



*Unlocking the potential of innovative medicines*

FIRST QUARTER

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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

- **fima CHEM**
  - Presentation of Phase I data at The International Liver Congress and the Annual Meeting of the US Cholangiocarcinoma Foundation
  - Interaction with authorities to determine fastest way to market
  - Preparing for repeated treatments in Phase II through an extension of Phase I
- **fima VACC**
  - Progressing the Phase I study in healthy volunteers for clinical validation of the vaccination technology
  - Awarded up to NOK 14.3 million from the Norwegian Research Council for further development of the vaccination platform

## CORPORATE

- Completed the fully underwritten rights issue of NOK 70 million

*The emerging interim Phase I data in bile duct cancer presented at the International Liver Congress supports our regulatory interactions to determine the fastest way to market for fimaCHEM. It is still early days, but we have promising signs of effect and survival from Phase I in this orphan indication. The completed fully underwritten rights issue of NOK 70 million enables PCI Biotech to strengthen the fimaCHEM asset through a Phase I extension, to explore safety of repeated treatments in parallel with the preparations for Phase II.*

*The near-term focus for the company is to get regulatory clarity on the requirements for a marketing authorisation for fimaporfin in bile duct cancer, initiate the Phase I extension and to complete the clinical translation of the promising preclinical results with fimaVACC.*

*Per Walday, CEO.*

## KEY FIGURES

<i>(In NOK 1,000)</i>	<b>2017 Q1</b>	<b>2016 Q1</b>	<b>2016 FY</b>
Other income	2 428	2 584	10 475
Operating costs	12 281	9 893	43 502
Operating results	-9 854	-7 309	-33 027
Financial items	221	173	843
<b>Comprehensive income</b>	<b>-9 632</b>	<b>-7 136</b>	<b>-32 184</b>
<b>Cash &amp; cash equivalents</b>	<b>69 929</b>	<b>39 635</b>	<b>14 002</b>
<b>Net cash flow from operating activities</b>	<b>-9 105</b>	<b>-9 614</b>	<b>-35 247</b>

## 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.

### INTERACTION WITH AUTHORITIES TO DETERMINE FASTEST WAY TO MARKET

The radiological images from the last two cohorts in Phase I of the bile duct cancer study were in 2016 submitted for centralised evaluation, as this is an expected requirement by regulatory authorities for pivotal clinical studies. The results confirmed the early promising response data at six months. Seven out of ten patients in the last two cohorts had radiologically evaluable cancer and four of these had objective tumour response, of which two were complete responses. Patients were enrolled in PCI Biotech's Phase I study in inoperable extrahepatic bile duct cancer for six months, and thereafter followed for survival only.

Per end March 2017 the interim average overall survival from Phase I was 14.5 months, with 25% of the patients still being alive. The survival data includes all dose cohorts, sixteen patients in total. The emerging Phase I data were presented at The International Liver Congress in April 2017 and are encouraging when seen in relation to the most appropriate published comparator data. 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 are not directly comparable to the data in the fimaCHEM Phase I study, as these studies include a wide range of different inoperable CCA patients, while the fimaCHEM Phase I study focuses on inoperable perihilar CCA patients.

While the early promising signs of efficacy represent an important milestone for the bile duct cancer programme, there may still be opportunity to optimise the treatment regimen as the Phase I results were based on a single fimaCHEM treatment. In order to further optimise the treatment PCI Biotech is about to start a Phase I extension study, with the objective to determine safety and tolerability of repeated treatments with fimaCHEM. A second fimaCHEM treatment will be done 3-4 months after the initial treatment. The extension study will include a minimum of 6 evaluable patients. To be evaluable for safety evaluation a patient need to be on the study for approximately 5 months, receive 2

fimaCHEM treatments and complete the first 4 cycles of the background treatment with gemcitabine and cisplatin.

Exploring safety of repeated treatments as an extension to the Phase I study permits parallel performance of other time-critical activities, such as completion of regulatory interactions and subsequent Phase II preparations, thereby streamlining the work towards initiation of a Phase II study that may encompass repeated fimaCHEM treatments. The extension study will be run in Europe. Safety read-out of 6 evaluable patients is expected to take approximately 3 quarters and external costs are estimated to be in the range of NOK 10-14 million, both depending on the patient recruitment rate and the number of subjects needed to reach 6 evaluable patients.

