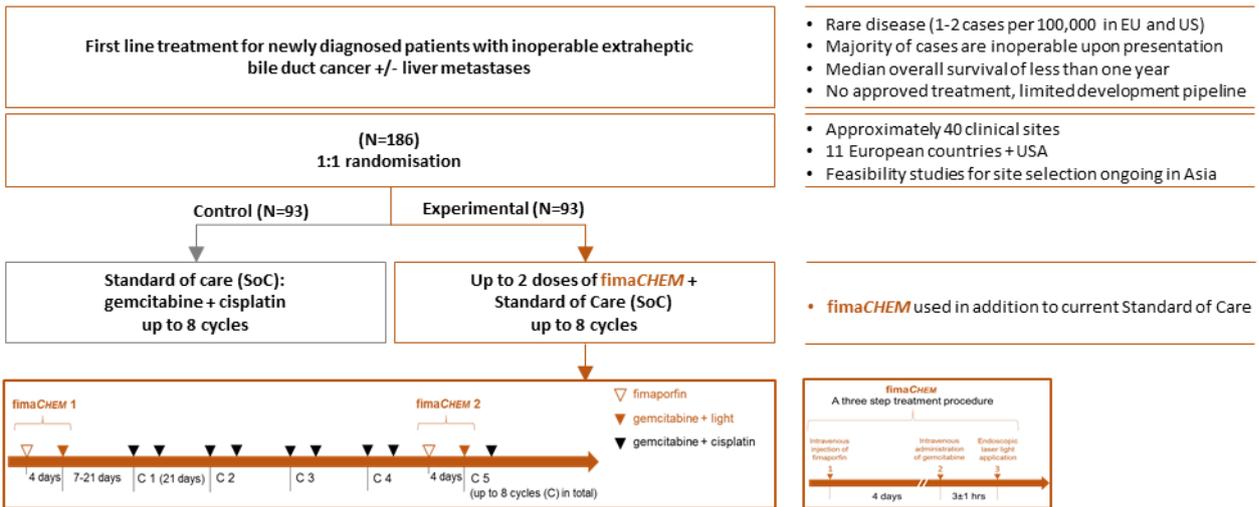
Start-up activities are going as planned for the RELEASE study, with site contract negotiations, regulatory and ethics approvals and final protocol harmonisation based on feedback from the different national regulatory bodies.

By mid-November, the company had received regulatory and ethics approvals for USA and 10 out of 11 planned European countries; Norway, Germany, France, Spain, Italy, Belgium, Poland, Sweden, Denmark and Finland. The remaining country is UK. The study will be executed in approximately 40 clinical sites, of which 23 European and US sites had opened for recruitment by mid-November. Site initiations for the RELEASE study are currently behind the expected level, causing a temporary effect on patient recruitment projections. Site activations are expected to be on track again early 2020 and PCI Biotech consequently reiterate the communicated timelines. Expected enrolment of the first US patient may slide into 1H 2020, as the first US site was opened only recently. Bile duct cancer has a higher incidence in Asia and the aim is to include sites in Asia in 2020. This will provide access to hospitals and key opinion leaders in Asia, and is also expected to secure the patient recruitment projections. A feasibility study in Asia has been performed and site selection is ongoing with the initial focus on South Korea and Taiwan.

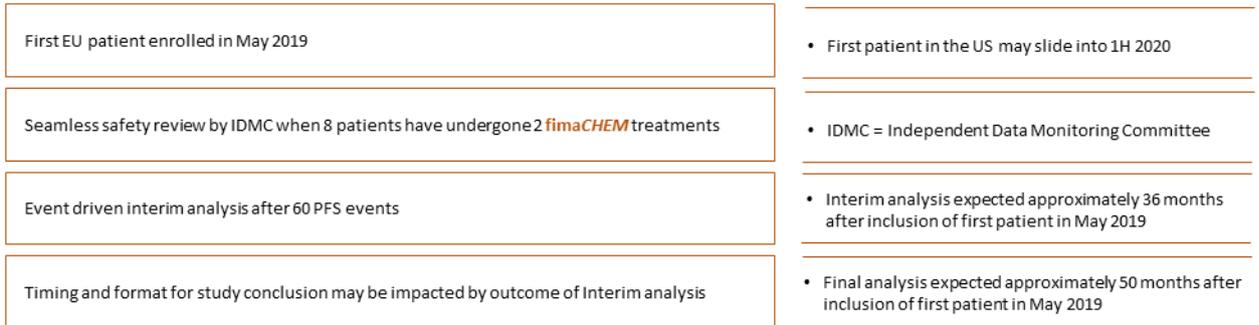
The RELEASE study design has been based on the outcome of meetings with the two leading regulatory authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).

