

# Unlocking the potential of innovative medicines

SECOND QUARTER AND FIRST HALF-YEAR REPORT

2018

# LEVERAGING THE PCI-TECHNOLOGY IN THREE DISTINCT AREAS



# TRIGGERED ENDOSOMAL RELEASE

#### **ABOUT PCI BIOTECH**

PCI Biotech is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange. The company develops therapeutic products based on its proprietary photochemical internalisation (PCI) technology. Originating from world leading research at the Oslo University Hospital - the Radium Hospital, the PCI technology works by inducing light-triggered endosomal release and may be 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 candidate is the photosensitiser fimaporfin (Amphinex®). A Phase I study of fimaporfin in cancer patients has been completed at University College Hospital in London and published in Lancet Oncology. Promising early signs of tumour response were seen in a clear majority of the 22 patients and the treatment seemed to be well tolerated, providing the first clinical proof-of-concept of the fimaporfin technology.



# HIGHLIGHTS

- fima *CHEM* 
  - Encouraging data from the Phase I study at the dose level selected for the pivotal study
  - Initial data suggests that two treatments are well tolerated
  - Preparations for pivotal study progressing towards initiation early 2019

# • fima VACC

- Phase I interim data suggests enhancement of several parameters of importance for vaccination
- Focus on analysis and characterisation of the clinical immune response
- fimaNAc
  - Extension of the top-10 pharma collaboration
  - Established research collaborations with the immunotherapy focused companies IMV in Canada and Bavarian Nordic in Denmark (subsequent event)
- CORPORATE
  - Oslo Børs listing, as a transfer from Oslo Axess
  - Proposed fully underwritten rights issue of NOK 360 million (subsequent event)

# **KEY FIGURES**

(In NOK 1,000)	2018 1H	2017 1H	2018 Q2	2017 Q2	2017 FY
Other income	4 375	4 833	2 137	2 405	10 250
Operating costs	26 230	21 892	9 330	9 611	53 681
Operating results	-21 855	-17 059	-7 193	-7 205	-43 431
Financial items	206	403	83	181	590
Comprehensive income	-21 649	-16 657	-7 110	-7 024	-42 841
Cash & cash equivalents	28 405	60 700	28 405	60 700	50 789
Net cash flow from operating activities	-22 428	-18 334	10 225	-9 229	-29 943



The proposed fully underwritten rights issue of NOK 360 million provides PCI Biotech with the funds needed for the pivotal fimaCHEM study until interim read-out for potential accelerated approval. The established underwriting syndicate shows that we both have a supportive shareholder base and significant interest from external investors, including a reputable international specialist investor.

The Phase I efficacy data at the dose selected for the fimaCHEM pivotal study is now mature enough for presentation. Median overall survival is currently 21.2 months in this cohort, and three of the five patients with measurable tumours show tumour response. Although the data sample is small, the results indicate a clear improvement over the best comparable published data. Our focus is now to bring fimaCHEM to the market as quickly as possible, through successful performance of the pivotal study, which is expected to start early 2019.

The dose-finding part of the fimaVACC Phase I study is completed with more than 90 subjects included, and a well-tolerated dosing regimen is identified. The focus in the coming months will be on in-depth analysis and characterisation of the immune responses.

Continued positive development in the fimaNAC programme, with two new research collaborations established over the past couple of months and the top-10 pharma collaboration extended to end of 2018.

# **OPERATIONAL REVIEW**

# fima *CHEM*

The **fime** *CHEM* programme aims to fulfil unmet medical needs by providing local enhancement of approved chemotherapies. The lead project – local enhancement of gemcitabine in bile duct cancer – is in clinical development with Amphinex, the intravenous formulation of fimaporfin.

# ENCOURAGING INTERIM OVERALL SURVIVAL DATA

The interim average overall survival from all dose cohorts (16 patients in total) in the Phase I study of fima*CHEM* for treatment of inoperable extrahepatic bile duct cancer (cholangiocarcinoma) patients was 18.5 months per August 2018, with 19% of the patients still being alive. The median overall survival ended at 14.4 months.

