

## Unlocking the potential of innovative medicines

THIRD QUARTER 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 (AmphinexTM). 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 THIRD QUARTER 2016 AND BEYOND

- 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 Gastro Week 2016
  - Granted Orphan Drug Designation of fimaporfin for treatment of bile duct cancer in EU
  - Lancet Oncology publication of the fimaporfin (Amphinex) first-in-man Phase I study, with independent expert commentary
- fima VACC
  - Initiated clinical validation of the vaccination technology a major development milestone
- fima*NAC* 
  - Research collaboration agreement with BioNTech signed
- Financials
  - The Company proposes to carry out a fully underwritten rights issue of NOK 70 million at a subscription price of NOK 7 per share

We have reached several important milestones for the fimaCHEM program in 2016. On the back of this progress, we were very pleased to recently announce a fully underwritten rights issue of NOK 70 million. The funding will enable the company to complete the initiated interactions with regulatory authorities to determine the best approach to marketing approval. In addition, the rights issue will fully fund translation of our fimaVACC technology into man. Improving immunogenicity of vaccine candidates is a main priority in the immunotherapy industry and we believe that the fimaVACC technology may play an important part in solving this challenge. We are also facing increased interest in our fimaNAC technology and we look forward to explore synergies with BioNTech's pioneering disruptive technologies.

Per Walday, CEO.



## **KEY FIGURES**

(In NOK 1,000)	2016 Q3	2016 YTD	2015 FY
Other Income	2 333	7 249	10 467
Operating costs	11 867	33 373	43 096
Operating results	-9 535	-26 124	-32 629
Financial items	259	542	707
Comprehensive income	-9 276	-25 582	-31 922
Cash & cash equivalents	20 663	20 663	49 249
Net cash flow from operating activities	-10 365	-28 587	-31 974

## **OPERATIONAL REVIEW**

#### fima *CHEM*

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

#### **ORPHAN DESIGNATION GRANTED IN EU FOR FIMAPORFIN IN BILE DUCT CANCER**

Orphan designation for fimaporfin in bile duct cancer, was received from the European Commission in August 2016. Bile duct cancer is a rare disease and PCI Biotech's business case is based on the assumption of approved orphan drug designations in both EU and US. The orphan drug designation in EU is therefore a key milestone for the programme that provides important development and commercialisation benefits for fimaporfin in this indication.

#### **CENTRAL EVALUATION CONFIRMS EARLY PROMISING RESPONSE RESULTS**

The central evaluation was performed by radiology experts from the US, according to the generally accepted response evaluation criteria in solid tumours (RECIST). The evaluation was finalised in September 2016 and the results confirmed the early promising response data. A total of 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, verified by central radiological expert review, represents an important milestone for the bile duct cancer programme. The patient numbers in the study are small, but the results suggest a several fold increase in objective tumour response rate compared to a similar patient population in the landmark study for the current standard treatment, published in the New England Journal of Medicine in 2010. Local tumour response in the bile duct is important in this cancer, to maintain biliary drainage, and response in tumour bulk may therefore have a greater effect on survival than would be the case for other cancers. The fima*CHEM* treatment boosts the chemotherapy effect locally in the bile duct, thereby directly targeting the area of most importance to treat. The fact that the treatment resulted in complete responses for two patients is also very encouraging. Two oncology experts in PCI Biotech's Scientific Advisory Committee; prof. Jan Vermorken and prof. Andrew Hughes, have reviewed the complete radiological read dataset from the central evaluation of Cohort III and IV. In their assessment they stated "The current clinical data are



supportive of the hypothesis that the addition of fima *CHEM* to gemcitabine-cisplatin with local hilar photosensitisation can result in enhanced local tumour control", and concluded that this warrants the commencement of further clinical development of fima *CHEM* in this indication.

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 indication without approved treatments. The strategy for the phase II part of the bile duct cancer study will be settled after completion of regulatory interactions with European and US authorities on the regulatory requirements for marketing authorisation for fima *CHEM* in bile duct cancer.

Further hospitals in selected European countries will be added in preparation for Phase II. Eleven sites are currently open. The Company also aims to expand the study to USA by opening an IND and seek orphan drug designation by the FDA.

#### 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.

#### LANCET ONCOLOGY PUBLICATION OF THE FIMAPORFIN (AMPHINEX<sup>™</sup>) FIRST-IN-MAN PHASE I STUDY

The first-in-man Phase I study with the proprietary drug fimaporfin performed at University College Hospital in London in patients with various advanced solid tumours has been 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.



