
*Unlocking the potential of innovative medicines*

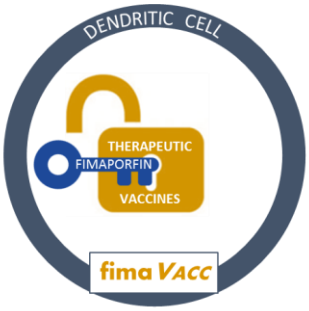
FIRST QUARTER REPORT

2018

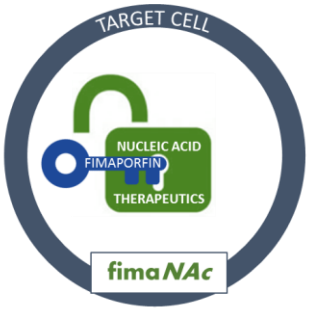
## LEVERAGING THE PCI-TECHNOLOGY IN THREE DISTINCT AREAS

### 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. 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 all 22 patients and the treatment seemed to be well tolerated, providing the first clinical proof-of-concept of the fimaporfin technology.

## HIGHLIGHTS

- **fimaCHEM**
  - **Encouraging interim overall survival data from Phase I in bile duct cancer**
  - **Preparations for pivotal phase progressing towards initiation 2H'18**
- **fimaVACC**
  - **Promising interim clinical results from Phase I suggesting enhancement of several parameters of importance for vaccination**
  - **Completed dose-finding part of the Phase I study**
- **fimaNAc**
  - **Extension of the top-10 pharma collaboration**
- **CORPORATE**
  - **Oslo Børs listing, as a transfer from Oslo Axess (subsequent event)**

## KEY FIGURES

| *(In NOK 1,000)* | **2018 Q1** | **2017 Q1** | **2017 FY** |
|---|---|---|---|
| Other income | 2 238 | 2 428 | 10 250 |
| Operating costs | 16 900 | 12 281 | 53 681 |
| Operating results | -14 663 | -9 854 | -43 431 |
| Financial items | 123 | 221 | 590 |
| **Comprehensive income** | **-14 540** | **-9 632** | **-42 841** |
| **Cash & cash equivalents** | **38 586** | **69 929** | **50 789** |
| **Net cash flow from operating activities** | **-12 203** | **-9 105** | **-29 943** |

***The dose-escalation part of the fimaCHEM Phase I study in bile duct cancer continues to deliver encouraging survival data, with the latest update from March 2018 providing an interim average overall survival of 17.4 months, with 25% of the patients still being alive. The company is currently focusing on completion of discussions with advisors and contract research organisations on the full study design, as well as completion of the extension study that may allow for repeated fimaCHEM treatment in the pivotal study.***

***The initial results from the fimaVACC Phase I study in healthy volunteers reported last year indicate enhanced overall T-cell responses at tolerable dose levels, as well as early responses and high response rates. The dose-finding part of the study is completed with more than 90 subjects included, offering a large library of clinical fimaVACC test samples. The near term focus is now on in-depth analysis and characterisation of the immune responses.***

***Our alliances in the fimaNAC programme are progressing well and the research collaboration with a top-10 pharma company, which entered into a new stage (in vivo) in Q3 2017, has been further extended to the end of Q2 2018.***

***The listing of PCI Biotech was on 27th April transferred from Oslo Axess to Oslo Børs. This is seen as a natural, important development step, as the Company is approaching a pivotal clinical phase, and the market cap and shareholder base have developed positively over the last years. The listing on Oslo Børs is expected to enhance the visibility, strengthen the Company profile and make the shares more attractive to investors.***

# 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.**

### ENCOURAGING INTERIM OVERALL SURVIVAL DATA

Per March 2018 the interim average overall survival from Phase I in the study of fimaCHEM for treatment of inoperable extrahepatic bile duct cancer (cholangiocarcinoma) patients was 17.4 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.