The Company now plans to expand clinical development into the US and has therefore initiated a process to engage bile duct cancer clinicians and other key stakeholders in the US. The Annual Meeting of the US Cholangiocarcinoma Foundation attracts both patients and leading clinicians in hepatobiliary cancers from all over the US. PCI Biotech co-sponsored this year's conference, held in Salt Lake City early February 2017. The Company also presented an overview of the Phase I results at the medical/scientific part of the meeting.

PCI Biotech has, based on the Phase I results, initiated processes to assess the fastest route to market for fimaCHEM in this life-threatening orphan 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 and PCI Biotech is considering all relevant alternatives for regulatory approval. The Company previously expected the regulatory interactions to be completed during first half of 2017, but the dialogues are now likely to continue into the second half of 2017.

#### **About bile duct cancer and PCI treatment**

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 fimaCHEM technology in preclinical studies. Light access for PCI treatment is easy through routinely used endoscopic methods.

## fimaVACC

The **fimaVACC** 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.

### PROGRESSING THE PHASE I STUDY IN HEALTHY VOLUNTEERS FOR CLINICAL VALIDATION OF THE VACCINATION TECHNOLOGY

PCI Biotech has followed a strategy to build a comprehensive and convincing preclinical dataset to prepare for clinical validation of the technology. The Company has initiated the clinical validation through a Phase I, healthy volunteer study, which is being performed in up to 80 healthy volunteers in the UK. The first subject was dosed in September 2016 and results from the first phase of the study are expected to be available in 1H 2017. The main objective of the study is to determine safety, tolerability and immune responses for fimaVACC.

Improving immunogenicity of vaccine candidates is a main priority in immunotherapy. PCI Biotech believes the fimaVACC technology may play an important part in solving this challenge. A successful clinical validation would provide substantial risk reduction for the fimaVACC asset, as well as significant value enhancement and new partnering opportunities.

In January 2016, PCI Biotech and Ultimovacs AS, a clinical stage cancer vaccine company, initiated a preclinical research collaboration. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership. The collaboration is supported by Innovation Norway by a grant of up to NOK 0.5 million for 2017.

The fimaVACC programme is supported by a grant from the Research Council of Norway (BIA-programme) of up to NOK 12.5 million and the grant is distributed over the years, 2014-2017. In January 2017 the Research Council of Norway (BIA-programme) awarded another grant of up to NOK 13.8 million distributed over the course of three and a half years, 2017-2020, subject to final contract negotiations.

#### **About immunotherapy with the PCI vaccination 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. There has been a renewed focus on such vaccines over the past few years, and the FDA approved the first such vaccine in 2010. However, there are still important unsolved issues and several companies have recently reported failed clinical studies.

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 target cells. The fimaVACC technology may solve the issue by effectively enhancing delivery of vaccine antigens to the appropriate cells in the immune system.

## fimaNAC

The **fimaNAC** programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage opportunistic programme subject to four active research collaborations.

### PROGRESSING PRECLINICAL RESEARCH COLLABORATIONS

The fimaNAC 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 fimaNAC technology. The collaboration partners span from an undisclosed big pharma company to three mid-/small-size biotech's: BioNTech, eTheRNA immunotherapies and RXi Pharmaceuticals. The research collaboration with the big pharma company was in December 2016 extended until the end of Q2 2017. Results from these research collaborations are not reported on an ongoing basis.

#### **About the PCI technology and nucleic acid therapy**

The PCI 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.

## FINANCIAL REVIEW

### Fully underwritten rights issue of NOK 70 million completed

An extraordinary general meeting resolved in December 2016 a fully underwritten rights issue of NOK 70 million which was completed in January 2017. The net proceeds of approximately NOK 65 million enables PCI Biotech to progress the fimaCHEM programme in bile duct cancer through regulatory interactions to determine fastest way to market in both EU and US, as well as other preparations for initiation of Phase II. Furthermore the proceeds will be allocated to the promising fimaVACC programme for immunotherapy and alliance management of the current research collaborations.

The rights issue of NOK 70 million was made at a price of NOK 7 per share, with pre-emptive subscription rights for existing shareholders. The capital increase was registered in the Norwegian Register of Business Enterprises on the 19<sup>th</sup> January 2017 and 10,000,000 new shares were admitted for trading the following day.

