PCI Biotech Holding ASA

Fourth Quarter 2014 Report and

preliminary full year 2014 results

Highlights

- **The modified ENHANCE study with Amphinex in recurrent head & neck cancer was progressed by completion of the two first cohorts and initiation of the third cohort in the intra-tumour light dose-escalation part**

- **The clinical study in inoperable bile duct cancer was initiated and progressed in 2014, with the first dose cohort completed and the second cohort initiated in the Phase I dose escalation part of the Phase I/II study with Amphinex in combination with gemcitabine**

- **Results showing that the PCI technology can significantly improve vaccination treatment in a melanoma model, was published December 2014 in Journal of Controlled Release, a well-renowned international pharmaceutical journal**

- **New supporting pre-clinical data with PCI Biotech's novel CTL-induction technology, for use within therapeutic vaccines, has been filed during 2014 to further strengthen the PCI vaccination patent estate**

- **PCI Biotech was awarded NOK 12.5 million over three years in a BIA grant from The Research Council of Norway for the project "Development of photochemical internalisation to enhance the effect of therapeutic and prophylactic vaccines"**

Post-closing events

- **Completion of the third light dose cohort in the ENHANCE study – patients for the next cohort are currently being screened**

- **Successful completion of the second dose cohort in the study for patients with inoperable bile duct cancer – enrolment for the next dose cohort has been initiated**

- **A fully underwritten rights issue of NOK 70 million was completed 12 February 2015**

- **In January 2015 PCI Biotech announced a successful Investigational New Drug application (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 programmes for Amphinex**

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Operational Review

Progress in development programs

PCI Biotech Holding ASA (PCI Biotech) is an oncology-focused company developing innovative products for cancer treatment. The products are based on PCI Biotech's patented technology, photochemical internalization (PCI). The PCI technology can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells, and can also be used as a platform that may both potentiate the effect of vaccines and enable macromolecules to reach intracellular targets.

Amphinex® in combination with bleomycin, head & neck cancer

PCI Biotech's lead candidate is the photosensitiser Amphinex. A Phase I study of Amphinex in combination with the cytotoxic agent bleomycin in cancer patients, and an extension to this study, have been completed at University College Hospital (UCH) in London. A total of 22 patients were treated in these studies, with the majority being head & neck cancer. A strong response to treatment was seen in all patients and Amphinex seemed to be well tolerated.

Phase II study in head & neck cancer patients – the ENHANCE study

The ENHANCE study is a single arm, multi-centre, phase II study to evaluate the safety and efficacy of Amphinex in combination with the generic cytotoxic agent bleomycin with superficial and interstitial laser light application. The target population is patients with recurrent head & neck squamous cell carcinoma unsuitable for surgery and radiotherapy. The study will include approximately 80 patients with progression free survival at 6 months as the primary endpoint.

Events in Q4 2014 and beyond

The treatment evaluation of the third light dose cohort in the intra tumour light dose optimisation part of the ENHANCE-study, was available in February 2015. No safety concerns were raised and clear tumour responses with clinical benefits were seen at this light dose level. However, re-growth of tumour in the rim of the treatment area in some patients suggests a need to increase the treatment margins to achieve a durable disease response.

A Dose Review Committee (DRC) of clinical experts and company representatives has been established to evaluate the results and provide recommendation for the continuation of the study. The DRC has recommended that an additional cohort of three patients is treated at the same light dose level, but with a modified treatment strategy extending the treatment margins. Patients for the next cohort are currently being screened.

In January 2015 PCI Biotech announced a successful Investigational New Drug application (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 programmes for Amphinex.

Two different light application procedures are used in the study; surface and intra-tumour illumination. Findings from some of the first patients included in the study indicated that treatment with intra-tumour illumination causes stronger local treatment effects than expected and desired and stronger treatment effects than previously observed with surface illumination in the phase I study. The intra-tumour illumination procedure is therefore being optimized in a separate part of the study, running in parallel to the open inclusion of patients for surface illumination. A Dose Review Committee (DRC) of clinical experts and company representatives has been established to evaluate the results and provide recommendation for the continuation of the study. The Amphinex dose has not been modified; the optimisation is performed solely by modifying the light dose. Total number of patients in the dose optimisation part of the study will depend on the number of light dose escalations needed to find an effective and safe light dose.