The survival and response data at the selected dose level (Cohort IV; 6 patients) for the pivotal study is now mature enough for comparison with published data. The interim average overall survival is 19.0 months per August 2018, with 33% of the patients still being alive. Five patients had measurable tumours at baseline and tumour response was seen in three (60%) of these patients. Per August 2018, the median overall survival in this group is 21.2 months. The data sample is small, but the results suggest a clear improvement over the best comparable published data (see information box below).

# PIVOTAL PHASE PREPARATIONS PROGRESSING TOWARDS START EARLY 2019

The promising early signs of efficacy in the Phase I study were based on a single fima *CHEM* treatment in addition to standard of care 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 promising signs of efficacy even further. In this study, the second fima *CHEM* treatment is done

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approximately 3-4 months after the initial treatment. The extension study will include a minimum of six evaluable patients. Four patients have passed the safety window without reports of adverse events that could limit repeated fima*CHEM* treatment (data from the last patient remains to be formally monitored by PCI Biotech's contract research organisation). The plan is now to initiate the pivotal 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 study.

The pivotal study design is based on the outcome of meetings with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). The pivotal development programme consists of a single open randomised two-arm study with 186 patients (93 patients per arm) comparing the standard of care (SoC) combination treatment with up to 8 cycles of gemcitabine and cisplatin vs. fima*CHEM* treatment plus SoC. The primary endpoint is progression free survival (PFS), with overall survival (OS) as key secondary endpoint. The study includes an interim analysis of PFS followed by analysis of objective response rate (ORR), with the potential for accelerated/conditional approval. The study also 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.

Patient recruitment into the extension study has been challenging, but actually in line with PCI Biotech's previous experience and the literature. PCI Biotech is performing an extensive feasibility study initiated this summer, reaching out to hospitals across Europe and USA. The collected data is encouraging and expected to provide a solid foundation for optimal selection of clinical sites to augment patient recruitment.

The pivotal study is expected to start early 2019, with the interim analysis of PFS and ORR for potential accelerated/conditional approval available approx. 36 months after initiation, while the final analysis is expected at approx. 50 months from initiation.

## About 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 cancer without approved chemotherapies and the development pipeline is weak. The annual incidence rate is 1-2 cases per 100,000 in the Western world, but rates are higher in most Asian countries. The majority of cases present as inoperable and there is a high-unmet need for improved treatment technologies.

Surgery is currently the only curative option for these patients, yet the majority of the tumours are inoperable. Standard treatment for inoperable patients is stenting to keep the bile duct open, followed by chemotherapy. Combination of the chemotherapeutics gemcitabine and cisplatin has become standard treatment, but there is a need to increase overall survival and quality of life.

Bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and there is a high need for new drug classes or alternative methods. The most studied and used drug is gemcitabine, which also is one of the drugs significantly enhanced by the fima *CHEM* technology in preclinical studies. Light access for fima *CHEM* treatment is easy through routinely used endoscopic methods.

#### About comparator data for inoperable bile duct cancer

The median overall survival (OS) in the studies that established gemcitabine plus cisplatin as standard treatment in cholangiocarcinoma (CCA) 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). Gallbladder cancer patients had a poorer outcome in the latter study and the median OS was 13 months when these patients were excluded. These results represents 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 CCA patients, while the fima*CHEM* Phase I study focuses on inoperable perihilar CCA patients.



# fima VACC

The **fime VACC** programme aims to enhance the cellular immune responses important for therapeutic effect of vaccines. This proprietary vaccination technology has entered clinical development, and is also subject to one active research collaboration.

# **ENCOURAGING INITIAL CLINICAL RESULTS**

Improving immunogenicity of vaccine candidates is a main priority in the immunotherapy industry and a successful translation of the promising fima *VACC* technology into man is a prerequisite to establish PCI Biotech in the immunotherapy field.

A Phase I study in healthy volunteers is ongoing, aiming for clinical translation of the promising preclinical immune response results into man. The main objective of the study is to determine safety, tolerability and immune responses for fima *VACC*.