### New grants

The fimaVACC programme received in January 2017 a grant of up to NOK 13.8 million from the Research Council of Norway (BIA-programme). The grant will be distributed over the course of three and a half years, 2017-2020, and is subject to final contract negotiations.

PCI Biotech and Ultimovacs AS, a Norwegian clinical stage cancer vaccine company, have received a grant of up to NOK 0.5 million for 2017, dedicated to the existing research collaboration within PCI Biotech's fimaVACC programme.

### Income Statement 1<sup>st</sup> Quarter (Q1) 2017

The Group has no revenue, but receives grants from various public sources such as the Norwegian Research Council and "SkatteFUNN". These grants are disclosed as other income. Other income for Q1 were NOK 2.4 million (2016: NOK 2.6 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 charged through the profit and loss statement, in line with previous

years. Research and development (R&D) costs were NOK 11.3 million for Q1 (2016: NOK 9.0 million). The increased costs compared to last year is mainly due to the Phase I fima VACC programme.

Net loss were NOK 9.6 million in Q1 (2016: NOK 7.1 million).

### **Cash flow and Balance sheet**

The company held cash and cash equivalents of NOK 69.9 million at the end of the quarter, compared to NOK 14.0 million at year-end 2016. PCI Biotech's cash management policy is to follow a low risk profile and assets are invested in short-term money market instruments or placed as bank deposits. All cash and cash equivalents were placed as bank deposits at the end of the year.

Cash flow from operating activities is mainly dependent on the activity level within R&D. Net cash flow from operating activities was NOK -9.1 million in the quarter (2016: NOK -9.6 million). The increase in short-term receivables from NOK 8.4 million at Q1 2016 to NOK 9.1 million at Q1 2017 is mainly due to increased "SkatteFUNN" grants.

## **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.

### **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 2017.

The rights issue of NOK 70 million completed in January 2017 was fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters received an underwriting fee equal to 2.0 per cent of their respective underwriting obligations. The Norwegian Radium Hospital Research Foundation and other larger shareholders participated in the underwriting syndicate. In addition, Hans Peter Bøhn, Chairman of the Board of PCI Biotech, and Lars Viksmoen, member of the Board of PCI Biotech, both entered into the underwriting agreement and had each separately underwritten NOK 1.0 million of the rights issue. The corresponding underwriting fees were settled in Q1 2017.

Please see Note 7 for further details.

### **Post-closing events**

In accordance with the authorisation granted by the Annual General Meeting 19 May 2016, the Board of Directors of PCI Biotech Holding ASA awarded a total of 340,000 share options to key employees in May 2017. 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 24.95, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after three years. The share options will lapse in Q3 2022. Please see Note 14 for further details.

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

## STRATEGY AND OUTLOOK

PCI Biotech's lead project is clinical development of fimaCHEM (fimaporfin (Amphinex®) in combination with gemcitabine) for treatment of inoperable bile duct cancer; an orphan disease with high unmet medical need. The promising early signs of efficacy in Phase I may have opened new opportunities and the company has initiated regulatory interactions with the aim to achieve clarity on the fastest route to market for this orphan indication. The development strategy will be determined after completion of these regulatory interactions, now likely to continue into the second half of 2017.

PCI Biotech believes the PCI technology has potential to play a role in the realisation of several new therapeutic modalities, including cancer immunotherapy (fimaVACC) and nucleic acid therapeutics (fimaNAC). The signed collaboration agreements show that external companies share this view.

Clinical validation of the promising fimaVACC 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. Results from the first phase of the study are expected to be available during the first half of 2017.

The strategy for the fimaNAC programme will continue to be an opportunistic approach, pursuing out-licensing opportunities.

The main priorities are to:

- Effectively drive the fimaCHEM development programme in inoperable bile duct cancer;
- Progress and finalise the fimaVACC phase I study in healthy volunteers;
- Alliance management and partnering activities across all commercially interesting areas for the PCI platform.

The Board of Directors emphasise that there are generally considerable uncertainty and risks associated with forward looking statements.