The trial was initially started in May 2012 and inclusion of patients for intra-tumour treatment was halted Q4 the same year. The study was thereafter redesigned and amended to include an intra-tumour light dose escalation part. The first patient in the light dose escalation part of the study was included in Q3 2013 and the treatment evaluation of light dose cohorts is on-going.

Proof of Concept (PoC) of efficacy and safety for intra-tumour treatment and final confirmation of light dose for the ENHANCE study will be achieved by inclusion of a total of 12 patients at the selected light dose. The company is actively working to speed up patient inclusion. New clinical sites have been opened and an amendment to the protocol during 2014 is expected to speed up patient inclusion. A total of 10 sites in selected European countries are now open. Finalisation of the PoC part of the study will depend on the number of light dose cohorts needed.

A market survey performed by Bridgehead International for PCI Biotech shows a total of 110.000 – 120.000 new incidents of head and neck cancer patients in the five major markets in Europe and the United States per year. Approximately 20% of these patients are expected to be eligible for Amphinex. The promising results from the phase I study together with PCI treatment benefits, the unmet medical need for better local treatment options and the potential market, represent an interesting market opportunity.

About head and cancer

Approximately 650 000 new cases of head & neck cancer are diagnosed worldwide each year, and the initial cure rate is 40-60%. 20-30% of these patients will experience recurrent disease, and for many, the current treatment options are sub-optimal due to locally advanced disease or the fact that further treatment will have strong functional or cosmetic consequences, also affecting the patient's quality of life. Median survival for recurrent head & neck patients is 6 – 9 months.

Surgery, radiation and chemotherapy, alone or in combination, are the most common treatment options. These are also the tools available to treat recurrent disease. Limitations to radiation treatment, resistance to chemotherapy and structural changes after previous surgery will in many cases imply a less effective treatment with a high rate of associated complications. There is a large unmet medical need for this patient group, both to improve survival and the patient's quality of life.

Clinical study in patients with inoperable bile duct cancer (Cholangiocarcinoma)

A Proof of Concept study for the use of PCI in patients with inoperable bile duct cancer was initiated Q1 2014. In this indication Amphinex is being used in combination with the generic cytotoxic agent gemcitabine.

Events in Q4 2014 and beyond

The treatment evaluation of the second dose cohort (3 patients) in the phase I/II study of Amphinex®-induced PCI of gemcitabine followed by gemcitabine/cisplatin treatment in patients with inoperable bile duct cancer (cholangiocarcinoma) was completed in February 2015. No safety concerns were observed at this dose level. As the phase I primary objective is to determine a tolerable dose, no efficacy results are available at this stage.

The Cohort Review Committee of clinical experts and company representatives that evaluates the results and provides recommendation for the continuation of the study has recommended that the study progresses into the next dose in accordance with the study protocol. Enrolment for the next dose cohort has been initiated.

The Proof of Concept study is an open-label, multi-centre phase I/II study in up to 45 patients to assess the safety and efficacy of Amphinex induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine in patients with inoperable bile duct cancer. The study consists of a dose escalation/phase I part to assess the tolerance of local bile duct treatment and a randomized double-arm phase II part. In phase II patients will be randomized to either a control arm (stenting alone followed by gemcitabine/cisplatin chemotherapy) or the PCI arm (stenting followed by Amphinex induced PCI treatment of gemcitabine followed by gemcitabine/cisplatin chemotherapy). The randomisation ratio for this study is 2.5:1 in favor of the PCI arm. The phase I primary objective is to determine a tolerable dose for local bile duct treatment with Amphinex induced PCI of gemcitabine, while the phase II primary objective is to assess efficacy in terms of progression free survival.