The interim clinical results on antigen-specific T-cell responses indicate that vaccination with welltolerated doses of fima *VACC* enhance cellular immune responses important for therapeutic effect of vaccines. The data also suggests that fima *VACC* triggers early T-cell responses and provides response in a high proportion of individuals, which are two highly sought-after features of vaccination platforms. The dose-finding part of the study is now completed, with more than 90 subjects included. The study has provided a vast number of clinical test samples and the focus for the coming months is to characterise the fima *VACC* immune response by targeted in-depth immune analysis of relevant samples.

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

## About 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 an immune response. Several companies have reported failed clinical studies in the past years, but the potential of combining vaccination with checkpoint inhibitors has triggered a renewed interest in therapeutic cancer vaccines. However, here are still important unsolved issues and improving the immunogenicity of vaccine candidates is a main priority in immunotherapy. PCI Biotech believes the fima *VACC* technology may play an important role in solving this challenge.

Effective induction of cytotoxic T-cells is key to realise the huge potential of therapeutic cancer vaccination, but vaccines often fail to generate such responses. One of the most important reasons is probably insufficient delivery of vaccine antigens to the appropriate presentation pathway in immune cells. The fima *VAcc* technology may solve this challenge by effectively enhancing the vaccine presentation through this pathway.



# fima*NAC*

The **fima***NAc* programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage collaborative programme subject to six active research collaborations.

# PRECLINICAL RESEARCH COLLABORATIONS

PCI Biotech has six active preclinical research collaborations in the area of nucleic acid therapeutics, established to evaluate technological compatibilities and synergies, and thereafter explore the potential for further partnerships.

A collaboration with an undisclosed top-10 pharma company, aiming to evaluate synergistic effects of fima*NAc* with their nucleic acid therapeutics technology was signed in September 2015. This agreement has been extended several times, most recently until the end of 2018 with the possibility for further extension. In 2017 the collaboration was expanded to include evaluation of technological compatibility and synergy based on *in vivo* studies.

PCI Biotech has also signed two new research collaborations over the last couple of months, both with key players in the immunotherapy field. In Q2 a preclinical research agreement was signed with IMV Inc (TSE:IMV) (OTCQX:IMMVD) Nova Scotia, Canada and in August 2018 a similar agreement was signed with Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) Kvistgaard, Denmark. Both companies are key players in the emerging field of immunotherapy, with multiple clinical programmes in cancer and infectious diseases.

# About the fimaNAc and nucleic acid therapy

The fimaNAc technology may enhance the delivery of most types of nucleic acids. Several forms of nucleic acids are widely acknowledged to have a large therapeutic potential, and numerous clinical trials are underway. The therapeutic potential of such compounds is challenged by the obstacles to achieve adequate intracellular access, which the fimaNAc technology may resolve.

The fima*NAc* programme has six active research collaborations with key players in the field of nucleic acid therapeutics. These aim to explore synergies between partners proprietary nucleic acid technologies and the fima*NAc* technology. The collaboration partners span from an undisclosed big pharma company to five mid-/small-size biotechs: Bavarian Nordic, BioNTech, eTheRNA immunotherapies, IMV and RXi Pharmaceuticals.

# **FINANCIAL REVIEW**

# Proposed fully underwritten rights issue of NOK 360 million

The Company has proposed to carry out a fully underwritten rights issue of NOK 360 million to be resolved at an extraordinary general meeting to be held on 14 September 2018. Please see further details under the post-closing event section.

The net proceeds and the existing cash is expected to finance the Company well into 2022, which is beyond the anticipated interim read-out of the planned pivotal fima*CHEM* study in inoperable bile duct cancer in 2021 and potential regulatory submission for accelerated/conditional marketing authorisation in 2022, as well as certain other activities related to the fima*CHEM* study. 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.



## **Income Statement**

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

The Group did not record revenues for Q2 and 1H 2018. Grants received from various public sources such as the Norwegian Research Council and "SkatteFUNN" were recorded as other income. Other income for Q2 and 1H 2018 amounted to NOK 2.1 million (NOK 2.4 million) and 4.4 million (NOK 4.8 million) respectively.

