# PCI Biotech Holding ASA

# Second Quarter and First half 2014 Report

## Highlights

- **Successful completion of the second light dose cohort in the modified ENHANCE study – a Phase II study in head & neck cancer patients. The study has been amended to include a light dose escalation run-in phase to optimise the intra-tumour treatment regimen and a Proof of Concept part to confirm safety and efficacy.**

- **Started inclusion of patients in the Phase I/II Proof of Concept study with Amphinex in combination with gemcitabine in patients with inoperable bile duct cancer (cholangiocarcinoma). The treatment evaluation of the first dose cohort is completed and enrolment for the second dose cohort is on-going.**

- **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".**

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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. Patient inclusion started in May 2012.

Two different light application procedures are used in the study; surface and intra-tumour illumination. Findings from some of the 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. 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 first patient in the light dose escalation part of the study was included in Q3 2013 and the treatment evaluation of the second light dose cohort (three patients) was available August 2014. No serious safety concerns were raised and strong clinical effects with clear indications of tumour response were seen at this light dose level. 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 recommended that three further patients are included at the same light dose level, before final selection of the light dose for proof of concept with intra-tumour treatment. Patients for the next group are currently being screened and will be treated with Amphinex as soon as possible. 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 and further sites in selected European countries are being opened. 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, represents an interesting market opportunity.

### 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 is initiated. In this indication Amphinex will be used in combination with the generic cytotoxic agent gemcitabine.

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 the first dose cohort (3 patients) was completed in April 2014. 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 company is actively working to speed up patient inclusion and a process to open further sites in selected European countries is on-going. 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 makes bile duct cancer an interesting market opportunity.

### PCI for vaccination

The company has increased the activity level in the vaccination area and has further documented and optimised the PCI effect for therapeutic vaccination, i. e. vaccination that aims to treat an already established disease in the patient. The 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 will be submitted 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 to 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 technology for use in therapeutic vaccines against cancer, but the project also includes use of the PCI technology by vaccination against certain types of viral and bacterial infections.

The two most important components in the immunological reaction to vaccines are the antibody and the cellular cytotoxic responses. For many vaccines, and especially for therapeutic vaccines, a strong cellular response is of great importance. A possible benefit when applying PCI within vaccination is that PCI can direct the immunological response towards a stronger cellular response. This could be important for the effect of therapeutic vaccines for example within cancer. 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

Effective adjuvant technologies are considered key to the success of therapeutic vaccination, and vaccine companies are seeking improved adjuvant technologies for their vaccine technologies. PCI Biotech's novel mode of action may allow the use of PCI as a new adjuvant system 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 and with few companies, but also here PCI may play a central role for companies seeking new solutions. The company is in discussion with potential partners who have shown interest in PCI for vaccines.

### PCI for macromolecules

PCI has the potential to increase the effect of different types of macromolecules, e.g. siRNA and Antibody Drug Conjugates (ADC). As part of the increased focus on partnering activities, the company is in discussion with potential partners that show interest in PCI for delivery of macromolecules.

## Financial Review

### Income Statement Results 2nd Quarter (Q2) 2014

The company received Norwegian grants and these are disclosed as other income. Other income in the quarter was NOK 1.9 million compared with NOK 1.7 million in Q2 2013.

R&D costs in Q2 2014 were NOK 9.6 million compared with NOK 6.6 million in Q2 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.

G&A costs in Q2 2014 were NOK 0.8 million compared with NOK 1.0 million in Q2 2013.

Total operating costs were NOK 10.3 million in Q2 2014 compared with NOK 7.6 million in Q2 2013.

Operating results were NOK -8.4 million in Q2 2014 compared with NOK -5.9 million in Q2 2013.

Cash flow from operations was NOK -9.5 million in Q2 2014, compared with NOK -7.2 million in Q2 2013. Net cash flow was NOK -9.2 million in Q2 2014, compared with NOK -6.7 million in Q2 2013.

## Income Statement Results first half (1H) 2014

The company received Norwegian grants and these are disclosed as other income. Other income was NOK 3.9 million in 1H 2014 compared with NOK 3.1 million in 1H 2013.