The Board of Directors and CEO  
PCI Biotech Holding ASA  
Oslo, 15 May 2017

Hans Peter Bøhn  
Chairman (sign)

Christina Herder  
(sign)

Hilde H. Steineger  
(sign)

Kjetil Taskén  
(sign)

Lars Viksmoen  
(sign)

Per Walday  
CEO (sign)

## CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

### PROFIT AND LOSS

<i>(In NOK 1,000)</i>	Note	2017 Q1	2016 Q1	2016 FY
<b>Other income</b>	5	2 428	2 584	10 475
Research and development	8	11 329	9 022	39 216
General and administrative		952	871	4 286
<b>Operating costs</b>		<b>12 281</b>	<b>9 893</b>	<b>43 502</b>
<b>Operating results</b>		<b>-9 854</b>	<b>-7 309</b>	<b>-33 027</b>
<b>Financial income and costs</b>				
Financial income		221	176	847
Financial expenses		0	3	4
<b>Net financial result</b>		<b>221</b>	<b>173</b>	<b>843</b>
<b>Profit/loss before income tax</b>		<b>-9 632</b>	<b>-7 136</b>	<b>-32 184</b>
Income tax	9	0	0	0
<b>Net profit/loss</b>	4	<b>-9 632</b>	<b>-7 136</b>	<b>-32 184</b>
Other comprehensive income		0	0	0
<b>Comprehensive income</b>		<b>-9 632</b>	<b>-7 136</b>	<b>-32 184</b>

### BALANCE SHEET

<i>(In NOK 1,000)</i>	Note	2017 31.03	2016 31.03	2016 31.12
<b>Fixed and intangible assets</b>				
Operating assets		4	9	5
<b>Total fixed and intangible assets</b>		<b>4</b>	<b>9</b>	<b>5</b>
<b>Current assets</b>				
Short term receivables	7	9 117	8 164	8 391
Cash & cash equivalents	7	69 929	39 635	14 002
<b>Total current assets</b>		<b>79 045</b>	<b>47 799</b>	<b>22 393</b>
<b>Total assets</b>		<b>79 049</b>	<b>47 808</b>	<b>22 398</b>
<b>Shareholders' equity and liabilities</b>				
<b>Shareholders' equity</b>				
Paid in capital		230 411	165 379	165 379
Other reserves		-161 458	-127 871	-152 293
<b>Total equity</b>	10	<b>68 953</b>	<b>37 508</b>	<b>13 086</b>
Trade debtors		842	1 198	2 080
Other short term liabilities		9 254	9 101	7 232
<b>Total liabilities</b>		<b>10 096</b>	<b>10 300</b>	<b>9 312</b>
<b>Total shareholders' equity and liabilities</b>		<b>79 049</b>	<b>47 808</b>	<b>22 398</b>

## CHANGE IN SHAREHOLDERS EQUITY

<i>(In NOK '000)</i>	2017 Q1	2016 Q1	2016 FY
<b>Equity at beginning of period</b>	<b>13 086</b>	<b>44 284</b>	<b>44 284</b>
Capital increase	65 032	-	-
Share option scheme	467	360	986
Comprehensive income in the period	-9 632	-7 136	-32 184
<b>Equity at end of period</b>	<b>68 953</b>	<b>37 508</b>	<b>13 086</b>

## CASH FLOW

<i>(In NOK '000)</i>	2017 Q1	2016 Q1	2016 FY
Ordinary profit before taxes	-9 632	-7 136	-32 184
Depreciation, amortisation and write off	1	1	5
Share options	467	360	986
Net financials	-221	-172	-843
Changes in working capital	59	-2 838	-4 053
<b>Cash flow from operating activities</b>	<b>-9 327</b>	<b>-9 786</b>	<b>-36 089</b>
Net financials	221	172	843
Taxes paid	-	-	-
<b>Net cash flow from operating activities</b>	<b>-9 105</b>	<b>-9 614</b>	<b>-35 247</b>
<b>Cash flow from financial activities</b>			
Net proceeds from share issues	65 032	-	-
<b>Net cash flow from financial activities</b>	<b>65 032</b>	<b>-</b>	<b>-</b>
<b>Net change in cash during the period</b>	<b>55 927</b>	<b>-9 614</b>	<b>-35 247</b>
Cash and cash equivalents at the beginning of the period	14 002	49 249	49 249
<b>Cash and cash equivalents at the end of the period</b>	<b>69 929</b>	<b>39 635</b>	<b>14 002</b>

## 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 (fimaCHEM), and as a platform that may both potentiate the effect of vaccines (fimaVACC) and delivery of nucleic acids (fimaNAC). PCI Biotech has one active clinical development project in the fimaCHEM 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 fimaVACC programme, a phase I study in healthy volunteers, for clinical proof of concept of fimaVACC's ability to enhance and direct the response of vaccines towards a stronger cellular type immunity. The fimaNAC 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 15 May 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 31<sup>st</sup>, 2016.