Expenditure on research activities is recognised as an expense in the period in which it was incurred. The Group has no development expenditure that qualifies for recognition as an asset under IAS 38 and all research expenses are recorded in the profit and loss statement, in line with previous years. Research and development (R&D) costs for Q2 and 1H 2018 totalled NOK 6.4 million (NOK 7.4 million) and 19.7 million (NOK 16.6 million) respectively. Operating costs for Q2 and 1H 2018 ended at NOK 9.3 million (NOK 9.6 million) and 21.9 million (NOK 17.1 million) respectively. Operating expenses are mainly driven by the R&D activity level and for 2018 there are two clinical phase I trials running, increasing the cost level compared to 2017.

Net loss for the quarter was NOK 7.1 million (NOK 7.0 million). Net loss for the first half was NOK 21.6 million (NOK 16.7 million).

### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 28.4 million at the end of the quarter, compared to NOK 50.8 million at year-end 2017, reflecting net negative cash flow from operating activities. All cash and cash equivalents were placed as bank deposits at the end of the quarter.

Cash flow from operations is mainly dependent on R&D activities. Net cash flow from operating activities was NOK -10.2 million (NOK -9.2 million) in the quarter and NOK -22.4 million (NOK -18.3 million) for the first half year.

## Share capital

One participant in the Company's share option program has on 12 April 2018 exercised 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.

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. The capital increase was registered in the Norwegian Register of Business Enterprises 17 April 2018 and has thus been completed. Subsequent to the transaction, the Company's share capital is NOK 74,984,670 divided into 24,994,890 shares. The capital increase resulted in gross proceeds of NOK 56,920.

Following completion of the proposed rights issue, the share capital of PCI Biotech will be increased by NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00. The share capital of PCI Biotech will be NOK 110,984,670 consisting of 36,994,890 shares, each with a nominal value of NOK 3.00.

On 27 April 2018 PCI Biotech was listed at Oslo Børs, as a transfer from Oslo Axess.



# 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 in 1H 2018.

## Post-closing events

The Company has proposed to carry out a fully underwritten rights issue of NOK 360 million, issuing 12,000,000 new shares at a subscription price of NOK 30 per share, with pre-emptive subscription rights for existing shareholders. The Board of Directors has resolved to call for an extraordinary general meeting to be held on 14 September 2018 to resolve the rights issue. The rights issue is fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters will receive an underwriting fee equal to 3.5 per cent of their respective underwriting obligations. Lars Viksmoen, member of the Board of PCI Biotech, has entered into the underwriting agreement and underwritten NOK 1.0 million of the rights issue. Completion of the rights issue is subject to shareholders' approval at the extraordinary general meeting to be held on 14 September 2018 and that an EEA-prospectus for the Rights Issue is approved by the Financial Supervisory Authority of Norway and published in accordance with applicable laws. Following completion of the proposed rights issue, the share capital of PCI Biotech will be increased by NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00. The share capital of PCI Biotech will be NOK 110,984,670 consisting of 36,994,890 shares, each with a nominal value of NOK 3.00.

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

PCI Biotech initiated in August 2018 a preclinical research collaboration with Bavarian Nordic A/S, a clinical stage biopharmaceutical corporation focused on developing state-of-the-art cancer immunotherapies and vaccines for infectious diseases. In brief, the collaborators will evaluate technology compatibility and synergy based on *in vivo* studies. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership.

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



# OUTLOOK

PCI Biotech's lead project is clinical development of fima *CHEM* (fimaporfin) in combination with gemcitabine for treatment of inoperable bile duct cancer; an orphan disease with high unmet medical need. Based on the encouraging early signs of efficacy in Phase I, the company has reached out to key regulators and received important guidance for a pivotal phase study. The final pivotal study design has been determined and a proposed funding of the study is in place, and the Company maintain full focus on the progression of the development programme towards this high-unmet need indication.

PCI Biotech believes the PCI technology has potential to play a role in the realisation of several new therapeutic modalities, including cancer immunotherapy (fima VACC) and nucleic acid therapeutics (fima NAC). The active research collaborations show that external companies share this view.