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

Study overview:



Milestones and timelines:



Endpoints:



Regular communication milestones

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

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

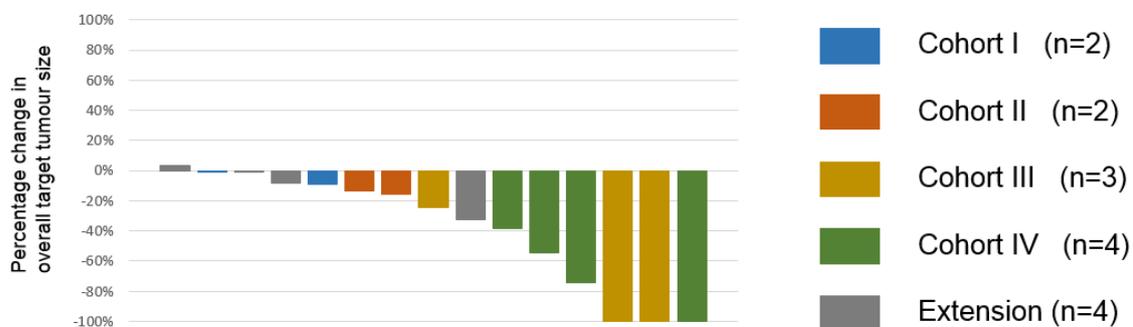
The RELEASE study builds on the favourable safety results and encouraging early signs of efficacy in the Phase I study, which was completed in Q1 2019.

Tumour response data from the full Phase I study (N=23) showed that more than 40% of the patients with radiologically evaluable tumours (n=15) had local target tumour response according to RECIST criteria.

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

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

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



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

The extension part with two **fimaCHEM** treatments provided less tumour response. Notably, the average tumour burden was markedly higher in these patients.

Tumour response translates into encouraging survival data

All patients have been followed-up for survival post-study, and per the end of October 2019 the full study translates to an interim median overall survival of approximately 15 months, with two patients still alive. The outcome range is up to 15.6 months.

The dose group in the dose escalation study that received the RELEASE study dose (n=6, cohort IV) had an interim median survival of 21.7 months. Three of these patients exceeded 30 months survival, including one patient still alive more than three years after treatment. The emerging median overall survival in the extension group (n=7), where patients received up to two treatments of the RELEASE dose, is currently approximately 15 months (outcome range up to 15.6 months) with one patient still alive. Five of the seven extension patients received two **fimaCHEM** treatments.

Although these are small patient groups with considerable heterogeneity, PCI Biotech finds it promising to see that the positive signs of tumour response seem to translate into encouraging survival data.

Bile duct cancer and the fimaCHEM technology

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

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

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

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

Comparator data for inoperable bile duct cancer

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

A post-hoc analysis of the data from intrahepatic bile duct cancer patients in the Valle *et al.* study showed that this subgroup had a prolonged survival, with a mOS of 15.4 months (Lamarca *et al.* J Natl Cancer Inst (2020) 112(2): djz071).

In the Okusaka *et al.* study, gallbladder cancer patients had a poorer outcome and the mOS was 13 months when these patients were excluded.

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

fimaVACC

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

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

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

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

Successful clinical proof-of-concept in healthy volunteers

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

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

fimaVACC provides highly desired features for therapeutic vaccination technologies:

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

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

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

Research and development supported by a grant

The **fimaVACC** programme is supported by a government grant from the Research Council of Norway (BIA-programme) of up to NOK 13.8 million, distributed over the course of three and a half years during 2017-2020.

