

## Unlocking the potential of innovative medicines

FOURTH QUARTER AND PRELIMINARY FULL YEAR REPORT

2016

### LEVERAGING THE PCI-TECHNOLOGY IN THREE DISTINCT AREAS



### TRIGGERED ENDOSOMAL RELEASE

#### **ABOUT PCI BIOTECH**

PCI Biotech is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange (Axess). The company is developing 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 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* 
  - Completed Phase I study in bile duct cancer, with early promising results confirmed at central expert review
  - Oral presentation of the Phase I results as late-breaking news at United European Gastroenterology Week 2016
  - Granted Orphan Drug Designation in EU
  - Successful Investigational New Drug (IND) application
  - Initiated interaction with authorities to determine fastest way to market
  - Lancet Oncology publication of the fimaporfin (Amphinex) first-in-man Phase I study – with independent expert commentary
- fima VACC
  - Initiated Phase I in healthy volunteers for clinical validation of the vaccination technology – a major development milestone
  - Research collaboration agreement with Ultimovacs signed
- fima*NAc* 
  - Research collaboration agreement with BioNTech and eTheRNA signed
  - Extension of the existing top 10 pharma agreement until end of Q2 2017

### **POST-PERIOD**

- The fully underwritten rights issue of NOK 70 million completed
- Awarded up to NOK 14.3 million for further development of fima VACC

It has been a transformative year for PCI Biotech, with promising signs of efficacy in the fimaCHEM Phase I bile duct cancer study, initiation of clinical Phase I for fimaVAcc, and establishment of further high quality partnerships in the fimaNAc programme. On the back of this progress, we also completed a fully underwritten rights issue of NOK 70 million that was more than 100% oversubscribed. The near term focus for the company is now to get regulatory clarity on the requirements for a marketing authorisation for fimaporfin in bile duct cancer and to complete the clinical translation of the promising preclinical results with fimaVAcc.

Per Walday, CEO.



### **KEY FIGURES**

(In NOK 1,000)	2016 Q4	2016 FY	2015 FY
Other Income	3 226	10 475	10 467
Operating costs	10 129	43 502	43 096
Operating results	-6 903	-33 027	-32 629
Financial items	301	843	707
Comprehensive income	-6 602	-32 184	-31 922
Cash & cash equivalents	14 002	14 002	49 249
Net cash flow from operating activities	-6 661	-35 247	-31 974

### **OPERATIONAL REVIEW**

### fima *CHEM*

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

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

A centralised radiological endpoint evaluation is an expected requirement by regulatory authorities for pivotal clinical studies. The radiological images from the last two cohorts in Phase I of the bile duct cancer study were therefore submitted for centralised evaluation. The results confirmed the early promising response data. Seven patients had radiologically evaluable cancer and four of these had objective tumour response, of which two were complete responses. These promising results were submitted and selected as late-breaking news for oral presentation at United European Gastroenterology Week (UEGW) in October 2016.

The early promising signs of efficacy represents an important milestone for the bile duct cancer programme. The patient numbers in the study are small, but the results suggest a significant increase in objective tumour response rate compared to what is normally achieved with the current standard treatment. Local tumour response in the bile duct is important to maintain biliary drainage and may therefore be more important for outcome than would be the case for many other cancers. The fima*CHEM* treatment boosts the chemotherapy effect locally in the bile duct, thereby directly targeting this area. The Company has, based on these promising results, initiated processes to assess the fastest way to market for fima*CHEM* in this life-threatening orphan disease without approved treatments.

Bile duct cancer is a rare disease and PCI Biotech aims for approved orphan drug designations in both EU and US. Orphan designation for fimaporfin in bile duct cancer, was received from the European Commission in August 2016. In December 2016 the Company received a successful Investigational New Drug (IND) review for Amphinex. The IND is a clearance by the United States Food and Drug Administration (FDA) to include patients in the USA in PCI Biotech's phase II clinical programme for Amphinex and is an important milestone for the Phase II study. Following the IND the Company has filed an Orphan Drug Designation (ODD) application in the US. The FDA has notified



that they have received the application and informed that the application review time can be up to 180 days, due to heavy work load. With the recently opened IND the Company is now planning to expand clinical development into USA and has therefore initiated a process to engage clinicians and other stakeholders in bile duct cancer (cholangiocarcinoma) in the US. The Annual Meeting of the US Cholangiocarcinoma Foundation attracts both bile duct cancer patients and key opinion leading clinicians in hepatobiliary cancers from all over US. PCI Biotech 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.