R&D costs in 1H 2014 were NOK 19.5 million, compared with NOK 14.5 million in 1H 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.

G&A costs in 1H 2014 were NOK 2.2 million compared with NOK 1.7 million in 1H 2013.

Total operating costs were NOK 21.7 million in 1H 2014 compared with NOK 16.2 million in 1H 2013.

Operating results were NOK -17.8 million in 1H 2014 compared with NOK -13.1 million in 1H 2013.

## Balance sheet and Cash flow

The company held cash and cash equivalents of NOK 29.2 million at the end of 1H 2014 compared with NOK 59.6 million at the end of 1H 2013 and NOK 46.6 million at year-end 2013. Total equity is NOK 26.9 million at the end of 1H 2014 compared with NOK 58.4 million at the end of 1H 2013. The change in equity reflects the loss in the period, a capital increase of NOK 0.4 million from one employee exercising share options in Q3 2013 and a net positive equity effect from the share option scheme of NOK 0.9 million.

Cash flow from operations and net cash flow was NOK -17.4 million in 1H 2014, compared with cash flow from operations NOK -12.6 million and net cash flow NOK 13.5 million in 1H 2013.

## Strategy

PCI Biotech's strategy within the various business areas is to prioritize commercialization through agreements with external partners. The company's goal is to establish 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.

## Language

From June 2014 PCI Biotech has been granted an exemption from Oslo Børs to publish information in English only, and the Company will seek to be 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 for first half 2014. See Note 6 for full disclosure of related party transactions.

## Post-closing events

25 August 2014 the Board of Directors extended the expiry date for 174.000 share options allocated in 2009. The original expiry date is one week after release of the Q2_1H 2014 Report and the extended expiry date is one week after release of the Q1 2015 Report. Out of the 174.000 share options, 60.000 share options are allocated to the CEO, Per Walday. PCI Biotech is not aware of any other post-closing events, other than events disclosed in this report, which could materially influence this interim financial statement.

## 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.

At current cost levels the company is financed into the second quarter 2015. The board of directors have therefore decided to initiate work on evaluating the company's capital need and financing alternatives. DNB Markets and Fondsfinans have been retained as financial advisors in connection with this evaluation.

## 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 maintain the 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;
- Ensure that the company has sufficient financial flexibility in the short and long term to achieve strategic and operational objectives

## Responsibility Statement

We confirm that, to the best of our knowledge, the unaudited condensed set of financial statements for the first half of 2014 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Company's and Group's consolidated assets, liabilities, financial position and results of operations, and that the interim management report includes a fair view of the information required under the Norwegian Securities Trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 25 August 2014

| | | |
|---|---|---|
| Erling Øverland<br>Chairman | Theresa Comiskey Olsen | Hilde Steineger |
| Kjetil Taskén | Kjell Stenberg | Per Walday<br>CEO |

# CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

## PROFIT AND LOSS

| *(In NOK 1,000)* | Note | Q2 2014 | Q2 2013 | 01.01 - 30.06 2014 | 01.01 - 30.06 2013 | 01.01 - 31.12 2013 |
|---|---|---|---|---|---|---|
| **Other Income** | 5 | **1 938** | **1 688** | **3 905** | **3 078** | **6 681** |
| Research and development | 8 | 9 550 | 6 551 | 19 509 | 14 523 | 32 789 |
| General and administrative | | 771 | 1 027 | 2 187 | 1 689 | 3 217 |
| **Operating costs** | | **10 321** | **7 578** | **21 696** | **16 212** | **36 006** |
| **Operating results** | | **-8 383** | **-5 890** | **-17 791** | **-13 134** | **-29 325** |
| **Financial income and costs** | | | | | | |
| Financial income | | 253 | 478 | 517 | 898 | 1 717 |
| Financial expenses | | 0 | 0 | 103 | 0 | 0 |
| **Net financial result** | | **253** | **478** | **413** | **898** | **1 717** |
| **Ordinary profit before taxes** | | **-8 131** | **-5 412** | **-17 378** | **-12 236** | **-27 608** |
| Tax on ordinary result | 9 | 0 | 0 | 0 | 0 | 0 |
| **Net profit/loss** | 4 | **-8 131** | **-5 412** | **-17 378** | **-12 236** | **-27 608** |
| Other comprehensive income | | 0 | 0 | 0 | 0 | 0 |
| **Comprehensive income** | | **-8 131** | **-5 412** | **-17 378** | **-12 236** | **-27 608** |