The first patient was included in January 2014 at Aintree University Hospital in Liverpool, UK, and the treatment evaluation of light dose cohorts is on-going. A Cohort Review Committee of clinical experts and company representatives has been established to evaluate the results and provide recommendation for the continuation of the study. Bile duct cancer is a rare disease and the company

is working actively to increase the patient recruitment rate. The eligible patient population has recently been expanded to also include metastatic patients and a total of 9 sites in selected European countries are now open. Finalisation of the phase I part of the study will depend on the number of dose escalations needed.

Available market information indicates approximately 11,000 new incidents of patients in the United States and the largest markets in Europe per year and about 20% of these patients are expected to be eligible for PCI treatment. The unmet medical need for better local treatment options and the fact that bile duct cancer is a rare disease that can achieve specific marketing benefits as an orphan indication, along with PCI treatment benefits make bile duct cancer an interesting market opportunity.

About bile duct cancer
Bile duct cancer originates in the bile ducts which drain bile from the liver into the small intestine. It is a rare cancer (an orphan disease) without approved chemotherapies and the development pipeline is weak. Annual incidence rates of 1-2 cases per 100,000 are seen in the Western world, but rates have been rising worldwide over the past several decades. The majority of cases present as inoperable and there is a high unmet need for improved treatment technologies.

PCI for vaccination – an innovative CTL-induction technology

Effective induction of CTLs (Cytotoxic T Lymphocytes) is key to realize the huge potential of therapeutic cancer vaccination, but this has been difficult to achieve with today's vaccination technologies. PCI Biotech's CTL induction technology may provide a solution to this problem, by substantially improving the potential to trigger the immune system to fight both cancers and infectious diseases. Induction of CTLs is essential for the generation of an immunological response that can attack tumour cells. Induction of CTLs is typically mediated through MHC Class I antigen presentation by antigen presenting cells (APCs). PCI-mediated CTL-induction works by effectively re-localising endocytosed antigens from endosomes to the cytosol in APCs, thereby making the antigens accessible for the MHC Class I presentation machinery.

Events in Q4 2014
Results showing that the PCI technology can significantly improve vaccination treatment in a melanoma model, were published December 2014 in Journal of Controlled Release, a well-renowned international pharmaceutical scientific journal.

The article has the title "Photosensitisation facilitates cross-priming of adjuvant-free protein vaccines and stimulation of tumour-suppressing CD8 T cells". In this article the researchers show that the PCI enhanced immune responses translates into a potent anti-tumour effect in animals, both if used as a prophylactic vaccine and if used for therapeutic vaccination in animals with already established tumours. The results of the study further substantiate PCI as a very potent CTL-inducing technology that can be used to enhance the effect of cancer immunotherapies involving therapeutic cancer vaccination.

The company has increased the activity level in the vaccination area and has further documented and optimised the PCI-mediated CTL-induction effect for therapeutic vaccination, i. e. vaccination that aims to treat an already established disease in the patient. Proof-of-principle for this effect has been established in mouse models for enhancement of both *in vivo* and *ex vivo* vaccination. The preclinical proof-of-principle results have been published in renowned scientific journals. Further supportive results from several studies performed this year in cooperation with NTNU in Trondheim, Norway, The Norwegian Radium Hospital, Oslo, Norway and University Hospital Zürich, Switzerland have been used to further strengthen the PCI vaccination patent estate. The company has in support and expansion of this work been awarded NOK 12.5 million in a BIA grant from The Research Council of Norway for the project "Development of photochemical internalization to enhance the effect of therapeutic and prophylactic vaccines". The project goal is to document that the PCI technology can be used to improve the efficacy of vaccines. The main focus of the project will be to verify and further develop the CTL-induction technology for use in therapeutic vaccines against cancer, but the project also includes use of the technology in vaccination against certain types of viral and bacterial infections.