The promising early signs of efficacy in the Phase I study were based on a single fima*CHEM* treatment. In order to further optimise the treatment the Company has initiated a process to evaluate the inclusion of fima*CHEM* retreatments.

The development strategy for fimaporfin in bile duct cancer will be settled after completion of regulatory interactions with European and US authorities. The Company expects to complete the regulatory interactions during first half of 2017.

The first-in-man Phase I study with the proprietary drug fimaporfin in patients with various advanced solid tumours was in July 2016 published in Lancet Oncology, the premier publication worldwide for original clinical trials research in oncology. The article was accompanied by an independent expert commentary commissioned by Lancet Oncology, which among others stated: "*The results of this phase 1, first-in-man, dose-escalation trial of a new photosensitiser, disulfonated tetraphenyl chlorine (TPCS2a), are encouraging. Of particular interest are the findings that the treatment approach seems to be effective in various difficult-to-treat malignancies…*". In this phase I study, fimaporfin was given at escalating doses in combination with the cytotoxic drug bleomycin to 22 patients with advanced and recurrent cancer. The treatment was found safe and tolerable, and provided significant anti-tumour effects in aggressive tumours.

### 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 the only current 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 is one of the drugs significantly enhanced by the fima *CHEM* technology in preclinical studies. Light access for PCI treatment is easy through routinely used endoscopic methods.



### fima VACC

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

## INITIATED PHASE I IN HEALTHY VOLUNTEERS FOR CLINICAL VALIDATION OF THE VACCINATION TECHNOLOGY – A MAJOR DEVELOPMENT MILESTONE

The Company 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 PCI Biotech driven phase I, healthy volunteer study. The healthy volunteer study is thoroughly prepared, with input from the Scientific Advisory Committee and other external advisors. The first subject was dosed in September 2016 and the study results are expected to be available in 1H 2017. The main objective of the study is to determine safety, tolerability and immune responses for fima *VACC*.

Improving immunogenicity of vaccine candidates is a main priority in the immunotherapy industry and PCI Biotech believes that the fima *VACC* technology may play an important part in solving this challenge. A successful clinical validation would provide substantial risk reduction for the fima *VACC* asset, as well as significant value enhancement and opening up for 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 fima VACC programme is supported by a grant from the Research Council of Norway (BIAprogramme) of up to NOK 12.5 million and the grant is distributed over the course of three 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 FDA approved the first such vaccine in 2010. There are however 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 the required T-cell responses. One of the most important reasons is probably insufficient delivery of vaccine antigens to the appropriate target cells. The fima *VACC* technology may solve the issue by effectively enhancing delivery of vaccine antigens to the appropriate cells in the immune system.



### fima*NAc*

The fime *NAc* programme provides a targeted intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage opportunistic programme with four active research collaborations.

### PRECLINICAL RESEARCH COLLABORATION WITH ETHERNA SIGNED

In December 2016 PCI Biotech and eTheRNA immunotherapies (Belgium), initiated a preclinical research collaboration. The partnership is governed by a preclinical research collaboration agreement. In brief, the collaborators will evaluate technology compatibility and synergy based on *in vivo* studies. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership.

In September 2016 PCI Biotech and BioNTech AG, a fully integrated biotechnology company developing individualised cancer immunotherapies, initiated a preclinical research collaboration involving the University of Zurich. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership. PCI Biotech has already a collaboration agreement with the University of Zurich and the research is funded through the existing agreement.

The existing research collaboration with a top 10 pharma company was in December 2016 further extended until the end of Q2 2017. The fima*NAc* programme now have four active research collaborations.

### About the PCI technology and nucleic acid therapy

The PCI technology may enhance the delivery of most types of nucleic acid technologies. Several forms of nucleic acids are widely acknowledged to have a large potential as therapeutic agents, 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.

### FINANCIAL REVIEW

### Income Statement 4<sup>th</sup> Quarter (Q4) 2016 and preliminary full year (FY) results

The Group has no revenue, but receives grants from different public sources such as the Norwegian Research Council and "SkatteFUNN". These grants are disclosed as other income. Other income for Q4 were NOK 3.2 million (2015: NOK 3.3 million) and for the full year (FY) other income were NOK 10.5 million (2015: 10.5 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 8.4 million for Q4 2016 (2015: NOK 10.1 million) and for the full year R&D costs were NOK 39.2 million (2015: NOK 38.8 million).