Clinical validation of the promising 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. Initial results are encouraging and the study is expected to provide important results for determination of the further development strategy.

The fima NAc programme follows a collaborative approach, pursuing out-licensing opportunities.

The main priorities of PCI Biotech are to:

- Effectively drive the fima *CHEM* development programme in inoperable bile duct cancer towards the market;
- Progress and finalise the fima VACC Phase I study in healthy volunteers;
- Alliance management and partnering activities across all commercially interesting areas for the PCI platform.

The Board of Directors and CEO PCI Biotech Holding ASA Oslo, 29 August 2018

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)



# **RESPONSIBILITY STATEMENT**

We confirm that, to the best of our knowledge, the unaudited condensed set of financial statements for the first half of 2018 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Group's consolidated assets, liabilities, financial position and results of operations, and that the interim management report includes a fair view of the information required under the Norwegian Securities Trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO PCI Biotech Holding ASA Oslo, 29 August 2018

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	2017
		Q2	Q2	1H	1H	FY
Other income	5	2 137	2 405	4 375	4 833	10 250
Research and development	8	6 359	7 338	19 694	16 716	40 988
General and administrative		2 971	2 273	6 536	5 176	12 693
Operating costs		9 330	9 611	26 230	21 892	53 681
Operating results		-7 193	-7 205	-21 855	-17 059	-43 431
Financial income and costs						
Financial income		85	211	208	403	677
Financial expenses		2	29	2	0	87
Net financial result		83	181	206	403	590
Profit/loss before income tax		-7 110	-7 024	-21 649	-16 657	-42 841
Income tax	9	0	0	0	0	0
Net profit/loss	4	-7 110	-7 024	-21 649	-16 657	-42 841
Other comprehensive income		0	0	0	0	0
Comprehensive income		-7 110	-7 024	-21 649	-16 657	-42 841

# **BALANCE SHEET**

(In NOK 1,000)	lote	2018	2017	2017
		30.06	30.06	31.12
Fixed and intangible assets				
Operating assets		20	3	22
Total fixed and intangible assets		20	3	22
Current assets				
Short term receivables	7	9 445	10 581	7 625
Cash & cash equivalents	7	28 405	60 700	50 789
Total current assets		37 850	71 281	58 414
Total assets		37 870	71 284	58 436
Shareholders' equity and liabilities				
Shareholders' equity				
Paid in capital		234 346	230 411	232 109
Other reserves		-211 917	-167 428	-190 266
Total equity	10	22 429	62 983	41 842
Other long term liabilities	14	2 280	630	2 009
Total long term liabilities		2 280	630	2 009
Trade debtors		626	1 563	1 497
Other short term liabilities		12 534	6 108	13 088
Total short term liabilities		13 161	7 671	14 585
Total liabilities		15 441	8 301	16 594
Total shareholders' equity and liabilities		37 870	71 284	58 436

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# **CHANGE IN SHAREHOLDERS EQUITY**

(In NOK '000)	2018 Q2	2017 Q2	2018 1H	2017 1H	2017 FY
Equity at beginning of period	28 558	68 953	41 842	13 086	13 086
Capital increase	44	-	44	65 032	66 729
Share option scheme	938	1 054	2 193	1 521	4 867
Comprehensive income in the period	-7 110	-7 024	-21 649	-16 657	-42 841
Equity at end of period	22 429	62 983	22 429	62 983	41 842

# **CASH FLOW**

(In NOK '000)	2018	2017	2018	2017	2017
	Q2	Q2	1H	1H	FY
Ordinary profit before taxes	-7 110	-7 024	-21 649	-16 657	-42 841
Depreciation, amortisation and write off	1	1	2	2	6
Share options	938	1 054	2 192	1 521	4 867
Net financials	83	-181	-206	-403	-677
Changes in working capital	-4 054	-3 260	-2 973	-3 200	8 025
Cash flow from operating activities	-10 142	-9 410	-22 633	-18 737	-30 620
Net financials	-83	181	206	403	677
Taxes paid	-	-	-	-	-
Net cash flow from operating activities	-10 225	-9 229	-22 428	-18 334	-29 943
Cash flow from financial activities					
Net proceeds from share issues	44	-	44	65 032	66 730
Net cash flow from financial activities	44	-	44	65 032	66 730
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Net change in cash during the period	-10 181	-9 229	-22 384	46 698	36 787
period	38 586	69 929	50 789	14 002	14 002
Cash and cash equivalents at the end of the period	28 405	60 700	28 405	60 700	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 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 type immunity. 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 29 August 2018.

