
*Unlocking the potential of innovative medicines*

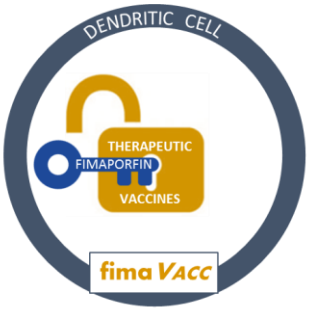
THIRD QUARTER REPORT

2017

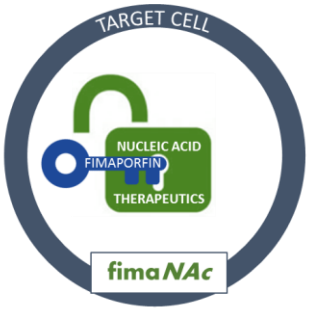
## LEVERAGING THE PCI-TECHNOLOGY IN THREE DISTINCT AREAS

### 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 a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange (Axess). The company develops therapeutic products based on its proprietary photochemical internalisation (PCI) technology. Originating from world leading research at the Norwegian 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 all 22 patients and the treatment seemed to be well tolerated, providing the first clinical proof-of-concept of the fimaporfin technology.

## HIGHLIGHTS

- fimaCHEM
  - Granted US Orphan Drug Designation
  - Phase I extension study progressing according to plan
- fimaVACC
  - Promising interim clinical results from Phase I suggesting enhancement of several parameters of importance for vaccination
  - Expanding the clinical Phase I study to identify optimal dosing
- fimaNAc
  - Extension of the top-10 pharma collaboration
- CORPORATE
  - Strengthened management team further by the appointment of Dr Hans Olivecrona as Chief Medical Officer

## KEY FIGURES

| *(In NOK 1,000)* | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| Other income | 2 350 | 2 333 | 7 183 | 7 249 | 10 475 |
| Operating costs | 12 806 | 11 867 | 34 690 | 33 373 | 43 502 |
| Operating results | -10 456 | -9 535 | -27 507 | -26 124 | -33 027 |
| Financial items | 175 | 259 | 570 | 542 | 843 |
| **Comprehensive income** | **-10 281** | **-9 276** | **-26 938** | **-25 582** | **-32 184** |
| **Cash & cash equivalents** | **53 755** | **20 663** | **53 755** | **20 663** | **14 002** |
| **Net cash flow from operating activities** | **-8 667** | **-10 365** | **-27 001** | **-28 587** | **-35 247** |

***Granting of orphan status from the FDA was an important milestone for the fimaCHEM programme during Q3 2017, as was the inclusion of the first patient in the Phase I study extension exploring the potential for repeated treatment in Phase II. The orphan status recognises the therapeutic benefits we seek to bring to the bile duct cancer patients in need of better local treatments. Regulatory interactions to clarify the fastest way to market continued during the quarter and are expected to be completed by end 2017.***

***The initial results from the the fimaVACC Phase I study indicate enhanced overall T-cell responses at tolerable dose levels. The results also suggest that vaccination with the fimaVACC technology provides both early responses and high response rates, which are two highly sought-after features of vaccination platforms. Notably, the best responses are seen at the lowest dose level tested. Further expansion of the Phase I study is therefore planned to investigate even lower doses.***

***The alliances in the fimaNAC programme have showed positive progress and the research collaboration with a top-10 pharma company entered into a new stage (in vivo) in Q3 2017.***

# OPERATIONAL REVIEW

## fimaCHEM

**The fimaCHEM 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.**

### GRANTED US ORPHAN DRUG DESIGNATION

The U.S. Food and Drug Administration (FDA) granted in September 2017 Orphan Drug Designation (ODD) to PCI Biotech's lead product candidate, fimaporfin, for the treatment of patients suffering from cholangiocarcinoma (bile duct cancer). This patient population has no approved treatment alternatives today and fimaCHEM (fimaporfin) has the potential to play a role in this area of high unmet medical need.

ODD is a significant regulatory milestone providing important development and commercialisation benefits and it recognises the therapeutic benefits fimaCHEM seek to bring to the bile duct cancer patients in need of better local treatments. ODD is now granted in both the US and EU.

### ENCOURAGING INTERIM OVERALL SURVIVAL DATA

Per November 2017 the interim average overall survival from Phase I in the study of fimaCHEM for treatment of inoperable extrahepatic bile duct cancer patients was 16.5 months, with 25% of the patients still being alive. The median overall survival ended at 14.4 months. The survival data includes all dose cohorts, 16 patients in total and are encouraging when seen in relation to the most appropriate published comparator data.