Effective CTL-inducing technologies are considered key to the success of therapeutic vaccination, and vaccine companies are seeking technologies that can improve their vaccination responses. PCI Biotech's novel mode of action may allow the use of PCI as a new vaccination technology for vaccines where existing adjuvant technologies do not work. There are a large number of therapeutic cancer vaccines under development and available market information shows an expected global market of more than 7 billion U.S. dollars in 2019. Within prophylactic vaccines the market is more mature with few companies, but also here PCI may play a central role for companies seeking new solutions. The company has presented new data at several vaccine- and partnering-meetings during 2014 and is currently in discussions with potential partners who have shown interest in PCI for vaccines.

About therapeutic cancer vaccination

The potential of therapeutic cancer vaccination - vaccines that treat cancer by inducing or strengthening an immune response - has long been recognised by the pharmaceutical industry. Over the past few years there has been a renewed focus on such vaccines, and the first vaccine was approved by FDA in 2010. Since then, pharmaceutical companies have announced a large number of development milestones for new therapeutic cancer vaccines, and the market for such vaccines is projected to grow to a value of approximately $8 billion by 2019. This is a promising area, but there are still important unsolved issues and several companies have recently reported failed clinical studies. Vaccination with protein or peptide antigens often fails to generate the strong cytotoxic responses that are needed for successful therapeutic vaccination. An important probable reason for this is insufficient access of antigens to the appropriate machinery inside the antigen presenting cells. Antigens typically enter these cells through endocytosis and PCI may be utilised to deliver these antigens to the immunisation machinery that is responsible for the cytotoxic immune response through the so-called MHC class-I-restricted antigen presentation.

PCI for macromolecules

The PCI technology may enhance the delivery of all molecules taken into the cell by endocytosis. This includes most types of macromolecules (such as proteins, nucleic acids and drugs carried by antibodies or nanoparticles).

Macromolecules are widely acknowledged to have a large potential as therapeutic agents, and numerous clinical trials with gene, protein and oligonucleotide therapy are underway. The therapeutic potential of such compounds is challenged by the obstacles of intracellular delivery, and many studies have been hampered by the lack of technologies for efficient delivery of the therapeutic molecules to the target cells. As part of the increased focus on partnering activities, the company is in discussions with potential partners interested in PCI for delivery of macromolecules.

Financial Review

Income Statement Results 4th Quarter (Q4) 2014

Other income in the quarter was NOK 1.5 million compared with NOK 2.0 million in Q4 2013. The company received Norwegian grants and tax incentive scheme (SkatteFUNN) and these are disclosed as other income.

R&D costs in Q4 2014 were NOK 9.7 million compared with NOK 10.1 million in Q4 2013. G&A costs in Q4 2014 were NOK 2.1 million compared with NOK 1.2 million in Q4 2013. The increase in G&A costs are related to the rights issue process and increased business development activities.

Total operating costs were NOK 11.8 million in Q4 2014 compared with NOK 11.3 million in Q4 2013.

Operating results were NOK -10.3 million in Q4 2014 compared with NOK -9.3 million in Q4 2013.

Income Statement Preliminary Results 2014 (full year)

Other income was NOK 7.3 in 2014 compared with NOK 6.7 million in 2013. The company received Norwegian grants and tax incentive scheme (SkatteFUNN) and these are disclosed as other income.

R&D costs in 2014 were NOK 39.3 million, compared with NOK 32.8 million in 2013. Costs to external partners and hospitals on pre-clinical and clinical trials were higher due to an increased activity level in all three major projects; head & neck cancer, bile duct cancer and vaccines. The cost increase is also partly exchange rate driven.

G&A costs in 2014 were NOK 4.4 million compared with NOK 3.2 million in 2013. The increase in G&A costs are related to the rights issue process and increased business development activities.
Total operating costs were NOK 43.8 million in 2014 compared with NOK 36.0 million in 2013.

Operating results were NOK -36.5 million in 2014 compared with NOK -29.3 million in 2013.

Balance sheet and Cash flow

The company held cash and cash equivalents of NOK 15.8 million at the end year end 2014 compared with NOK 46.6 million at year end 2013. Total equity is NOK 9.1 million at year end 2014 compared with NOK 43.4 million at year end 2013. The change in equity reflects the loss in the period and a net positive equity effect from the share option scheme of NOK 1.6 million in 2014 (NOK 0.9 million in 2013).