Immunotherapy with the fimaVACC technology

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

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

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

fimaNAC

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

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

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

In the third quarter of 2019 PCI Biotech received initial positive feedback on a patent application for intracellular delivery of mRNA, which remains a major hurdle for realising the broad therapeutic potential of mRNA. The patent application may provide an important competitive advantage and generate valuable intellectual property (IP) for the **fimaNAC** programme, as several of the current research collaborations are within the field of mRNA delivery.

The fimaNAC technology and nucleic acid therapy

Several forms of nucleic acids are widely acknowledged to have significant therapeutic potential and numerous clinical trials are underway.

The therapeutic potential of compounds such as nucleic acids is however limited by the challenge of delivering sufficient amounts of large molecules into the cells. PCI Biotech believes the fimaNAC technology may resolve this issue through enhanced delivery of the majority of nucleic acid types.

Corporate

Management changes

Dr. Hans Olivecrona was appointed CMO in August 2017. From July 2019 Dr. Olivecrona has functioned as a CMO via a consultancy agreement. PCI Biotech has initiated a process to recruit a new in-house CMO. The company is also actively working on recruitment to the vacant chief business development officer position.

Financial review

Income Statement

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

The Group has not recorded revenues for the financial year 2019 nor 2018. Grants received from public sources as the Norwegian Research Council and “SkatteFUNN” are recorded as other income. Other income for Q3 and YTD 2019 amounted to NOK 2.4 million (NOK 2.2 million) and NOK 7.3 million (NOK 6.6 million) respectively.

Research and development (R&D) expenses for Q3 and YTD 2019 totalled NOK 18.0 million (NOK 8.7 million) and NOK 61.5 million (NOK 28.4 million) respectively. Operating expenses for Q3 and YTD 2019 were NOK 20.9 million (NOK 10.6 million) and NOK 70.7 million (NOK 36.9 million) respectively. Operating expenses are mainly driven by the R&D activity level. Preparations for and initiation of the pivotal fimaCHEM trial are the main cost driver, compared to last year.

Net financial results for Q3 and YTD 2019 were NOK 4.2 million (NOK 0.1 million) and NOK 0.1 million (NOK 0.3 million), respectively. The net positive financial result in Q3 2019 is mainly driven by exchange rate fluctuation on bank deposits placed in Euro, as a hedge of the foreign currency risk for the pivotal

study initiated in 2019. Since inception in October 2018, the hedging effects on expenses have been beneficial, but the Euro bank deposits have had a net negative effect for 2019.

Net loss for the quarter was NOK 14.3 million (NOK 8.4 million). YTD net loss was NOK 63.3 million (NOK 30.0 million). The increased net loss compared to last year is mainly due to increased R&D activities.

Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 284.3 million at the end of Q3 2019, compared to NOK 349.3 million per end of 2018, reflecting net negative cash flow of NOK 64.0 million YTD and NOK 1.0 million net negative exchange rate effect on bank deposits in foreign currency. Cash flow from operating activities was NOK -18.8 million in Q3 2019 (NOK -7.8 million) and NOK -62.0 million (NOK 30.6 million) YTD. Cash flow from operations is mainly dependent on R&D activities. All cash and cash equivalents were placed as bank deposits at the end of the quarter.

PCI Biotech acquired in Q2 and Q3 2019 the first lot of lasers to be used in the pivotal RELEASE study, impacting non-current assets compared to last year. In addition, PCI Biotech adopted IFRS 16 Leases for the first time in 2019, applying the modified retrospective method. The implementation effects for 2019 are disclosed under note 16 Right of use assets and lease liabilities.

Short term receivables per end of Q3 2019 increased by NOK 10.1 million compared to end of 2018, mainly due to advance payments in connection with initiation of the RELEASE study and timing effects. Current liabilities were generally higher per the end of Q3 2019 compared to the end of 2018, due to the increased R&D activities.