## fima VACC

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

# INITIATED CLINICAL VALIDATION OF THE VACCINATION TECHNOLOGY – A MAJOR DEVELOPMENT MILESTONE

The company has followed a strategy to build a comprehensive and convincing pre-clinical dataset to prepare for clinical validation of the technology. The translation of results from preclinical to clinical is one of the major challenges in pharmaceutical development. The company has decided to expedite 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 is estimated to be completed 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 fima *VACC* 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 course of three years, 2014-2017.

#### 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 for this is probably insufficient delivery of vaccine antigens to the appropriate target cells. The fima *Vacc* technology may solve the issue by effectively enhancing appropriate delivery of vaccine antigens to the appropriate cells in the immune system.

### fima*NAC*

The **fima***NAc* programme provides an intracellular delivery technology for nucleic acid therapeutics. It is a preclinical stage opportunistic programme with three active research collaborations.

#### INITIATED PRECLINICAL RESEARCH COLLABORATION WITH BIONTECH

In September 2016 PCI Biotech and BioNTech AG, a fully integrated biotechnology company developing individualized cancer immunotherapies, initiated a preclinical research collaboration involving the University of Zurich.



The partnership is governed by a preclinical research collaboration agreement. In brief, the preclinical research collaboration will evaluate technology compatibility and synergy based on in vivo studies performed by 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.

In addition PCI Biotech has two active research collaborations, with an undisclosed top-10 pharma company and with RXi Pharmaceuticals. The research to investigate optimisation of technological synergies are ongoing and the companies will evaluate the data generated in these research collaborations and based on this explore the potential for further partnerships.

#### 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 3<sup>rd</sup> Quarter (Q3) 2016 and year to date (YTD) 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 Q3 was NOK 2.3 million (2015: NOK 2.4 million) and for the first nine months (YTD) other income was NOK 7.2 million (2015: 7.1 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 was NOK 11.0 million for Q3 2016 (2015: NOK 11.0 million) and for the first nine months R&D costs was NOK 30.8 million (2015: NOK 28.8 million). The increased costs compared to 2015 are due to higher activities within the clinical programmes.

Net loss was NOK 9.3 million in Q3 (2015: NOK 9.3 million) and for the first nine months net loss was NOK 25.6 million (2015: NOK 23.5 million).

#### Cash flow and Balance sheet

The company held cash and cash equivalents of NOK 20.7 million at the end of the quarter, compared to NOK 49.2 million at year-end 2015. All cash and cash equivalents are placed as bank deposits at the end of the quarter. Cash flow from operating activities is mainly dependent on the activity level within R&D. Net cash flow from operating activities was NOK -10.4 million in the quarter (2015: NOK - 9.4 million) and NOK -28.6 million for the first nine months (2015: NOK -27.3 million). The increase in short-term receivables from NOK 7.6 million in Q3 2015 to NOK 9.8 million in Q3 2016, is mainly due to increased "SkatteFUNN" grants.

## 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 is exposed to for 2016 are associated with progress and performance of R&D programmes.



#### **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 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 proposed to carry out a fully underwritten rights issue of NOK 70 million at a subscription price of NOK 7 per share, with pre-emptive subscription rights for existing shareholders. The Board of Directors has resolved to call for an extraordinary general meeting to be held on 8 December 2016 to resolve the rights issue.

The rights issue is fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters will receive an underwriting fee equal to 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, have both entered into the underwriting agreement and have each separately underwritten NOK 1.0 million of the rights issue.

Completion of the rights issue is subject to shareholders' approval at the EGM to be held on 8 December 2016 and that an EEA-prospectus for the Rights Issue is approved by the Financial Supervisory Authority of Norway and published in accordance with applicable laws.

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<sup>®</sup>) 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.

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 a phase I study in healthy volunteers is ready to be initiated.