## BALANCE SHEET

| *(In NOK 1,000)* | Note | 30.06 2014 | 30.06 2013 | 31.12 2013 |
|---|---|---|---|---|
| **Fixed and intangible assets** | | | | |
| Operating assets | | 16 | 21 | 18 |
| **Total fixed and intangible assets** | | **16** | **21** | **18** |
| **Current assets** | | | | |
| Short term receivables | *7* | 5 830 | 4 813 | 6 123 |
| Cash & cash equivalents | *7* | 29 188 | 59 608 | 46 595 |
| **Total current assets** | | **35 018** | **64 421** | **52 718** |
| **Total assets** | | **35 034** | **64 442** | **52 736** |
| **Shareholders equity and liabilities** | | | | |
| **Shareholders equity** | | | | |
| Paid in capital | | 99 911 | 190 903 | 99 911 |
| Other reserves | | -72 972 | -132 458 | -56 515 |
| **Total equity** | *10* | **26 939** | **58 445** | **43 396** |
| Trade debtors | | 2 052 | 1 590 | 4 061 |
| Other short term debt | | 6 044 | 4 407 | 5 279 |
| **Total debt** | | **8 096** | **5 997** | **9 340** |
| **Total shareholders equity and liabilities** | | **35 034** | **64 442** | **52 736** |

## CHANGE IN SHAREHOLDERS EQUITY

| *(In NOK '000)* | Note | Paid in capital | Share premium | Other paid in capital | Retained earnings | Total |
|---|---|---|---|---|---|---|
| Balance at 31 December 2012 | | **22 999** | **76 524** | **94 306** | **-124 122** | **69 706** |
| Share option scheme | 10 | - | - | 975 | - | 975 |
| Comprehensive income in the period | | - | - | - | -12 236 | -12 236 |
| Allocation | | - | - | - | - | - |
| Balance at 30 June 2013 | | **22 999** | **76 524** | **95 281** | **-136 358** | **58 445** |
| Capital increase | | 180 | 208 | - | - | 388 |
| Share option scheme | 10 | - | - | -66 | - | -66 |
| Comprehensive income in the period | | - | - | -15 372 | - | -15 372 |
| Allocation | | - | - | -79 843 | 79 843 | - |
| Balance at 31 December 2013 | | **23 179** | **76 732** | **-** | **-56 515** | **43 396** |
| Share option scheme | 10 | - | - | 921 | - | 921 |
| Comprehensive income in the period | | - | - | - | -17 378 | -17 378 |
| Allocation | | - | - | -921 | 921 | - |
| Balance at 30 June 2014 | | **23 179** | **76 732** | **-** | **-72 972** | **26 939** |

## CASH FLOW

| *(In NOK '000)* | Q2 2014 | Q2 2013 | 01.01-30.06 2014 | 01.01-30.06 2013 | 01.01-31.12 2013 |
|---|---|---|---|---|---|
| Ordinary profit before taxes | -8 131 | -5 412 | -17 378 | -12 236 | -27 608 |
| Depreciation, Amortization and Write Off | 1 | 1 | 2 | 1 | 4 |
| Share options | 353 | 535 | 921 | 975 | 909 |
| Net financials | -253 | -478 | -413 | 898 | -1 717 |
| Changes in working capital | -1 469 | -1 859 | -952 | -2 215 | -181 |
| Cash flow from operations | -9 498 | -7 213 | -17 820 | -12 577 | -28 593 |
| | | | | | |
| Net financials | 253 | 478 | 413 | -898 | 1 717 |
| Taxes paid | - | - | - | - | - |
| Net cash flow from operations | -9 245 | -6 735 | -17 407 | -13 475 | -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** | -9 245 | -6 735 | -17 407 | -13 475 | -26 488 |
| Cash and cash equivalents at the beginning of the period | 38 433 | 66 343 | 46 595 | 73 083 | 73 083 |
| **Cash and cash equivalents at the end of the period** | 29 188 | 59 608 | 29 188 | 59 608 | 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 25 August 2014.