The employee share option program

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

Share capital

After completion of a share issue of 40,000 shares in September 2019, following exercise of share options and with net proceeds of NOK 0.3 million, the Company's share capital is NOK 111,797,670 divided into 37,265,890 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting.

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 end September 2019. Please see note 7 Related party transactions for further details.

Post-closing events

The ongoing collaboration with AstraZeneca has in November 2019 been expanded to evaluate whether synergies established in oncology *in vivo* models are transferrable to additional disease areas. The research collaboration runs to the end of 2019 and the companies have agreed to use the following 6 months until end of June 2020 to evaluate the potential for further collaboration.

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

Outlook

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

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

The final pivotal study design has thus been determined and funding expected to finance the study to interim read-out is in place, and the first patient was enrolled in May 2019. During this next step, the company maintains its full commitment to advance the programme with the ambition of helping patients currently left without effective treatment options achieve a good quality of life.

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

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

- Effectively drive the fimaCHEM clinical development programme in inoperable extrahepatic bile duct cancer towards the market
- Implement the strategy for the next phase of development for fimaVACC
- Manage alliance and partnering activities across all commercially interesting areas for the PCI platform

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 26 November 2019

Hans Peter Bøhn
Chairman (sign)

Christina Herder
Director (sign)

Hilde Furberg
Director (sign)

Andrew Hughes
Director (sign)

Lars Viksmoen
Director (sign)

Per Walday
CEO (sign)

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION PROFIT AND LOSS

<i>(In NOK 1,000)</i>						
	Note	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Other income	6	2 425	2 238	7 275	6 613	9 585
Research and development	7,9	18 039	8 719	61 545	28 413	40 337
General and administrative		2 881	1 905	9 204	8 441	13 767
Operating expenses		20 920	10 624	70 749	36 854	54 104
Operating results		-18 495	-8 386	-63 474	-30 241	-44 519
Financial income and expenses						
Financial income		4 649	56	6 415	265	9 890
Financial expenses		425	6	6 280	10	151
Net financial result	8	4 224	50	135	255	9 739
Profit/Loss before income tax		-14 271	-8 336	-63 339	-29 986	-34 780
Income tax	10	0	0	0	0	0
Net profit/loss		-14 271	-8 336	-63 339	-29 986	-34 780
Other comprehensive income		0	0	0	0	0
Total comprehensive income	5	-14 271	-8 336	-63 339	-29 986	-34 780

BALANCE SHEET

<i>(In NOK 1,000)</i>				
	Note	2019 30.09	2018 30.09	2018 31.12
Non-current assets				
Property, plant and equipment	17	4 797	19	17
Right to use asset	16	1 362	0	0
Total non-current assets		6 159	19	17
Current assets				
Short term receivables	8	17 815	10 587	7 713
Cash & cash equivalents	8	284 332	20 536	349 326
Total current assets		302 147	31 123	357 039
Total assets		308 306	31 142	357 056
Equity and liabilities				
Equity				
Paid in capital	11,12	562 125	234 345	560 942
Other reserves		-283 199	-219 435	-220 988
Total equity		278 926	14 910	339 954
Liabilities				
Other long term liabilities	14	293	1 397	107
Lease liabilities	16	857	0	0
Total long term liabilities		1 150	1 397	107
Trade debtors		1 783	2 067	1 889
Lease liabilities	16	493	0	0
Other short term liabilities	7,13,17	25 954	12 768	15 106
Total short term liabilities		28 230	14 835	16 995
Total liabilities		29 380	16 232	17 102
Total equity and liabilities		308 306	31 142	357 056

CHANGE IN EQUITY

<i>(In NOK '000)</i>	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Equity at beginning of period	291 541	22 429	339 954	41 842	41 842
Capital increase	345	-	1 183	44	328 833
Share option scheme	1 310	817	1 127	3 011	4 059
Comprehensive income in the period	-14 271	-8 336	-63 339	-29 986	-34 780
Equity at end of period	278 926	14 910	278 926	14 910	339 954