## PHASE I EXTENSION STUDY AND OTHER PREPARATIONS FOR PHASE II ARE PROGRESSING ACCORDING TO PLAN

The early promising signs of efficacy represent an important milestone for the bile duct cancer programme. However there may still be opportunity to optimise the treatment regimen as the Phase I results were based on a single fima*CHEM* treatment. In order to further optimise the treatment regimen before Phase II, a Phase I extension study has been initiated with the objective to determine safety and tolerability of repeated treatments with fima*CHEM*. The second fima*CHEM* treatment will be done 3-4 months after the initial treatment. The extension study will include a minimum of 6 evaluable patients and the first patient was treated in August 2017. The study is on schedule for readout of safety and tolerability of a minimum of 6 evaluable patients in first half of 2018.

Based on the encouraging Phase I results, PCI Biotech is assessing the fastest route to market for fima*CHEM* in this life-threatening rare disease without approved treatments. The development strategy for fimaporfin in bile duct cancer will be determined after completion of regulatory interactions with both European and US authorities. The interactions continued through the third quarter with productive discussions to establish a strong and viable development strategy. The regulatory interactions are expected to be completed by year-end 2017.

The Phase I extension study and other time-critical activities, such as completion of regulatory interactions and relevant Phase II preparations, are performed in parallel, thereby minimising time to initiation of a potential pivotal Phase II study with repeated treatment. The aim is to initiate a pivotal study in 1H 2018.

The company will expand clinical development into the US and has therefore engaged and conducted a clinical advisory board meeting with key bile duct cancer clinicians in the US, in parallel with the regulatory discussions.

**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 and 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 fima*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.**

### PROMISING INITIAL CLINICAL RESULTS

PCI Biotech initiated in Q3 2016 clinical validation of the fima*VACC* technology through a Phase I study in healthy volunteers. To date more than 70 subjects have been included, and tolerability of intradermal treatment with fima*VACC* is established. The initial clinical results on overall T-cell responses indicate that vaccination with well-tolerated doses of fima*VACC* enhance cellular immune responses important for therapeutic effect of vaccines. The data also suggest that fima*VACC* trigger early T-cell responses and provide high response rates, which are two highly sought-after features of vaccination platforms.

### EXPANDING THE CLINICAL STUDY TO IDENTIFY OPTIMAL DOSING

The study continues to determine optimal dose level and further characterise the immune response aiming to identify a fima*VACC* regimen for optimal immune responses. Notably, the best responses have been seen at the lowest dose level tested. A lowest possible dose level is favourable in order to minimise potential local tolerability issues in future vaccines and the study is therefore being expanded to explore even lower dose levels. The continued dosing and optimisation work will require inclusion of a higher number of subjects than originally anticipated and the planned enrolment level has increased totalling up to 170 subjects. The total number of subjects has doubled compared to the original plan, and the total cost estimate increased by approximately 50%. The study may extend into 2H 2018 for completion of the optimisation part.

**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. There are however still important unsolved issues and improving immunogenicity of vaccine candidates is a main priority in immunotherapy. PCI Biotech believes the fimaVacc 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 for cytotoxic T-cell induction. The fimaVacc 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 opportunistic programme subject to four active research collaborations.**

### PRECLINICAL RESEARCH COLLABORATION

In July 2017 the preclinical research collaboration with an undisclosed top-10 pharma company, initiated in September 2015, was extended until the end of 2017. The aim of the extension is to determine whether PCI Biotech's fima*NAc* technology has the potential to enhance the therapeutic effect of the partner's nucleic acid therapeutic compounds. The collaboration agreement has been expanded to cover evaluation of technological compatibility and synergy based on *in vivo* studies. The companies will evaluate the data generated in this research collaboration and explore the potential for further partnership based on this outcome. The extended evaluation period spans over six months, but may be further extended.

**About the fima*NAc* and nucleic acid therapy**

The fima*NAc* 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 fima*NAc* technology may resolve.

The fima*NAc* programme has four 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 three mid-/small-size biotechs: BioNTech, eTheRNA immunotherapies and RXi Pharmaceuticals.

# CORPORATE

### Dr Hans Olivecrona appointed as Chief Medical Officer

Dr Hans Olivecrona MD PhD was appointed Chief Medical Officer (CMO) in October 2017. Dr Olivecrona will also serve as a member of PCI Biotech's executive management. He will lead the execution of all clinical development programmes, and be a key contributor to the identification and implementation of new opportunities and pipeline expansions.