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	2017
	Q2	Q2	1H	1H	FY
Result allocated to shareholders (NOK'000)	-7 110	-7 024	-21 649	-16 657	-42 841
Weighted average of outstanding shares ('000)	24 993	24 900	24 990	23 747	24 348
Earnings per share (NOK per share)	-0.28	-0.28	-0.87	-0.70	-1.76

Diluted earnings per share:

	2018	2017	2018	2017	2017
	Q2	Q2	1H	1H	FY
Result allocated to shareholders (NOK'000)	-7 110	-7 024	-21 649	-16 657	-42 841
Weighted average of outstanding shares ('000)	25 720	25 295	25 717	24 132	24 348
Earnings per share (NOK per share)	-0.28	-0.28	-0.87	-0.70	-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

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

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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	2017
	Q2	Q2	1H	1H	FY
The Norwegian Radium Hospital Research Foundation	568	923	1 035	1 745	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.

### 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	247	981	5 717	2 500	9 445
Total receivables	247	981	5 717	2 500	9 445

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). PCI Biotech has not implemented any 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 Q2	2017 Q2	2018 1H	2017 1H	2017 FY
Clinical studies	3 625	4 277	13 618	9 741	23 886
Pre-clinical studies	1 671	2 245	3 202	5 114	12 539
CMC and equipment	577	317	1 816	722	1 770
Patents	487	500	1 058	1 139	2 793
Other costs	0	0	0	0	0
Total	6 359	7 338	19 694	16 716	40 988

PCI Biotech has no development expenditure that qualifies for recognition of an asset under IAS 38 Intangible assets and all research expenditures are charged through the income 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 83.6 million in non-capitalised deferred tax assets, which mainly relates to carry forward losses.

#### 11. Share options

Share options outstanding at the end of the per	riod have the following expiry date and exercise pr	ices:
-------------------------------------------------	-----------------------------------------------------	-------

	Exercise price in NOK	Number of	shares
Expiry date	per share	31.12.2017	30.06.2018
2018 - Q3*	10.55	85 000	85 000
2018 - Q3*	10.02	40 000	40 000
2020 - Q3	9.11	73 500	66 000
2020 - Q3	3.79	110 000	105 500
2022 - Q3	24.95	340 000	340 000
2022 - Q3	22.35	90 000	90 000
Total		738 500	726 500

\*The lifetime of 125,000 share options originally expiring in Q3 2018, during the rights issue process, have been extended with one year in August 2018. The total expected P&L effect of the change, based on calculation using the Black- Scholes valuation method, is estimated to NOK -0.1 million.



One participant in the Company's share option program exercised 12<sup>th</sup> 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.

Overview options 2018, Senior executives	Total holdings 31.12 2017	Allocated	Lapsed	Exercised	Expired	Total holdings 30.06 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	0	0	106 000
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	0	0	515 500

## 12. Share capital

The Company's share capital is NOK 74,984,670 divided into 24,994,890 shares, 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	8 000	3.00	24 000
30.06.2018	24 994 890	3.00	74 984 670

Following the exercise of share options on 12 April 2018, 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. Subsequent to the transaction, the Company's share capital is NOK 74,984,670 divided into 24,994,890 shares after the subsequent event. The capital increase results in gross proceeds of NOK 56,920.

The Company has proposed to carry out a fully underwritten rights issue of NOK 360 million to be resolved at an extraordinary general meeting to be held on 14 September 2018. Following completion of the proposed rights issue, the share capital of PCI Biotech will be increased by NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00. The share capital of PCI Biotech will be NOK 110,984,670 consisting of 36,994,890 shares, each with a nominal value of NOK 3.00. Please see further details under the post-closing event section.