Net loss were NOK 6.6 million in Q4 (2015: NOK 8.4 million) and for the full year net loss were NOK 32.2 million (2015: NOK 31.9 million).

### Cash flow and Balance sheet

The company held cash and cash equivalents of NOK 14.0 million at the end of the year, compared to NOK 49.2 million at year-end 2015. 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 -6.7 million in the quarter (2015: NOK -4.6 million) and NOK -35.2 million for the

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full year (2015: NOK -32.0 million). The increase in short-term receivables from NOK 7.1 million at year-end 2015 to NOK 8.1 million at year-end 2016 is mainly due to increased "SkatteFUNN" grants for 2016. The decrease in short term liabilities from NOK 8.7 million at year-end 2015 to NOK 7.0 million at year-end 2016 is mainly due to lower patient cost accruals.

### OTHER

### **Risks and uncertainty factors for 2016**

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 2015, the most important risks the company was exposed to for 2016 were 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 related party transactions in 2016. See Note 6 for full disclosure of related party transactions.

#### **Post-closing events**

The Company has 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.

The rights issue 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. Hans Peter Bøhn, Chairman of the Board 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 have been settled in 2017. Net proceeds from the rights issue was approximately NOK 65.0 million.

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 fima *VACC* programme.

The fima *VACC* 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 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 fima *CHEM* (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 final development strategy will be settled after completion of these regulatory interactions.

PCI Biotech believes that the PCI technology has the potential to play a role in the realisation of several new therapeutic modalities, including cancer immunotherapy (fima*VACC*) and nucleic acid therapeutics (fima*NAc*), and the signed agreements 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 and study results are expected to be available during first half of 2017.

The strategy for the fima *NAc* programme will continue to be an opportunistic approach, pursuing outlicensing opportunities.

The main priorities are to:

- Effectively progress 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 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, 27 February 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**

(In NOK 1,000)	Note	2016	2015	2016	2015
	Note	Q4	Q4	FY	FY
Other Income	5	3 226	3 323	10 475	10 467
Research and development	8	8 369	10 083	39 216	38 844
General and administrative		1 760	1 779	4 286	4 252
Operating costs		10 129	11 862	43 502	43 096
Operating results		-6.003	-9 520	-33 027	-32 620
		-0 903	-0 539	-33 021	-32 029
Financial income and costs					
Financial income		301	193	847	867
Financial expenses		0	33	4	160
Net financial result		301	160	843	707
Ordinary profit before taxes		-6 602	-8 379	-32 184	-31 922
Tax on ordinary result	9	0	0	0	0
Net profit/loss	4	-6 602	-8 379	-32 184	-31 922
Other comprehensive income		0	0	0	0
Comprehensive income		-6 602	-8 379	-32 184	-31 922

### **BALANCE SHEET**

(In NOK 1,000) Note	2016	2015
	31.12	31.12
Fixed and intangible assets		
Operating assets	5	10
Total fixed and intangible assets	5	10
Current assets		
Short term receivables 7	8 114	7 139
Cash & cash equivalents 7	14 002	49 249
Total current assets	22 116	56 388
Total assets	22 122	56 398
Shareholders' equity and liabilities		
Shareholders' equity		
Paid in capital	165 379	165 379
Other reserves	-152 292	-121 094
Total equity10	13 087	44 284
Trade debtors	2 078	3 371
Other short term liabilities	6 956	8 742
Total liabilities	9 035	12 114
Total shareholders' equity and liabilities	22 122	56 398



### **CHANGE IN SHAREHOLDERS EQUITY**

(In NOK '000)	2016 Q4	2015 Q4	2016 FY	2015 FY
Equity at beginning of period	19 615	52 339	44 284	9 114
Capital increase	-	-	-	65 468
Share option scheme	74	323	986	1 624
Comprehensive income in the period	-6 602	-8 379	-32 184	-31 922
Equity at end of period	13 087	44 284	13 087	44 284