#### 5. Earnings per share

Earnings per share

	2017 Q1	2016 Q1	2016 FY
Result allocated to shareholders (NOK'000)	-9 632	-7 136	-32 184
Weighted average of outstanding shares ('000)	22 593	14 900	14 900
Earnings per share (NOK per share)	-0.43	-0.48	-2.16

Diluted earnings per share:

	2017 Q1	2016 Q1	2016 FY
Result allocated to shareholders (NOK'000)	-9 632	-7 136	-32 184
Weighted average of outstanding shares ('000)	22 968	14 965	15 003
Earnings per share (NOK per share)	-0.43	-0.48	-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. The Company received Norwegian grants and tax incentive scheme (SkatteFUNN) in the period and these are disclosed as other income.

#### 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):

<b>Purchase of services</b>	<b>2017 Q1</b>	<b>2016 Q1</b>	<b>2016 FY</b>
The Norwegian Radium Hospital Research Foundation	870	900	3 060

At the end of the quarter, PCI Biotech had NOK 0.7 million in short-term liability to The Norwegian Radium Hospital Research Foundation.

In connection with the fully underwritten rights issue of NOK 70 million resolved in January 2017, the underwriters received an underwriting fee equal to 2.0 per cent of their underwriting obligations. The Norwegian Radium Hospital Research Foundation and other larger shareholders participated in the underwriting syndicate. In addition, Hans Peter Bøhn, Chairman of the Board of Directors of PCI Biotech, and Lars Viksmoen, member of the Board of PCI Biotech, had both entered into the underwriting agreement and had each separately underwritten NOK 1.0 million of the rights issue. The corresponding underwriting fees were settled in January 2017.

## 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):

	<b>Not due (prepaid expenses)</b>	<b>Less than 3 months</b>	<b>3 to 12 months</b>	<b>More than 12 months</b>	<b>Total</b>
Trade receivables	-	-	-	-	-
Other receivables	816	230	6 821	1 250	9 117
<b>Total receivables</b>	<b>816</b>	<b>230</b>	<b>6 821</b>	<b>1 250</b>	<b>9 117</b>

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

	<b>2017 Q1</b>	<b>2016 Q1</b>	<b>2016 FY</b>
Clinical studies	6 136	3 703	20 331
Pre-clinical studies	2 135	2 792	10 480
CMC and equipment	1 819	1 523	4 687
Patents	1 239	1 004	3 718
Other costs	0	0	0
<b>Total</b>	<b>11 329</b>	<b>9 022</b>	<b>39 216</b>

## 10. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 73.1 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:

Expiry date	Exercise price in NOK per share	Number of options	
		31.03.2017	31.12.2016
2017 - Q3	19.90	86 500	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
<b>Total</b>		<b>395 000</b>	<b>395 000</b>

The exercise prices have, due to the capital increase resolved in the quarter, been recalculated in Q1 2017 according to the employee share option agreements.

Overview options, Senior executives	Total holdings 31.12.2016	Allocated	Lapsed	Exercised	Expired	Total holdings 31.03.2017
Per Walday, CEO	25 000	0	0	0	0	25 000
Ronny Skuggedal, CFO	66 000	0	0	0	0	66 000
Anders Høgset, CSO	17 000	0	0	0	0	17 000
Gaël L'Hévéder, CBDO	91 000	0	0	0	0	91 000
Kristin Eivindvik, PD	24 500	0	0	0	0	24 500
<b>Sum</b>	<b>223 500</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>223 500</b>

See Note 14 for post-closing events regarding granting of share options to key employees in May 2017.