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 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.

The Company has more than 3,400 shareholders at the end of the quarter.



## 10 largest shareholders per 30 June 2018:

Name	No. of shares	Ownership
FONDSAVANSE AS	2 540 840	10,17 %
MP PENSJON PK	1 344 522	5,38 %
Myrlid AS	1 240 000	4,96 %
RADIUMHOSPITALETS	1 154 415	4,62 %
NORDNET LIVSFORSIKRI	647 979	2,59 %
GRESSLIEN ODD ROAR	539 500	2,16 %
BERG-LARSEN ALEXANDER	479 278	1,92 %
Nordnet Bank AB	462 852	1,85 %
SYVERTSEN SVEIN ERIK	361 107	1,44 %
Jandersen Kapital AS	360 000	1,44 %
Total 10 largest shareholders	<u>9 130 493</u>	<u>36,53 %</u>
Others	15 864 397	63,47 %
Total	24 994 890	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	30.06.2018	31.12.2017
Hans Peter Bøhn	Chairman	83 556	83 556
Christina Herder	Board member	8 355	8 355
Kjetil Taskén (Kjetil Taskén AS)	Board member*	NA	4 000
Lars Viksmoen (Stocken Invest AS)	Board member	4 000	4 000
Hilde H. Steineger	Board member	0	0
Andrew Hughes	Board member**	0	NA
Per Walday	CEO	65 133	65 133
Anders Høgset	CSO	62 456	62 456
Ronny Skuggedal	CFO	25 066	25 066
Gaël L'Hévéder	CBDO	10 000	10 000
Kristin Eivindvik	PD	17 948	17 948
Total		276 514	280 514

\* 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.

#### 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 1-5 years for potential future exercise of share options in PCI Biotech's employee share option scheme.

#### 15. Subsequent events

The Company has proposed to carry out a fully underwritten rights issue of NOK 360 million, issuing 12,000,000 new shares at a subscription price of NOK 30 per share, with pre-emptive subscription rights for existing shareholders. The Board of Directors has resolved to call for an extraordinary general meeting to be held on 14 September 2018 to resolve the rights issue. The rights issue is fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters will receive an underwriting fee equal to 3.5 per cent of their respective underwriting obligations. Lars Viksmoen, member of the Board of PCI Biotech, has entered into the underwriting agreement and underwritten NOK 1.0 million of the rights issue. Completion of the rights issue is subject to shareholders' approval at the extraordinary general meeting to be held on 14 September 2018 and that an EEA-prospectus for the Rights Issue is approved by the Financial Supervisory Authority of Norway and published in accordance with applicable laws. Following completion of the proposed rights issue, the share capital of PCI Biotech will be increased by NOK 36,000,000 through an issue of 12,000,000 new shares, each with a nominal value of NOK 3.00. The share capital of PCI Biotech will be NOK 110,984,670 consisting of 36,994,890 shares, each with a nominal value of NOK 3.00.

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

PCI Biotech initiated in August 2018 a preclinical research collaboration with Bavarian Nordic A/S, a clinical stage biopharmaceutical corporation focused on developing state-of-the-art cancer immunotherapies and vaccines for infectious diseases. In brief, the collaborators will evaluate technology compatibility and synergy based on *in vivo* studies. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership.

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



# **DEFINITIONS AND GLOSSARY**

Amphinex: EMA: FDA: Fimaporfin:	Trade name of the clinical intravenous formulation of fimaporfin European Medicines Agency US Food and Drug Administration Generic name of the photosensitiser active ingredient TPCS2a
	Independent Data Monitoring Committee
IND In vitro:	Studies performed with cells or biological malaculas studied outside their normal
in viiro.	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: 1H Q2:	Norwegian kroner Financial year (1 <sup>st</sup> January – 31 <sup>st</sup> December) First half of the year (1 <sup>st</sup> January – 30 <sup>th</sup> June) Second quarter (1 <sup>st</sup> April – 30 <sup>th</sup> June)

# FINANCIAL CALENDAR

Q3 Report 2018

13 November 2018

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# FORWARD LOOKING STATEMENTS

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

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