CASH FLOW

<i>(In NOK '000)</i>	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Ordinary profit before taxes	-14 271	-8 336	-63 339	-29 986	-34 780
Depreciation, amortisation and write off	304	1	610	4	5
Share options	-1 310	818	-1 127	3 011	4 059
Currency gain(-)/ loss(+) not related to operations	-3 845	0	1 005	0	-9 092
Net interest paid/received	-491	50	-404	-256	-782
Changes in working capital and other non-cash adjustments	850	-352	1 238	-3 324	420
Cash flow from operating activities	-18 763	-7 819	-62 016	-30 551	-40 170
Net interest paid/received	491	-50	404	256	782
Acquisition of non-current assets	-3 043	-	-3 066	-	-
Net cash flow from investing activities	-2 551	-50	-2 662	256	782
Cash flow from financial activities					
Leasing liability payment	-164	-	-493	-	-
Net proceeds from share issues	345	-	1 183	44	328 834
Net cash flow from financial activities	181	-	690	44	328 834
Net change in cash during the period	-21 133	-7 869	-63 988	-30 253	289 445
Exchange rate effect on bank deposits in foreign currency	3 845	0	-1 005	0	9 092
Cash and cash equivalents at the beginning of the period	301 621	28 405	349 326	50 789	50 789
Cash and cash equivalents at the end of the period	284 332	20 536	284 332	20 536	349 326

SELECTED EXPLANATORY NOTES:

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA, the fully owned subsidiary PCI Biotech AS and the dormant Icelandic Branch PCI Biotech Utibu. The PCI Biotech shares have been listed on Oslo Børs since 27 April 2018 under the ticker PCIB, as a transfer of listing from Oslo Axess. The company is headquartered in Oslo, Norway.

PCI Biotech has developed a unique and patented photochemical intracellular drug delivery technology for use in cancer therapy and other diseases. The technology may also be used to enhance the immunological response of vaccines. The company collaborates closely with The Norwegian Radium Hospital in Oslo, Norway and receives substantial funding on several projects from the Research Council of Norway. The company has an extensive international collaboration network with recognised expert groups in both drug delivery and vaccination. Photochemical Internalisation (PCI) is a proprietary technology for light-directed intracellular drug delivery by triggered endosomal release.

The PCI technology has potential to improve the efficacy of both existing drugs and new classes of drugs, such as therapeutic vaccines, gene therapy and other therapies based on nanotechnology or on biotechnological principles. The company's objective is to prove the clinical usefulness of the technology with various drugs and subsequently license out the technology to partners for further development and marketing. Revenues will be generated at the time of partnering and onwards from up-front payments, milestone payments and royalties from sales. PCI Biotech works on the development of PCI products for enhanced delivery of existing cancer drugs (fimaCHEM), and as a platform that may both potentiate the effect of vaccines (fimaVACC) and delivery of nucleic acids (fimaNAC). PCI Biotech has two active clinical development programmes; one project in the fimaCHEM programme and the other in the fimaVACC programme. The fimaCHEM project has initiated the pivotal clinical RELEASE study with registration intent for the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agents gemcitabine for treatment of inoperable extrahepatic bile duct cancer. The fimaVACC project has completed a Phase I study in healthy volunteers, which has provided clinical proof-of-concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular immune response. The fimaNAC programme is in preclinical stage.

2. Basis of presentation

These condensed unaudited interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These condensed interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 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 26 November 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 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Result allocated to shareholders (NOK'000)	-14 271	-8 336	-63 339	-29 986	-34 780
Weighted average of outstanding shares ('000)	37 239	24 995	37 217	24 992	27 797
Earnings per share (NOK per share)	-0.38	-0.33	-1.70	-1.20	-1.25

Diluted earnings per share:

	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Result allocated to shareholders (NOK'000)	-14 271	-8 336	-63 339	-29 986	-34 780
Weighted average of outstanding shares ('000)	37 922	25 721	37 922	25 718	28 353
Earnings per share (NOK per share)	-0.38	-0.33	-1.70	-1.20	-1.25

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

6. Segment information and Other income

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

7. Related party transactions

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

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

Purchase of services	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
The Norwegian Radium Hospital Research Foundation	531	457	1 110	1 383	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	6 025	6 103	1 412	4 275	17 815
Total receivables	6 025	6 103	1 412	4 275	17 815

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

Foreign currency risk

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

In the quarter exchange rate fluctuation on cash deposits placed in Euro generated a positive accounting effect of NOK 3.9 million. From inception in October 2018 the Euro deposits have a net positive accounting effect of NOK 8.0 million.