Cash flow from operations was NOK -4.0 million in Q4 2014, compared with NOK -6.4 million in Q4 2013. Net cash flow was NOK -3.9 million in Q4 2014, compared with NOK -5.9 million in Q4 2013. The reduced cash flow deficit in Q4 2014 compared with Q4 2013 is due to timing differences of received Norwegian grants.

Cash flow from operations was NOK -31.5 million in 2014, compared with NOK -28.6 million in 2013. Net cash flow was NOK -30.8 million in 2014, compared with net cash flow NOK -26.5 million in 2013.

Language

From June 2014 PCI Biotech has been granted an exemption from Oslo Axess to publish information in English only, and the Company has been granted the same exemption for the future annual reports.

Related party transactions

PCI Biotech is relying on services provided by third parties, included related parties, as a result of its organizational set-up. PCI Biotech considers its business relationship with The Norwegian Radium Hospital Research Foundation as the only material related party transaction in 2014. See Note 6 for full disclosure of related party transactions.

Risks and uncertainty factors for 2014

PCI Biotech is exposed to uncertainties and risk factors, which may influence some or all of the company's activities. There are no significant changes in the risks and uncertainty factors compared to the descriptions in the Annual Report 2013. The most important risks the company is exposed to for 2014 are associated with progress and performance of R&D programs and financial uncertainty. Through the rights issue completed in February 2015 the company is fully financed for the next 12 months following the date of this report.

Post-closing events

A fully underwritten rights issue of NOK 70 million was completed 12 February 2015. The rights issue was oversubscribed. 7,000,000 new shares were issued in the rights issue. Approximately 6.56 million new shares have been allocated to subscribers on the basis of exercised subscription rights. Approximately 0.44 million new shares have been allocated to holders of subscription rights as a result of oversubscription. No allocation has been made to subscribers without subscription rights.

Through the rights issue, PCI Biotech received gross proceeds in the amount of NOK 70 million and the net proceeds are estimated to approximately NOK 64.9 million. The transaction cost includes a guarantee fee of 3.0%. The Company's extraordinary general meeting held on 6 January 2015, resolved to increase the share capital of the company with NOK 21,000,000 through the issue of 7,000,000 new shares as a result of the rights issue. Following the completion of the rights issue the share capital is NOK 44,179,170 divided by 14,726,390 shares, each with a nominal value of NOK 3.00 and represents one voting right per share. The new shares were admitted to trading on the Oslo Axess from 13 February 2015.

The new available funds are expected to give a financial runway of approximately two years, with the current cost base. The Board of Directors has initiated a strategic review to ensure optimal use of proceeds.

Except for the above and events disclosed in Note 11 in this Q4 2014 Report, PCI Biotech is not aware of any post-closing events, which could materially influence this interim financial statement.

Strategy

PCI Biotech's strategy within the various business areas is to prioritize commercialization through agreements with external partners. The company envisages establishing partnerships based on data from the phase II part of the ongoing clinical studies, and potential phase III studies will be performed in cooperation with or by other companies within the field of oncology. The possibilities of entering into partnerships depend on the quality of phase II results. Within vaccines and macromolecules PCI Biotech's strategy is to use preclinical results to enter into various agreements for further development and use of PCI as a platform technology.

Outlook

PCI Biotech will continue to focus on the clinical development of Amphinex in combination with cancer drugs for localised cancer treatment, based on the company's unique PCI technology. The company will also maintain the high activity level in pre-clinical development and licensing of PCI as a versatile and innovative platform.

Main priorities:

- Effectively progress the light dose optimization and proof of concept of intra-tumour head and neck cancer treatment of Amphinex and bleomycin;
- Complete the first part of the proof of concept study of bile duct cancer treatment with Amphinex and gemcitabine;
- Solidify a robust vaccination IP estate and further strengthen the promising preclinical results;
- Partnering activities across all commercially interesting areas for the PCI platform.