### **CASH FLOW**

(In NOK '000)	2016 Q4	2015 Q4	2016 FY	2015 FY
Ordinary profit before taxes	-6 602	-8 379	-32 184	-31 922
Depreciation, Amortisation and Write Off	1	1	5	4
Share options	74	323	986	1 624
Net financials	-301	-160	-843	-707
Changes in working capital	-134	3 407	-4 053	-1 680
Cash flow from operating activities	-6 962	-4 808	-36 089	-32 681
Net financials	301	160	843	707
Taxes paid	-	-	-	-
Net cash flow from operating activities	-6 661	-4 648	-35 247	-31 974
Cash flow from financial activities				
Net proceeds from share issues	-	-	-	65 469
Net cash flow from financial activities	-	-	-	65 469
Net change in cash during the period Cash and cash equivalents at the beginning of	-6 661	-4 648	-35 247	33 495
the period	20 663	53 897	49 249	15 /54
the period	14 002	49 249	14 002	49 249



### 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 different 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 focuses on the development of PCI products for enhanced delivery of marketed 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 study in the fima*CHEM* programme, a phase I/II trial in bile duct cancer with the lead candidate fimaporfin (Amphinex) in combination with the chemotherapeutic agent gemcitabine. The company also has one active study in the 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 Interim Financial Statements should be read in conjunction with the Consolidated Financial Statements for the year ended 31 December 2015 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. They were approved for issue by the Board of Directors on 11 April 2016. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the 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 interim condensed financial information on 27 February 2017.

### 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 2015.

The new standards and interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2016 and that could affect PCI Biotech are discussed in accounting policies, part 4, to the consolidated financial statements for 2015. In the 2015 financial statements, PCI Biotech made evaluations that at current stage *IFRS 15 Revenue from contract with* 



*customers* and *IFRS 16 Leases* are not expected to have a material impact on the Group's financial position, performance and/or disclosure.

### 4. Earnings per share

#### Earnings per share

	2016	2015	2016	2015
	Q4	Q4	FY	FY
Result allocated to shareholders (NOK'000)	-6 602	-8 379	-32 184	-31 922
Weighted average of outstanding shares ('000)	14 900	14 900	14 900	13 967
Earnings per share (NOK per share)	-0.44	-0.56	-2.16	-2.29

Diluted earnings per share:				
	2016 Q4	2015 Q4	2016 FY	2015 FY
Result allocated to shareholders (NOK'000)	-6 602	-8 379	-32 184	-31 922
Weighted average of outstanding shares ('000)	15 079	14 900	15 003	14 025
Earnings per share (NOK per share)	-0.44	-0.56	-2.16	-2.29

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.

### 5. 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.

### 6. 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 and legal services provided by former board member Theresa Comiskey Olsen during her term as board member (ended her term in May 2015), represents related party transactions. The following table shows the extent of such transactions in the reported periods (all figures in NOK '000):

Purchase of services	2016 Q4	2015 Q4	2016 FY	2015 FY
The Norwegian Radium Hospital				
Research Foundation	834	886	3 060	3 488
Theresa Comiskey Olsen	NA	NA	NA	17*

\* Comiskey Olsen ended her term as board member in May 2015 and transactions up to that date are disclosed.

At the end of the year, PCI Biotech had NOK 1.25 million in short term liability to The Norwegian Radium Hospital Research Foundation. Please see note 13 for information regarding related parties obligations per year-end in relation to the underwriting syndicate for the rights issue completed in January 2017.



### 7. Credit risk, foreign currency risk and interest risk

#### Credit risk

PCI Biotech has no sales for 2015 and 2016 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 Less than 3 expenses) months		3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	305	1 916	5 893	8 114
Total receivables	305	1 916	5 893	8 114

A majority of the short term receivables relates to accrued, not received grants (BIA) and tax incentive scheme (SkatteFUNN) for 2016.

#### 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.

#### 8. Research and Development costs

#### All figures in '000 NOK

	2016 Q4	2015 Q4	2016 FY	2015 FY
Clinical studies	3 683	4 376	20 331	17 808
Pre-clinical studies	2 712	3 687	10 480	11 876
CMC and equipment	1 264	1 042	4 687	4 941
Patents	709	978	3 718	4 220
Other costs	0	0	0	0
Total	8 368	10 083	39 216	38 844

#### 9. Deferred tax and deferred tax assets

At the end of the year, the group held NOK 69.4 million in non-capitalised deferred tax assets, which mainly relates to carry forward losses.