Dr Olivecrona brings extensive experience in the development and commercialisation of novel therapeutics. In his most recent role Dr Olivecrona held the position as Senior Medical Director at Swedish Orphan Biovitrum (Sobi AB) in Stockholm, Sweden, with the responsibility for medical affairs and all medical aspects of business development for Sobi's international partner product portfolio. Prior to this, Dr Olivecrona held various positions spanning from preclinical and clinical development to regulatory interactions. Dr Olivecrona has a PhD from the Karolinska Institute and his work experience includes 20 years of academic clinical background, mainly within oncological surgery with a specialty in gastrointestinal cancers. Dr Olivecrona also headed a hospital research facility and is the author of numerous scientific publications.

# FINANCIAL REVIEW

### Income Statement

(Figures in brackets = same period 2016 unless stated otherwise).

The Group did not record revenues for Q3 2017. Grants received from various public sources such as the Norwegian Research Council and "SkatteFUNN" were recorded as other income. Other income for

Q3 amounted to NOK 2.4 million (NOK 2.3 million) and for the first nine months (YTD) other income was NOK 7.2 million (NOK 7.2 million).

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 Q3 and YTD totalled NOK 11.6 million (NOK 11.0 million) and NOK 31.5 million (NOK 30.8 million) respectively.

Net loss for the quarter was NOK 10.3 million (NOK 9.3 million) and net loss YTD was NOK 26.9 million (NOK 25.6 million).

### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 53.8 million at the end of the quarter, compared to NOK 14.0 million at year-end 2016. The increase is due to net proceeds of NOK 66.8 million from capital increases in 2017, offset by the result of the year. 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 activity. Net cash flow from operating activities was NOK -8.7 million in the quarter (NOK -10.4 million) and NOK -27.0 million YTD (NOK -28.6). The increase in short-term receivables from NOK 8.4 million at year-end 2016 to NOK 12.0 million at the end of the quarter was mainly due to increased “SkatteFUNN” grants not yet received.

## OTHER

### Risks and uncertainty factors for 2017

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 2016, the most important risks the company is exposed to in 2017 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 2016.

### 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 Q3 2017.

### Post-closing events

The Board of Directors of PCI Biotech Holding ASA awarded a total of 90,000 share options to key employees in October 2017 and the share options were allotted to the newly hired Chief Medical Officer, Hans Olivecrona. Please see note 11 and 12 for further details.

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 (Amphinex®)) in combination with gemcitabine for treatment of inoperable bile duct cancer; an orphan disease with high unmet medical need. Based on the promising early signs of efficacy in Phase I, the company has initiated regulatory interactions with the aim to achieve clarity on the fastest route to market for this orphan indication without any approved drugs. The development strategy will be determined after completion of these regulatory interactions, which are expected to be completed by year-end 2017.

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 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 promising and the study is expected to be completed in 2H 2018.

The fima*NAc* programme will continue to follow an opportunistic 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;
- 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, 27 November 2017

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

# CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

## PROFIT AND LOSS

| *(In NOK 1,000)* | Note | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|---|
| **Other income** | 5 | **2 350** | **2 333** | **7 183** | **7 249** | **10 475** |
| Research and development | 8 | 11 560 | 11 014 | 31 481 | 30 847 | 39 216 |
| General and administrative | | 1 246 | 853 | 3 209 | 2 526 | 4 286 |
| **Operating costs** | | **12 806** | **11 867** | **34 690** | **33 373** | **43 502** |
| **Operating results** | | **-10 456** | **-9 535** | **-27 507** | **-26 124** | **-33 027** |
| **Financial income and costs** | | | | | | |
| Financial income | | 175 | 259 | 570 | 546 | 847 |
| Financial expenses | | 0 | 0 | 0 | 4 | 4 |
| **Net financial result** | | **175** | **259** | **570** | **542** | **843** |
| **Profit/loss before income tax** | | **-10 281** | **-9 276** | **-26 938** | **-25 582** | **-32 184** |
| Income tax | 9 | 0 | 0 | 0 | 0 | 0 |
| **Net profit/loss** | 4 | **-10 281** | **-9 276** | **-26 938** | **-25 582** | **-32 184** |
| Other comprehensive income | | 0 | 0 | 0 | 0 | 0 |
| **Comprehensive income** | | **-10 281** | **-9 276** | **-26 938** | **-25 582** | **-32 184** |