Interest risk

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

9. Research and Development

All figures in '000 NOK

	2019 Q3	2018 Q3	2019 YTD	2018 YTD	2018 FY
Clinical studies	13 602	5 194	49 843	18 812	27 499
Pre-clinical studies	1 532	1 311	4 818	4 513	5 943
CMC and equipment	1 590	1 109	4 298	2 925	3 846
Patents	1 315	1 105	2 586	2 163	3 049
Other expenses	0	0		0	0
Total	18 039	8 719	61 545	28 413	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 102.7 million in non-capitalised deferred tax assets (22% tax rate), which mainly relates to carry forward losses.

11. Share options

Share options outstanding from the company's share option program for employees have the following expiry date and exercise prices:

Expiry date	Exercise price in NOK per share option	Number of share options	
		31.12.2018	30.09.2019
2020 - Q3	7.84	41 000	26 000
2020 - Q3	3.26	45 500	34 500
2022 - Q3	21.48	340 000	325 000
2022 - Q3	19.24	90 000	0
2024 - Q3	25.78	0	320 000
Total		516 500	705 500

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

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

Overview share options, Senior executives	Total holdings 31.12.2018	Allocated	Lapsed	Exercised	Expired	Total holdings 30.09.2019
Per Walday, CEO	104 000	60 000	0	0	0	164 000
Ronny Skuggedal, CFO	116 000	40 000	0	40 000	0	116 000
Anders Høgset, CSO	66 000	40 000	0	0	0	106 000
Gaël L'Hévéder, CBDO*	21 000	0	0	11 000	10 000	0
Kristin Eivindvik, PD	33 500	0	0	0	0	33 500
Hans Olivecrona, CMO**	90 000	0	0	30 000	60 000	0
Sum	430 500	140 000	0	81 000	70 000	419 500

* Left the Company 31 March 2019 and all unexercised share options were terminated.

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

12. Share capital

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2018	37 164 890	3.00	111 494 670
Exercise of share options	101 000	3.00	303 000
30.09.2019	37 265 890	3.00	111 797 670

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

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

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

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

10 largest shareholders per 30 September 2019:

Name	No. of shares	Ownership
FONDSAVANSE AS	3 760 443	10,09 %
MP PENSJON PK	2 658 805	7,13 %
MYRLID AS	2 415 000	6,48 %
RADIUMHOSPITALET'S FORSKNINGSSTIFT.	1 281 415	3,44 %
NORDNET LIVSFORSIKRING AS	1 103 768	2,96 %
GRESSLIEN	655 000	1,76 %
NORDNET BANK AB	584 034	1,57 %
JANDERSEN KAPITAL AS	540 000	1,45 %
BERG-LARSEN	483 607	1,30 %
VESLIK AS	337 690	0,91 %
Total 10 largest shareholders	13 819 762	37,08 %
<i>Others</i>	<i>23 446 128</i>	<i>62,92 %</i>
<i>Total</i>	<i>37 265 890</i>	<i>100,00 %</i>

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

Name	Position	No. of shares	
		31.12.2018	30.09.2019
Hans Peter Bøhn	Chairman	123 662	123 662
Lars Viksmoen (Stocken Invest AS)	Board member	12 966	12 966
Christina Herder	Board member	10 000	10 000
Hilde Furberg (Borkenholm AS)	Board member*	NA	4 000
Andrew Hughes	Board member	0	0
Hilde H. Steineger	Board member**	0	NA
Per Walday	CEO	68 300	68 300
Anders Høgset	CSO	63 300	63 300
Ronny Skuggedal	CFO	28 300	43 000
Kristin Eivindvik	CDO	18 800	18 800
Gaël L'Hévéder	CBDO***	62 000	NA
Hans Olivecrona	CMO****	0	NA
Total		387 328	344 028

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

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

*** Gaël L'Hévéder resigned and left PCI Biotech by end of March 2019 and holdings are reported to that date.

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

13. Other short term liabilities

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

14. Other long term liabilities

Long term liabilities include public duties payables due in 1-5 years for potential future exercises of share options in PCI Biotech's employee share option scheme and lease liabilities due in 1-3 years according to IFRS 16. See note 16 for further details regarding IFRS 16 implementation in 2019 and the related long term lease liability.