The Board of Directors and CEO
PCI Biotech Holding ASA
Lysaker, 23 February 2015

Erling Øverland Chairman	Theresa Comiskey Olsen	Hilde Steineger
Kjetil Taskén	Kjell Stenberg	Per Walday CEO

CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK 1,000)	Note	Q4 2014	Q4 2013	01.01 - 31.12 2014	01.01 - 31.12 2013
Other Income	5	**1 542**	**1 986**	**7 297**	**6 681**
Research and development	8	9 719	10 102	39 341	32 789
General and administrative		2 088	1 207	4 428	3 217
Operating costs		**11 807**	**11 309**	**43 769**	**36 006**
Operating results		**-10 265**	**-9 323**	**-36 472**	**-29 325**
Financial income and costs					
Financial income		143	474	812	1 717
Financial expenses		84	0	180	0
Net financial result		**59**	**474**	**632**	**1 717**
Ordinary profit before taxes		**-10 206**	**-8 849**	**-35 840**	**-27 608**
Tax on ordinary result	9	0	0	0	0
Net profit/loss	4	**-10 206**	**-8 849**	**-35 840**	**-27 608**
Other comprehensive income		0	0	0	0
Comprehensive income		**-10 206**	**-8 849**	**-35 840**	**-27 608**

BALANCE SHEET

(In NOK 1,000)	Note	31.12 2014	31.12 2013
Fixed and intangible assets			
Operating assets		14	18
Total fixed and intangible assets		**14**	**18**
Current assets			
Short term receivables	*7*	4 614	6 123
Cash & cash equivalents	*7*	15 754	46 595
Total current assets		**20 368**	**52 718**
Total assets		**20 382**	**52 736**
Shareholders equity and liabilities			
Shareholders equity			
Paid in capital		99 911	99 911
Other reserves		-90 797	-56 515
Total equity	*10*	**9 114**	**43 396**
Trade debtors		2 586	4 061
Other short term debt		8 682	5 279
Total debt		**11 269**	**9 340**
Total shareholders equity and liabilities		**20 382**	**52 736**

CHANGE IN SHAREHOLDERS EQUITY

(In NOK '000)	Paid in capital	Share premium	Other paid in capital	Retained earnings	Total
Balance at 31 December 2012	**22 999**	**76 524**	**94 305**	**-124 122**	**69 706**
Capital increase	180	208	-	-	388
Share option scheme	-	-	909	-	909
Comprehensive income in the period	-	-	-27 608	-	-27 608
Allocation	-	-	-67 606	67 606	-
Balance at 31 December 2013	**23 179**	**76 732**	**-**	**-56 515**	**43 396**
Share option scheme	-	-	1 558	-	1 558
Comprehensive income in the period	-	-	-	-35 840	-35 840
Balance at 31 December 2014	**23 179**	**76 732**	**1 558**	**-92 355**	**9 114**

CASH FLOW

(In NOK '000)	Q4 2014	Q4 2013	01.01-31.12 2014	01.01-31.12 2013
Ordinary profit before taxes	-10 206	-8 849	-35 840	-27 608
Depreciation, Amortization and Write Off	1	1	4	4
Share options	300	429	1 558	909
Net financials	-59	-474	-632	-1 717
Changes in working capital	6 015	2 487	3 436	-181
Cash flow from operations	-3 949	-6 406	-31 473	-28 593
Net financials	59	474	632	1 717
Taxes paid	-	-	-	-
Net cash flow from operations	-3 891	-5 932	-30 841	-26 876
Cash flow from investments				
Purchase of tangible assets	-	-	-	-
Net cash flow from investments	-	-	-	-
Cash flow from financial activities				
Net proceeds from share issues	-	-	-	388
Net cash flow from financial activities	-	-	-	388
Net change in cash during the period	-3 891	-5 932	-30 841	-26 488
Cash and cash equivalents at the beginning of the period	19 645	52 527	46 595	73 083
Cash and cash equivalents at the end of the period	15 754	46 595	15 754	46 595

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 Islandic 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 at Lysaker, 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 effect both of 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 licensees. PCI Biotech focuses on the development of PCI products for enhanced delivery of marketed cancer drugs, and as a platform that may both potentiate the effect of vaccines and enable macromolecules to reach intracellular targets. PCI Biotech has two active clinical studies with the lead candidate Amphinex: a phase II trial in head & neck cancer with the cytotoxic agent bleomycin and a phase I/II trial in bile duct cancer with the cytotoxic agent gemcitabine. The company has an on-going preclinical program to document the use of PCI to enhance and direct the immune response of vaccines towards a stronger cellular response.