## BALANCE SHEET

| *(In NOK 1,000)* | Note | 2017 30.09 | 2016 30.09 | 2016 31.12 |
|---|---|---|---|---|
| **Fixed and intangible assets** | | | | |
| Operating assets | | 2 | 6 | 5 |
| **Total fixed and intangible assets** | | **2** | **6** | **5** |
| **Current assets** | | | | |
| Short term receivables | *7* | 11 987 | 9 811 | 8 391 |
| Cash & cash equivalents | *7* | 53 755 | 20 663 | 14 002 |
| **Total current assets** | | **65 741** | **30 474** | **22 393** |
| **Total assets** | | **65 743** | **30 480** | **22 398** |
| **Shareholders' equity and liabilities** | | | | |
| **Shareholders' equity** | | | | |
| Paid in capital | | 232 133 | 165 379 | 165 379 |
| Other reserves | | -176 195 | -145 764 | -152 293 |
| **Total equity** | *10* | **55 937** | **19 615** | **13 086** |
| Trade debtors | | 921 | 3 991 | 2 080 |
| Other short term liabilities | | 8 886 | 6 874 | 7 232 |
| **Total liabilities** | | **9 806** | **10 865** | **9 312** |
| **Total shareholders' equity and liabilities** | | **65 743** | **30 480** | **22 398** |

## CHANGE IN SHAREHOLDERS EQUITY

| *(In NOK '000)* | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| **Equity at beginning of period** | **62 983** | **28 687** | **13 086** | **44 284** | **44 284** |
| Capital increase | 1 721 | - | 66 754 | - | - |
| Share option scheme | 1 514 | 203 | 3 035 | 912 | 986 |
| Comprehensive income in the period | -10 281 | -9 276 | -26 938 | -25 582 | -32 184 |
| **Equity at end of period** | **55 937** | **19 615** | **55 937** | **19 615** | **13 086** |

## CASH FLOW

| *(In NOK '000)* | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| Ordinary profit before taxes | -10 281 | -9 276 | -26 938 | -25 582 | -32 184 |
| Depreciation, amortisation and write off | 1 | 1 | 2 | 3 | 5 |
| Share options | 1 514 | 203 | 3 035 | 912 | 986 |
| Net financials | -175 | -259 | -569 | -542 | -843 |
| Changes in working capital | 99 | -1 293 | -3 100 | -3 920 | -4 053 |
| Cash flow from operating activities | -8 842 | -10 624 | -27 569 | -29 128 | -36 089 |
| Net financials | 175 | 259 | 569 | 542 | 843 |
| Taxes paid | - | - | - | - | - |
| Net cash flow from operating activities | -8 667 | -10 365 | -27 001 | -28 587 | -35 247 |
| **Cash flow from financial activities** | | | | | |
| Net proceeds from share issues | 1 721 | - | 66 754 | - | - |
| Net cash flow from financial activities | 1 721 | - | 66 754 | - | - |
| **Net change in cash during the period** | -6 945 | -10 635 | 39 753 | -28 586 | -35 247 |
| Cash and cash equivalents at the beginning of the period | 60 700 | 31 028 | 14 002 | 49 249 | 49 249 |
| **Cash and cash equivalents at the end of the period** | **53 755** | **20 663** | **53 755** | **20 663** | **14 002** |

# 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. 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 one active clinical development project in the fima*CHEM* programme, with the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agent gemcitabine for treatment of bile duct cancer. The company also has one active study in the fima*VACC* programme, 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 2016 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the condensed interim financial statements is consistent with the Annual Financial Statements. This interim report has not been subject to an audit. The going concern assumption has been applied when preparing this interim financial report. The board of directors approved the condensed interim financial information on 27 November 2017.

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 2016.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2017 or later and that could affect PCI Biotech are discussed in accounting policies, part 4, to the consolidated financial statements for 2016. In the 2016 financial statements, PCI Biotech made evaluations that at current stage *IFRS 15 Revenue from contract with customers*, *IFRS 16 Leases, IFRS 9 Financial Instruments* and amendments to *IAS 7 Cash Flows* are not expected to have a material impact on the Group'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 31st, 2016.