### PREPARATIONS FOR PIVOTAL PHASE PROGRESSING TOWARDS INITIATION 2H'18

The promising early signs of efficacy in the Phase I study were based on a single fimaCHEM 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 fimaCHEM, as this may well increase the promising signs of efficacy even further. In this study, the second fimaCHEM treatment is in this study done approximately 3-4 months after the initial treatment. The extension study will include a minimum of 6 evaluable patients. The study is on schedule for readout of safety and tolerability of a minimum of 6 evaluable patients in second half of 2018. The fimaCHEM treatment in the pivotal study may include one or two treatments, depending on the outcome of the extension study.

Last year, the Company initiated processes to assess the fastest way to market for fima*CHEM* in this life-threatening orphan disease without approved treatments. In December 2017 PCI Biotech announced the preliminary outcome of meetings with European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). The interactions with the regulatory authorities were initiated with the intent to determine the fastest route to market for fimaporfin, including the design of a pivotal study to support future marketing authorisation applications in EU and the USA. A common understanding was reached on several important factors for a pivotal study with fimaporfin in inoperable cholangiocarcinoma, including the sufficiency of a single randomised two-arm study and the potential for accelerated/conditional approval based on interim results. The randomised study will provide the opportunity to generate robust comparative data of importance for market acceptance of fimaporfin as a first line treatment. Further information on the study and the development strategy will be announced following completion of discussions with clinical advisors.

**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

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 therefore a very important step to establish PCI Biotech in the immunotherapy field.

The company initiated clinical validation of the promising fima*VACC* technology in September 2016 through a Phase I, healthy volunteer study, in up to 170 healthy volunteers in the UK. The main objective of the study is to determine safety, tolerability and immune responses for fima*VACC*.

The interim 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* triggers early T-cell responses and provides high response rates, which are two highly sought-after features of vaccination platforms. The best responses were seen at the lowest dose level tested and the study was therefore expanded with further dose cohorts investigating lower dose levels. 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 near-term focus is to further characterise the fima*VACC* immune response by performing 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 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. 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

PCI Biotech has four active preclinical research collaborations in the area of nucleic acid therapeutics, established to evaluate technologically 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 June 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, aimed at determining whether PCI Biotech's fima*NAc* technology has the potential to enhance the therapeutic effect of the partner's nucleic acid therapeutics.

**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.

# FINANCIAL REVIEW

### Income Statement

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

The Group did not record revenues for Q1 2018. Grants received from various public sources such as the Norwegian Research Council and “SkatteFUNN” were recorded as other income. Other income for Q1 amounted to NOK 2.2 million (NOK 2.4 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 Q1 totalled NOK 13.3 million (NOK 9.4 million). Operating costs ended at NOK 16.9 million (NOK 12.3 million). 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 14.5 million (NOK 9.6 million).

### Cash flow and balance sheet

The Group held cash and cash equivalents of NOK 38.6 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 -12.2 million in the quarter (NOK -9.1 million). The increase in total short-term liabilities from NOK 14.6 million at year-end 2017 to NOK 16.6 million at the end of the quarter is mainly due to the higher R&D activity level

## 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 Q1 2018.

### Post-closing events

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, has 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. Please see note 12 for further details.

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

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 promising 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 requires further discussions with clinical advisors and the development strategy will be announced following completion of these discussions.

PCI Biotech believes the PCI technology has potential to also 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 promising and the study is expected to provide important results for determination of the development strategy.

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 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, 7 May 2018

| | | |
|---|---|---|
| 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 | 2018 Q1 | 2017 Q1 | 2017 FY |
|---|---|---|---|---|
| **Other income** | 5 | **2 238** | **2 428** | **10 250** |
| Research and development | 8 | 13 335 | 9 378 | 40 988 |
| General and administrative | | 3 565 | 2 903 | 12 693 |
| **Operating costs** | | **16 900** | **12 281** | **53 681** |
| **Operating results** | | **-14 663** | **-9 854** | **-43 431** |
| **Financial income and costs** | | | | |
| Financial income | | 123 | 221 | 677 |
| Financial expenses | | 0 | 0 | 87 |
| **Net financial result** | | **123** | **221** | **590** |
| **Profit/loss before income tax** | | **-14 540** | **-9 632** | **-42 841** |
| Income tax | 9 | 0 | | 0 |
| **Net profit/loss** | 4 | **-14 540** | **-9 632** | **-42 841** |
| Other comprehensive income | | 0 | | 0 |
| **Comprehensive income** | | **-14 540** | **-9 632** | **-42 841** |