### 10. 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 options	
Expiry date	per share	31.12.2016	31.12.2015
2016 – Q3	14.07	-	170 000
2017 - Q3	27.38	86 500	86 500
2018 - Q3	14.52	85 000	85 000
2018 - Q3	13.78	40 000	40 000
2020 - Q3	12.53	73 500	73 500
2020 - Q3	5.21	110 000	110 000
Total		395 000	565 000

Overview options, Senior executives	Total holdings 31.12.2015	Allocated	Lapsed	Exercised	Expired	Total holdings 31.12.2016
Per Walday, CEO	105 000	0	0	0	80 000	25 000
Ronny Skuggedal, CFO	66 000	0	0	0	0	66 000
Anders Høgset, CSO	77 000	0	0	0	60 000	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
Sum	363 500	0	0	0	140 000	223 500

### 11. Share capital

The share capital is NOK 44 701 170 divided by 14 900 390 shares, each with a nominal value of NOK 3.00 and each giving one vote at the Company's general meeting. The company has approximately 2 200 shareholders per year-end 2016 (2015: 1 450). Please see Note 13 regarding post-closing events and the rights issue completed in January 2017.

	No. of shares	Nominal value per share in NOK	Share capital in NOK
31.12.2015	14 900 390	3.00	44 701 170
Events	-	3.00	-
31.12.2016	14 900 390	3.00	44 701 170



10 largest shareholders per 31 December 2016:

Name	No. of shares	Ownership
FONDSAVANSE AS	1 500 000	10,07
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 059 853	7,11
VICAMA AS	516 302	3,47
MYNA AS	441 496	2,96
MP PENSJON PK	416 531	2,80
NORDNET LIVSFORSIKRING	340 994	2,29
SEB, SKANDINAVISKA ENSKILDA BANKEN	335 176	2,25
GRESSLIEN ODD ROAR	320 000	2,15
VINTERSTUA AS	276 000	1,85
SYVERTSEN SVEIN ERIK	258 050	1,73
Total 10 largest shareholders	<u>5 464 402</u>	<u>36,7 %</u>
Others	9 435 988	63,3 %
Total	14 900 390	100 %

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

				Subscription
		No. of	shares	rights
Name	Position	31.12.2015	31.12.2016	31.12.2016
Hans Peter Bøhn	Board member	50 000	50 000	33 556
Christina Herder	Board member	0	5 000	3 355
Kjetil Taskén (Kjetil Taskén AS)	Board member	0	4 000	0
Lars Viksmoen (Stocken Invest AS)	Board member	0	4 000	0
Hilde H. Steineger	Board member	0	0	0
Per Walday	CEO	44 019	34 019	29 542
Anders Høgset	CSO	47 977	29 177	32 198
Ronny Skuggedal	CFO	15 000	15 000	10 066
Gaël L'Hévéder	CBDO	10 000	10 000	0
Kristin Eivindvik	PD	13 235	7 985	8 882
Total		180 231	159 181	117 599

All subscription rights per 31.12.2016 were subscribed for in December 2016 and are part of the shareholding portfolio when the rights issue was completed in January 2017.



#### 12. Other short term liabilities

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

#### 13. Material events subsequent to the end of the reporting period

The Company has 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.

The rights issue 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. Hans Peter Bøhn, Chairman of the Board 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 have been settled in 2017. Net proceeds from the rights issue was approximately NOK 65.0 million.

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

The fima *VACC* 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 is not aware of any other post-closing events, which could materially influence this interim financial statement.



### **DEFINITIONS AND GLOSSARY**

Amphinex: FDA: Fimaporfin: IND	Trade name of the clinical intravenous formulation of fimaporfin US Food and Drug Administration Generic name of the photosensitiser active ingredient TPCS2a 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: NOK: Q4:	Financial year (1 <sup>st</sup> January – 31 <sup>st</sup> December) Norwegian kroner Fourth quarter (1 <sup>st</sup> October – 31 <sup>st</sup> December)

### FINANCIAL CALENDAR

Annual Report 2016	24 April	2017
Q1 2017 Report	16 May	2017
General Meeting 2017	29 May	2017
Q2 2017 Report and presentation	29 August	2017
Q3 2017 Report	14 November	2017

### **INVESTOR CONTACT**

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### FORWARD LOOKING STATEMENTS

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

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