## 12. Share capital

The Company completed a fully underwritten rights issue of NOK 70 million in gross proceeds at a subscription price of NOK 7 per share, with pre-emptive subscription rights for existing shareholders. The capital increase was registered in the Norwegian Register of Business Enterprises on the 19<sup>th</sup> January 2017 and 10,000,000 new shares were admitted for trading the following day. The new share capital in the Company per 19<sup>th</sup> January 2017 is NOK 74,701,170 divided into 24,900,390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. Net proceeds from the rights issue was approximately NOK 65.0 million.

	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
<b>31.03.2017</b>	<b>24 900 390</b>	<b>3.00</b>	<b>74 701 170</b>

The Annual General Meeting held 19 May 2016 authorised the Board of Directors to execute share capital increases by issuing up to 745,000 shares with a nominal value of NOK 3 in connection with the company's employee incentive program. The authorisation is valid until the Annual General Meeting in 2017, however no later than 30 June 2017.

The Company has approximately 3,000 shareholders (year-end 2016: 2,200) at the end of the quarter.

**10 largest shareholders per 31 March 2017:**

Name	No. of shares	Ownership
FONDSAVANSE AS	2 540 840	10,20
RADIUMHOSPITALET FORSKNINGSSSTIFTELSE	1 761 273	7,07
MP PENSJON PK	1 539 504	6,18
NORDNET LIVSFORSIKRING	741 376	2,98
BERG-LARSEN ALEXANDER	546 660	2,20
GRESSLIEN ODD ROAR	537 000	2,16
VICAMA AS	500 000	2,01
NORDNET BANK AB	472 954	1,90
SYVERTSEN SVEIN ERIK	437 107	1,76
MYRLID AS	413 572	1,66
<b>Total 10 largest shareholders</b>	<b>9 490 286</b>	<b>38,1 %</b>
<i>Others</i>	<i>15 410 104</i>	<i>61,9 %</i>
<i>Total</i>	<i>24 900 390</i>	<i>100 %</i>

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

Name	Position	No. of shares		Subscription rights
		31.03.2017	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	63 561	34 019	29 542
Anders Høgset	CSO	61 375	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	16 867	7 985	8 882
<b>Total</b>		<b>276 780</b>	<b>159 181</b>	<b>117 599</b>

\*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 31.03.2017.

### 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

In accordance with the authorisation granted by the Annual General Meeting 19 May 2016, the Board of Directors of PCI Biotech Holding ASA awarded a total of 340,000 share options to key employees in May 2017. 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 24.95, equal to the volume weighted average share price (VWAP) for the last 5 days of trade prior to the grant date. The options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after three years. The share options lapse in Q3 2022.

Of these share options, 95,000 share options were allotted to Per Walday, CEO. After the allocation, Per Walday holds a total portfolio of 120,000 unexercised share options and 63,561 shares.

60,000 share options were allotted to Anders Høgset, CSO. After the allocation, Anders Høgset holds a total portfolio of 77,000 unexercised share options and 61,375 shares.

50,000 share options were allotted to Ronny Skuggedal, CFO. After the allocation, Ronny Skuggedal holds a total portfolio of 116,000 unexercised share options and 25,066 shares.

20,000 share options were allotted to Kristin Eivindvik, PD. After the allocation, Kristin Eivindvik holds a total portfolio of 44,500 unexercised share options and 16,867 shares.

15,000 share options were allotted to Gaël L'Hévéder, CBDO. After the allocation, Gaël L'Hévéder holds a total portfolio of 106,000 unexercised share options and 10,000 shares.

The current authorisation, as of 19 May 2016, allows for a total of 745,000 share options, of which 735,000 now have been granted by the Board of Directors.

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 (1 <sup>st</sup> January – 31 <sup>st</sup> December)
NOK:	Norwegian kroner
Q1:	Fourth quarter (1 <sup>st</sup> January – 31 <sup>st</sup> March)

## FINANCIAL CALENDAR

General Meeting 2017	29 May	2017
Q2 2017 Report and presentation	29 August	2017
Q3 2017 Report	14 November	2017

## INVESTOR CONTACT

Contact person: Ronny Skuggedal, CFO, email: [rs@pcibiotech.no](mailto: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](mailto:post@pcibiotech.com)  
web: [www.pcibiotech.com](http://www.pcibiotech.com)

## **PCI BIOTECH AS**, subsidiary

Ullernchausséen 64  
N-0379 Oslo  
Norway