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

The main priorities for the next 12 months are to:

- Effectively progress the fima CHEM development programme in inoperable bile duct cancer;
- Translate the promising preclinical results with fima VACC to the clinical setting through a welldesigned 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, 21 November 2016

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	2015
		Q3	Q3	YTD	YTD	FY
Other Income	5	2 333	2 415	7 249	7 144	10 467
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Research and development	8	11 014	11 049	30 847	28 761	38 844
General and administrative		853	782	2 526	2 473	4 252
Operating costs		11 867	11 831	33 373	31 234	43 096
Operating results		-9 535	-9 416	-26 124	-24 090	-32 629
Financial income and costs						
Financial income		259	219	546	674	867
Financial expenses		0	99	4	127	160
Net financial result		259	120	542	546	707
Ordinary profit before taxes		-9 276	-9 296	-25 582	-23 544	-31 922
Tax on ordinary result	9	0	0	0	0	0
Net profit/loss	4	-9 276	-9 296	-25 582	-23 544	-31 922
Other comprehensive income		0	0	0	0	0
Comprehensive income		-9 276	-9 296	-25 582	-23 544	-31 922

#### **BALANCE SHEET**

(In NOK 1,000) Note	2016 30.09	2015 30.09	2015 31.12
Fixed and intangible assets			
Operating assets	6	11	10
Total fixed and intangible assets	6	11	10
Current assets			
Short term receivables 7	9 811	7 643	7 139
Cash & cash equivalents 7	20 663	53 897	49 249
Total current assets	30 474	61 540	56 388
Total assets	30 480	61 551	56 398
Shareholders' equity and liabilities Shareholders' equity			
Paid in capital	165 379	165 379	165 379
Other reserves	-145 764	-113 040	-121 094
Total equity10	19 615	52 339	44 284
Trade debtors Other short term liabilities	3 991 6 874	2 517 6 695	3 371 8 742
Total liabilities Total shareholders' equity and liabilities	10 865 30 480	9 212 61 551	<u>12 114</u> 56 398



#### **CHANGE IN SHAREHOLDERS EQUITY**

(In NOK '000)	2016 Q3	2015 Q3	2016 YTD	2015 YTD	2015 FY
Equity at beginning of period	28 687	61 327	44 284	9 114	9 114
Capital increase	-	-	-	65 468	65 468
Share option scheme	203	308	912	1 301	1 624
Comprehensive income in the period	-9 276	-9 296	-25 582	-23 544	-31 922
Equity at end of period	19 615	52 339	19 615	52 339	44 284

#### **CASH FLOW**

(In NOK '000)	2016 Q3	2015 Q3	2016 YTD	2015 YTD	2015 FY
Ordinary profit before taxes	-9 276	-9 296	-25 582	-23 544	-31 922
Depreciation, Amortisation and Write Off	1	1	3	3	4
Share options	203	308	912	1 301	1 624
Net financials	-259	-120	-542	-546	-867
Changes in working capital	-1 293	-431	-3 920	-5 086	-1 680
Cash flow from operating activities	-10 624	-9 538	-29 128	-27 872	-32 841
Net financials	259	120	542	546	867
Taxes paid	-	-	-	-	-
Net cash flow from operating activities	-10 365	-9 419	-28 587	-27 326	-31 974
Cash flow from financial activities					
Net proceeds from share issues	-	-	-	65 469	65 469
Net cash flow from financial activities	-	-	-	65 469	65 469
Net change in cash during the period	-10 365	-9 419	-28 586	38 143	33 495
Cash and cash equivalents at the					
beginning of the period	31 028	63 316	49 249	15 754	15 754
Cash and cash equivalents at the end of the period	20 663	53 897	20 663	53 897	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 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 an on-going preclinical fima *VACC* programme ready to enter clinical testing, to enhance and direct the response of vaccines towards a stronger cellular type immunity.

#### 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. The 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 21 November 2016.

#### 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	2015
	Q3	Q3	YTD	YTD	FY
Result allocated to shareholders (NOK'000)	-9 276	-9 296	-25 582	-23 544	-31 922
Weighted average of outstanding shares ('000)	14 900	14 900	14 900	13 656	13 967
Earnings per share (NOK per share)	-0.62	-0.62	-1.72	-1.72	-2.29

#### Diluted earnings per share:

	2016 Q3	2015 Q3	2016 YTD	2015 YTD	2015 FY
Result allocated to shareholders (NOK'000)	-9 276	-9 296	-25 582	-23 544	-31 922
Weighted average of outstanding shares ('000)	14 964	14 900	14 977	13 734	14 025
Earnings per share (NOK per share)	-0.62	-0.62	-1.72	-1.72	-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 revenues are not influenced by any cyclicality of operations. The company received Norwegian grants and tax incentive scheme (SkatteFUNN) and these are shown 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, who ended her term as board member 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 Q3	2015 Q3	2016 YTD	2015 YTD	2015 FY
The Norwegian Radium Hospital					
Research Foundation	675	886	2 203	2 543	3 488
Theresa Comiskey Olsen	NA	NA	NA	17*	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 quarter, PCI Biotech had NOK 675 thousand in short term liability to The Norwegian Radium Hospital Research Foundation.