## 5. Earnings per share

Earnings per share

| | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -10 281 | -9 276 | -26 938 | -25 582 | -32 184 |
| Weighted average of outstanding shares ('000) | 24 920 | 14 900 | 24 138 | 14 900 | 14 900 |
| Earnings per share (NOK per share) | -0.41 | -0.62 | -1.12 | -1.72 | -2.16 |

Diluted earnings per share:

| | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -10 281 | -9 276 | -26 938 | -25 582 | -32 184 |
| Weighted average of outstanding shares ('000) | 25 229 | 14 964 | 24 446 | 14 977 | 15 003 |
| Earnings per share (NOK per share) | -0.41 | -0.62 | -1.12 | -1.72 | -2.16 |

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

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

| Purchase of services | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| The Norwegian Radium Hospital Research Foundation | 473 | 675 | 1 842 | 2 203 | 3 060 |

At the end of the quarter PCI Biotech had NOK 0.8 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 2016 and 2017 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 | 307 | 7 931 | - | 3 750 | 11 987 |
| Total receivables | **307** | **7 931** | **-** | **3 750** | **11 987** |

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

| | 2017 Q3 | 2016 Q3 | 2017 YTD | 2016 YTD | 2016 FY |
|---|---|---|---|---|---|
| Clinical studies | 7 853 | 7 921 | 18 508 | 16 648 | 20 331 |
| Pre-clinical studies | 1 140 | 1 004 | 5 744 | 7 768 | 10 480 |
| CMC and equipment | 1 329 | 1 112 | 4 083 | 3 422 | 4 687 |
| Patents | 1 238 | 977 | 3 146 | 3 009 | 3 718 |
| Other costs | 0 | 0 | 0 | 0 | 0 |
| **Total** | **11 560** | **11 014** | **31 481** | **30 847** | **39 216** |

## 10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 77.2 million in non-capitalised deferred tax assets, which mainly relates to carry forward losses.

## 11. Share options

Participants in the Company's share option program exercised on September 5th 2017 (last day before expiry) a total number of 86,500 share options at a strike price of NOK 19.90, corresponding to a total number of 86,500 shares.

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

| Expiry date | Exercise price in NOK per share | Number of options 30.09.2017 | 31.12.2016 |
|---|---|---|---|
| 2017 - Q3 | 19.90 | - | 86 500 |
| 2018 - Q3 | 10.55 | 85 000 | 85 000 |
| 2018 - Q3 | 10.02 | 40 000 | 40 000 |
| 2020 - Q3 | 9.11 | 73 500 | 73 500 |
| 2020 - Q3 | 3.79 | 110 000 | 110 000 |
| 2022 – Q3 | 24.95 | 340 000 | - |
| **Total** | | **648 500** | **395 000** |

| Overview options, Senior executives | Total holdings 31.12.2016 | Allocated | Lapsed | Exercised | Expired | Total holdings 30.09.2017 |
|---|---|---|---|---|---|---|
| Per Walday, CEO | 25 000 | 95 000 | 0 | 16 000 | 0 | 104 000 |
| Ronny Skuggedal, CFO | 66 000 | 50 000 | 0 | 0 | 0 | 116 000 |
| Anders Høgset, CSO | 17 000 | 60 000 | 0 | 11 000 | 0 | 66 000 |
| Gaël L'Hévéder, CBDO | 91 000 | 15 000 | 0 | 0 | 0 | 106 000 |
| Kristin Eivindvik, PD | 24 500 | 20 000 | 0 | 11 000 | 0 | 33 500 |
| **Sum** | **223 500** | **240 000** | **0** | **38 000** | **0** | **425 500** |

The Board of Directors of PCI Biotech Holding ASA awarded a total of 90,000 share options to key employees in October 2017, please see note 14 Subsequent events for further details.

## 12. Share capital

Participants in the Company's share option program exercised in September 2017 a total number of 86,500 share options at a strike price of NOK 19.90, corresponding to a total number of 86,500 shares. The exercise was done on the last day before the share options expired. By issuing 86,500 new shares, each share of par value NOK 3.00, the capital increase resulted in gross proceeds of NOK 1,721,350. After the transaction the Company's share capital is NOK 74,960,670 divided into 24,986,890 shares, each giving one vote at the Company's general meeting.

| | No. of shares | Nominal value per share in NOK | Share capital in NOK |
|---|---|---|---|
| 31.12.2016 | 14 900 390 | 3.00 | 44 701 170 |
| Rights Issue | 10 000 000 | 3.00 | 30 000 000 |
| Exercise of share options | 86 500 | 3.00 | 259 500 |
| **30.06.2017** | **24 986 890** | **3.00** | **74 960 670** |

The Annual General Meeting held 29 May 2017 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 2 years. The Board of Directors have utilised the authorisation to issue 86,500 shares by end of September 2017.