## BALANCE SHEET

| *(In NOK 1,000)* | Note | 2018 31.03 | 2017 31.03 | 2017 31.12 |
|---|---|---|---|---|
| **Fixed and intangible assets** | | | | |
| Operating assets | | 21 | 4 | 22 |
| **Total fixed and intangible assets** | | **21** | **4** | **22** |
| **Current assets** | | | | |
| Short term receivables | *7* | 8 838 | 9 117 | 7 625 |
| Cash & cash equivalents | *7* | 38 586 | 69 929 | 50 789 |
| **Total current assets** | | **47 424** | **79 045** | **58 414** |
| **Total assets** | | **47 445** | **79 049** | **58 436** |
| **Shareholders' equity and liabilities** | | | | |
| **Shareholders' equity** | | | | |
| Paid in capital | | 232 109 | 230 411 | 232 109 |
| Other reserves | | -203 551 | -161 458 | -190 266 |
| **Total equity** | *10* | **28 558** | **68 953** | **41 842** |
| Other long term liabilities | | 2 260 | 0 | 2 009 |
| **Total long term liabilities** | | **2 260** | **0** | **2 009** |
| Trade debtors | | 2 109 | 842 | 1 497 |
| Other short term liabilities | | 14 519 | 9 254 | 13 088 |
| **Total short term liabilities** | | **16 627** | **10 096** | **14 585** |
| **Total liabilities** | | **18 887** | **10 096** | **16 594** |
| **Total shareholders' equity and liabilities** | | **47 445** | **79 049** | **58 436** |

## CHANGE IN SHAREHOLDERS EQUITY

| *(In NOK '000)* | **2018 Q1** | **2017 Q1** | **2017 FY** |
|---|---|---|---|
| **Equity at beginning of period** | **41 842** | **13 086** | **13 086** |
| Capital increase | - | 65 032 | 66 729 |
| Share option scheme | 1 256 | 467 | 4 867 |
| Comprehensive income in the period | -14 540 | -9 632 | -42 841 |
| **Equity at end of period** | **28 558** | **68 953** | **41 842** |

## CASH FLOW

| *(In NOK '000)* | **2018 Q1** | **2017 Q1** | **2017 FY** |
|---|---|---|---|
| Ordinary profit before taxes | -14 540 | -9 632 | -42 841 |
| Depreciation, amortisation and write off | 1 | 1 | 6 |
| Share-based payments | 1 256 | 467 | 4 867 |
| Net financials | -123 | -221 | -677 |
| Changes in working capital | 1 080 | 59 | 8 025 |
| Cash flow from operating activities | -12 326 | -9 327 | - 30 620 |
| Net financials | 123 | 221 | 677 |
| Taxes paid | - | - | - |
| Net cash flow from operating activities | -12 203 | -9 105 | -29 943 |
| **Cash flow from financial activities** | | | |
| Net proceeds from share issues | - | 65 032 | 66 730 |
| Net cash flow from financial activities | - | 65 032 | 66 730 |
| **Net change in cash during the period** | -12 203 | 55 927 | 36 787 |
| Cash and cash equivalents at the beginning of the period | 50 789 | 14 002 | 14 002 |
| **Cash and cash equivalents at the end of the period** | **38 586** | **69 929** | **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 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 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 7 May 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 prinsiples, 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 31st, 2017.