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

#### Credit risk

PCI Biotech trades only with recognised, creditworthy third parties, of which most are governmental institutions. Receivable balances are monitored on an ongoing basis with the result that the company's exposure to bad debts is not significant and therefore no offset of bad debts has been recognised at the end of the quarter.

Maturity profile on receivables at the end of the quarter (all figures in '000 NOK):

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	9 811	-	-	9 811
Total receivables	9 811	-	-	9 811

A majority of other 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.

#### 8. Research and Development costs

All figures in '000 NOK

	2016 Q3	2015 Q3	2016 YTD	2015 YTD	2015 FY
Clinical studies	7 921	5 326	16 648	13 432	17 808
Pre-clinical studies	1 004	3 156	7 768	8 189	11 876
CMC and equipment	1 112	1 549	3 422	3 899	4 941
Patents	977	1 018	3 009	3 241	4 220
Other costs	0	0	0	0	0
Total	11 014	11 049	30 847	28 761	38 844

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

At the end of the quarter, the group held NOK 70.0 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:

		Number of shares		
Expiry date	Exercise price in NOK per share	30.09.2016	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 2016, Senior executives	Total holdings 31.12.2015	Allocated	Lapsed	Exercised	Expired	Total holdings 30.09.2016
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	0	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 1 450 shareholders.

	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	-
30.09.2016	14 900 390	3,00	44 701 170



10 largest shareholders per 30 September 2016:

Name	No. of shares	Ownership
FONDSAVANSE AS	2 149 138	14,42
PHOTOCURE ASA	1 483 339	9,96
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 359 853	9,13
MP PENSJON PK	916 531	6,15
VICAMA AS	743 288	4,99
BERGEN KOMMUNALE PENSJONSKASSE	350 000	2,35
GRESSLIEN ODD ROAR	310 000	2,08
STOREBRAND VEKST JPMORGAN EUROPE LTD	307 083	2,06
LGJ INVEST AS	250 487	1,68
MYNA AS	210 000	1,41
Total 10 largest shareholders	<u>8 079 719</u>	<u>54,2 %</u>
Others	6 820 671	45,8 %
Total	14 900 390	100 %

Shares owned, directly or indirectly, by members of the board, senior executives and their personally related parties per 31.12.2015 and per 30.09.2016:

		No. of shares	
Name	Position	31.12.2015	30.09.2016
Hans Peter Bøhn	Chairman	50 000	50 000
Christina Herder	Board member	0	5 000
Kjetil Taskén	Board member	0	0
Hilde H. Steineger	Board member	0	0
Lars Viksmoen	Board member	0	0
Per Walday	CEO	44 019	44 019
Ronny Skuggedal	CFO	15 000	15 000
Anders Høgset	CSO	47 977	47 977
Gaël L'Hévéder	CBDO	10 000	10 000
Kristin Eivindvik	PD	13 235	13 235
Total		180 231	185 231



#### 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 proposed to carry out a fully underwritten rights issue of NOK 70 million at a subscription price of NOK 7 per share, with pre-emptive subscription rights for existing shareholders. The Board of Directors has resolved to call for an extraordinary general meeting to be held on 8 December 2016 to resolve the rights issue.

The rights issue is fully underwritten, subject to customary terms and conditions, by an underwriting syndicate. The underwriters will receive an underwriting fee equal to 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, have both entered into the underwriting agreement and have each separately underwritten NOK 1.0 million of the rights issue.

Completion of the rights issue is subject to shareholders' approval at the EGM to be held on 8 December 2016 and that an EEA-prospectus for the Rights Issue is approved by the Financial Supervisory Authority of Norway and published in accordance with applicable laws.

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: In vitro:	Trade name of the clinical intravenous formulation of fimaporfin US Food and Drug Administration Generic name of the photosensitiser active ingredient TPCS2a 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.
PCI:	Photochemical internalisation
PFS:	Progression Free Survival
R&D:	Research and Development
NOK:	Norwegian kroner
Q3:	Third quarter (1 <sup>st</sup> July – 30 <sup>th</sup> September)
YTD:	Year to date (1 <sup>st</sup> January – 30 <sup>th</sup> September)
FY:	Financial year (1 <sup>st</sup> January – 31 <sup>st</sup> December)

#### **FINANCIAL CALENDAR**

Q4 2016 Report and presentation	14 February	2017
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**

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 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.

## 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

Ullernchausséen 64 N-0379 Oslo Norway