The Annual General Meeting held 29 May 2017 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 2017 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 2 years.

The Company has more than 2,900 shareholders (year-end 2016: 2,200) at the end of the quarter.

**10 largest shareholders per 30 September 2017:**

| Name | No. of shares | Ownership |
|---|---|---|
| FONDSAVANSE AS | 2 540 840 | 10,17 % |
| MP PENSJON PK | 1 447 504 | 5,79 % |
| RADIUMHOSPITALETS | 1 447 274 | 5,79 % |
| NORDNET LIVSFORSIKRING | 758 366 | 3,04 % |
| Myrlid AS | 555 900 | 2,22 % |
| GRESSLIEN ODD ROAR | 561 064 | 2,25 % |
| AASEN KJETIL MYRLID | 500 000 | 2,00 % |
| BERG-LARSEN ALEXANDER | 487 281 | 1,95 % |
| Nordnet Bank AB | 449 816 | 1,80 % |
| SYVERTSEN SVEIN ERIK | 437 107 | 1,75 % |
| **Total 10 largest shareholders** | **9 185 152** | **36,76 %** |
| *Others* | 15 801 738 | 63,24 % |
| *Total* | 24 986 890 | 100 % |

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 | | Subscription rights |
|---|---|---|---|---|
| **Name** | **Position** | **30.09.2017** | **31.12.2016** | **31.12.2016*** |
| Hans Peter Bøhn | Chairman | 83 556 | 50 000 | 33 556 |
| Christina Herder | Board member | 8 355 | 5 000 | 3 355 |
| Kjetil Taskén (Kjetil Taskén AS) | Board member | 4 000 | 4 000 | 0 |
| Lars Viksmoen (Stocken Invest AS) | Board member | 4 000 | 4 000 | 0 |
| Hilde H. Steineger | Board member | 0 | 0 | 0 |
| Per Walday | CEO | 65 133 | 34 019 | 29 542 |
| Anders Høgset | CSO | 62 456 | 29 177 | 32 198 |
| Ronny Skuggedal | CFO | 25 066 | 15 000 | 10 066 |
| Gaël L'Hévéder | CBDO | 10 000 | 10 000 | 0 |
| Kristin Eivindvik | PD | 17 948 | 7 985 | 8 882 |
| **Total** | | **280 514** | **159 181** | **117 599** |

*All subscription rights per 31.12.2016 were subscribed for in the share issue resolved in January 2017. There were no remaining subscription rights per 30.09.2017.

## 13. Other short term liabilities

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

## 14. Subsequent events

The Board of Directors of PCI Biotech Holding ASA awarded a total of 90,000 share options to key employees in October 2017 and the share options were allotted to the newly hired Chief Medical Officer, Hans Olivecrona. Each share option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 22.35 and the share options will expire in Q3 2022.

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 |
| FDA: | US Food and Drug Administration |
| Fimaporfin: | Generic name of the photosensitiser active ingredient TPCS2a |
| IND | Investigational New Drug |
| In vitro: | Studies performed with cells or biological molecules studied outside their normal biological context; for example proteins are examined in solution, or cells in artificial culture medium. |
| In vivo: | Studies in which the effects of various biological entities are tested on whole, living organisms usually animals. |
| ODD: | Orphan Drug Designation |
| PCI: | Photochemical internalisation |
| PFS: | Progression Free Survival |
| R&D: | Research and Development |
| | |
| FY: | Financial year (1st January – 31st December) |
| NOK: | Norwegian kroner |
| Q3: | Third quarter (1st July – 30th September) |
| YTD | Year to date (1st January – 30th September) |

## FINANCIAL CALENDAR

| | |
|---|---|
| Annual Report 2017 | 19 March 2018 |
| Q1 Report 2018 | 8 May 2018 |
| Q2 Report 2018 | 28 August 2018 |
| Q3 Report 2018 | 13 November 2018 |

## INVESTOR CONTACT

Contact person: Ronny Skuggedal, CFO, email: rs@pcibiotech.no, mob: +47 9400 5757

## 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.

**PCI BIOTECH HOLDING ASA**
Ullernchausséen 64
N-0379 Oslo
Norway

Phone: +47 67 11 54 00
email: post@pcibiotech.com
web: www.pcibiotech.com

**PCI BIOTECH AS,** subsidiary
Ullernchausséen 64
N-0379 Oslo
Norway