2. Basis of presentation

These Interim Financial Statements should be read in conjunction with the Consolidated Financial Statements for the year ended 31 December 2013 (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 24 March 2014. 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 board of directors approved the interim condensed financial information on 23 February 2015.

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 2013.

The new standards, interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2014 and that could affect the PCI Biotech are discussed in accounting policies, part 3, to the consolidated financial statements for 2013. In the 2013 financial statements, PCI Biotech made evaluations that none of these are expected to have significant effect for PCI Biotech.

4. Earnings per share

Earnings per share:

	Q4 2014	Q4 2013	FY 2014	FY 2013
Result allocated to shareholders (in NOK '000)	(10 206)	(8 849)	(35 840)	(27 608)
Weighted average of outstanding shares (in '000)	7 726	7 726	7 726	7 696
Earnings per share (NOK per share)	-1,32	-1,15	-4,64	-3,59

Diluted earnings per share:

	Q4 2014	Q4 2013	FY 2014	FY 2013
Result allocated to shareholders (in NOK '000)	(10 206)	(8 849)	(35 840)	(27 608)
Weighted average of outstanding shares (in '000)	8 129	8 137	8 179	8 165
Earnings per share (NOK per share)	-1,32	-1,15	-4,64	-3,59

Weighted average of outstanding diluted shares is weighted number of average shares adjusted with share options. Earning 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 and legal services provided by board member Theresa Comiskey Olsen 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	Q4 2014	Q4 2013	FY 2014	FY 2013
The Norwegian Radium Hospital Research Foundation	879	428	2 698	1 582
Theresa Comiskey Olsen	19	17	104	20

At the end of the quarter, PCI Biotech had NOK 601 thousand in short term debt to The Norwegian Radium Hospital Research Foundation and no NOK 8 thousand short term debt to Theresa Comiskey Olsen.

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 on going 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 Q4 2014.

Maturity profile on receivables as per 31 December 2014 (all figures in '000 NOK):

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	4 614	-	-	4 614
Total receivables	**4 614**	**-**	**0**	**4 614**

A majority of other receivables relates to accrued, not received grants 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

	Q4 2014	Q4 2013	FY 2014	FY 2013
Clinical studies	4 506	4 212	19 267	16 724
Pre-clinical studies	2 902	2 144	10 745	6 742
CMC and equipment	1 050	3 241	5 396	7 391
Patents	1 261	504	3 933	1 931
Other costs	0	0	0	0
Total	**9 719**	**10 102**	**39 341**	**32 789**

9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 57.0 million in non-capitalised deferred tax assets.

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 shares	
Expiry date	per share	31.12.2014	31.12.2013
2015 - Q2	6.47	174 000	174 000
2015 - Q3	37.24	90 000	90 000
2016 - Q3	19.02	170 000	170 000
2017 - Q3	37.02	86 500	86 500
2018 - Q3	19.63	85 000	85 000
2018 - Q3	18.64	40 000	40 000
Total		**645 500**	**645 500**

11. Material events subsequent to the end of the reporting period

PCI Biotech has received from Norwegian tax authorities (Skatt Øst) an initial rejection of extension of advance registration for VAT (Value Added Tax) for the future periods 2015-2016. PCI Biotech does not agree with the basis for the initial rejection made by the authorities and has submitted a formal appeal. If the appeal is not in favour of PCI Biotech, it will have an impact on the future cash burn and/or spending.

The rights issue of NOK 70 million (gross amount) was finalised in February 2015.

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