15. Financial assets and liabilities

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

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

As of year-end 2018 PCI Biotech had no agreements that classified as financial lease under IAS 17. Under the new standard for leases, IFRS 16, PCI Biotech identified office lease as the only applicable right-to-use asset. IFRS 16 was implemented by PCI Biotech with effects as of 1 January 2019, applying the modified retrospective method and 2018 figures have therefore not been restated. The relevant non-cancellable operating lease commitment per 1 January 2019 was NOK 2.0 million for 2019-2021, not including an extension option due to not reasonable certainty about option exercise. Discounted value applying an incremental borrowing rate of 6% was NOK 1.8 million.

On transition to IFRS 16, PCI Biotech recognised NOK 1.8 million in right of use assets and a corresponding lease liability which are disclosed in the balance sheet as long- and short term liabilities depended on maturity of the corresponding lease payments. Accounting principles applied are described in the annual financial statement for the year ended 31 December 2018, under accounting principles section 4.

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

All figures in '000 NOK

Right of use asset – office

Initial recognition 01.01.2019	1,815
Acquisition costs 30.09.2019	1,815
Depreciation Q1 2019	151
Depreciation Q2 2019	151
Depreciation Q3 2019	151
Accumulated depreciation and impairment 30.09.2019	453
Total right of use assets 30.09.2019	1,362
Lower of remaining lease term or economic life	2.5 years
Depreciation method	Linear

Lease liabilities - office

Initial recognition 01.01.2019	1,815
Payments for the principal portion of the lease liability	-493
Interest expenses on the lease liability	28

Total lease liabilities as of 30.09.2019	1,350
Whereof:	
Short term lease liabilities < 1 year	493
Long term lease liabilities > 1 year	857

Income statement YTD 2019 – office lease

Depreciation	-453
Effect on Operating results	-453
Interest expenses on the lease liabilities	-28
Effect on Net financial result	-28
Net Comprehensive income effect	-481

The net comprehensive income effect from implementation of IFRS 16 in 2019 will not impact cash flow. Payments for the principal portion of the lease liabilities (kNOK 493) for YTD 2019 are not charged to profit and loss under IFRS 16 and will only have cash flow effects for 2019, while for 2018 these payments were charged directly to profit and loss under IAS 17.

The impact of IFRS 16 adoption on net comprehensive income for YTD 2019 compared to IAS 17, where the only income statement effect were payments for the principal portion of the lease liability, is kNOK 12 positive (kNOK -493 income effect under IAS 17 versus kNOK -481 income effect under IFRS 16).

17. Property, plant and equipment

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

Equipment	Q3 2019	Q3 2018	YTD 2019	YTD 2018
Carrying value at the beginning of the period	2 136	20	17	22
Additions	2 817	-	4 936	-
Depreciation in the period	156	1	156	3
Carrying value at the end of the period	4 797	19	4 797	19

18. Subsequent events

The ongoing collaboration with AstraZeneca has in November 2019 been expanded to evaluate whether synergies established in oncology *in vivo* models are transferrable to additional disease areas. The research collaboration runs to the end of 2019 and the companies have agreed to use the following 6 months (until end June 2020) to evaluate the potential for further collaboration.

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

FINANCIAL CALENDAR

Q4 Report 2019	26 February	2020
Annual Report	22 April	2020
Q1 Report 2020	6 May	2020
Q2 Report 2020	26 August	2020
Q3 Report 2020	11 November	2020

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.



Unlocking the potential of innovative medicines

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