## 5. Earnings per share

Earnings per share

| | 2018 Q1 | 2017 Q1 | 2017 FY |
|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -14 540 | -9 632 | -42 841 |
| Weighted average of outstanding shares ('000) | 24 988 | 22 593 | 24 348 |
| Earnings per share (NOK per share) | -0.58 | -0.43 | -1.76 |

Diluted earnings per share:

| | 2018 Q1 | 2017 Q1 | 2017 FY |
|---|---|---|---|
| Result allocated to shareholders (NOK'000) | -14 540 | -9 632 | -42 841 |
| Weighted average of outstanding shares ('000) | 25 727 | 22 968 | 24 826 |
| Earnings per share (NOK per share) | -0.58 | -0.43 | -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

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 Q1 | 2017 Q1 | 2017 FY |
|---|---|---|---|
| The Norwegian Radium Hospital Research Foundation | 459 | 870 | 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 | 348 | 1 523 | 5 717 | 1 250 | 8 838 |
| Total receivables | **348** | **1 523** | **5 717** | **1 250** | **8 838** |

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

| | Q1 2018 | Q1 2017 | FY 2017 |
|---|---|---|---|
| Clinical studies | 9 993 | 5 465 | 23 886 |
| Pre-clinical studies | 1 531 | 2 869 | 12 539 |
| CMC and equipment | 1 239 | 405 | 1 770 |
| Patents | 572 | 639 | 2 793 |
| Other costs | 0 | 0 | 0 |
| **Total** | **13 335** | **9 378** | **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 81.3 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 period have the following expiry date and exercise prices:

| | Exercise price in NOK | Number of shares | |
|---|---|---|---|
| Expiry date | per share | 31.12.2017 | 31.03.2018 |
| 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 | 340 000 |
| 2022 - Q3 | 22.35 | 90 000 | 90 000 |
| **Total** | | **738 500** | **738 500** |

As a subsequent event, 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.

| Overview options 2018, Senior executives | Total holdings 31.12.2017 | Allocated | Lapsed | Exercised | Expired | Total holdings 31.03.2018 |
|---|---|---|---|---|---|---|
| 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 74,960,670 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 |
|---|---|---|---|
| 31.12.2017 | **24 986 890** | **3.00** | **74 960 670** |
| Rights Issue | | | |
| Exercise of share options | | | |
| **31.03.2018** | **24 986 890** | **3.00** | **74 960 670** |

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 will be 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 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 and 8,000 shares in April 2018 as a subsequent event.

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 3,500 shareholders at the end of the quarter.

**10 largest shareholders per 31 March 2018:**

| Name | No. of shares | Ownership |
|---|---|---|
| FONDSAVANSE AS | 2 540 840 | 10,17 % |
| MP PENSJON PK | 1 394 522 | 5,58 % |
| RADIUMHOSPITALETS FORSKNINGSSTIFTELSE | 1 261 262 | 5,05 % |
| Myrlid AS | 1 240 000 | 4,96 % |
| NORDNET LIVSFORSIKRING | 663 870 | 2,66 % |
| GRESSLIEN ODD ROAR | 530 000 | 2,12 % |
| BERG-LARSEN ALEXANDER | 480 181 | 1,92 % |
| Nordnet Bank AB | 467 233 | 1,87 % |
| SYVERTSEN SVEIN ERIK | 393 907 | 1,58 % |
| Jandersen Kapital AS | 360 000 | 1,44 % |
| **Total 10 largest shareholders** | **9 331 815** | **37,35 %** |
| *Others* | 15 655 075 | 62,65 % |
| *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 | |
|---|---|---|---|
| **Name** | **Position** | **31.03.2018** | **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 | 4 000 | 4 000 |
| Lars Viksmoen (Stocken Invest AS) | Board member | 4 000 | 4 000 |
| Hilde H. Steineger | Board member | 0 | 0 |
| 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** | | **280 514** | **280 514** |

## 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

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 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, has 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 will be NOK

74,984,670 divided into 24,994,890 shares. The capital increase results in gross proceeds of NOK 56,920.

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

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 |
| Q1: | First quarter (1st January – 31st March) |

## FINANCIAL CALENDAR

| | |
|---|---|
| Q2 Report 2018 | 30 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