## 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:

| | Q2 2014 | Q2 2013 | 1H 2014 | 1H 2013 | FY 2013 |
|---|---|---|---|---|---|
| Result allocated to shareholders (in NOK '000) | (8 131) | (5 412) | (17 378) | (12 236) | (27 608) |
| Weighted average of outstanding shares (in '000) | 7 726 | 7 666 | 7 726 | 7 666 | 7 696 |
| Earnings per share (NOK per share) | -1,05 | -0,71 | -2,25 | -1,60 | -3,59 |

Diluted earnings per share:

| | Q2 2014 | Q2 2013 | 1H 2014 | 1H 2013 | FY 2013 |
|---|---|---|---|---|---|
| Result allocated to shareholders (in NOK '000) | (8 131) | (5 412) | (17 378) | (12 236) | (27 608) |
| Weighted average of outstanding shares (in '000) | 8 195 | 8 135 | 8 195 | 8 113 | 7 696 |
| Earnings per share (NOK per share) | -1,05 | -0,71 | -2,25 | -1,60 | -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 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 | Q2 2014 | Q2 2013 | 1H 2014 | 1H 2013 | FY 2013 |
|---|---|---|---|---|---|
| The Norwegian Radium Hospital Research Foundation | 532 | 478 | 1 118 | 923 | 1 600 |
| Theresa Comiskey Olsen | 55 | 0 | 85 | 3 | 88 |

At the end of the quarter, PCI Biotech had NOK 0.4 million in short term debt to The Norwegian Radium Hospital Research Foundation and NOK 55 thousand in 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 first half 2014.

Maturity profile on receivables as per 30 June 2014 (all figures in '000 NOK):

| | Not due | Less than 3 months | 3 to 12 months | Total |
|---|---|---|---|---|
| Trade receivables | - | - | - | - |
| Other receivables | 5 830 | - | - | 5 830 |
| Total receivables | **5 830** | **-** | **0** | **5 830** |

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

**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 currency risk.

**Interest risk**
PCI Biotech has no interest bearing debt.

## 8. Research and Development costs

All figures in '000 NOK

| | Q2 2014 | Q2 2013 | 1H 2014 | 1H 2013 | FY 2013 |
|---|---|---|---|---|---|
| Clinical studies | 6 782 | 3 900 | 10 506 | 8 336 | 16 724 |
| Pre-clinical studies | 1 752 | 1 661 | 4 633 | 3 187 | 6 742 |
| CMC and equipment | 933 | 556 | 2 983 | 2 279 | 7 391 |
| Patents | 82 | 434 | 1 387 | 721 | 1 931 |
| Other costs | 0 | 0 | 0 | 0 | 0 |
| **Total** | **9 550** | **6 551** | **19 509** | **14 523** | **32 789** |

## 9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 51.6 million in non-capitalised deferred tax assets.

## 10. Share options

As a post-closing event on 25 August 2014 the Board of Directors extended the expiry date for 174.000 share options allocated in 2009. The original expiry date is one week after release of the Q2_1H 2014 Report and the extended expiry date is one week after release of the Q1 2015 Report. Out of the 174.000 share options, 60.000 share options are allocated to the CEO, Per Walday. 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 | 30.06.2014 | 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

25 August 2014 the Board of Directors extended the expiry date for 174.000 share options allocated in 2009. The original expiry date is one week after release of the Q2_1H 2014 Report and the extended expiry date is one week after release of the Q1 2015 Report. Out of the 174.000 share options, 60.000 share options are allocated to the CEO, Per Walday. PCI Biotech is not aware of any other post-closing events, other than events disclosed in this report, which could materially influence this interim financial statement.