

# PCI Biotech Holding ASA

# **First Quarter 2015 Report**

# Highlights

- The modified ENHANCE study with Amphinex in recurrent head & neck cancer was progressed by completion of the third intra-tumour light dose-escalation cohort. The protocol has now been amended to allow a modified treatment strategy with increased treatment margins and patients for the next dose cohort are currently being screened.
- Successful completion of the second dose cohort in the Phase I dose escalation part of the Phase I/II study with Amphinex in combination with gemcitabine for patients with inoperable bile duct cancer. Enrolment for the third dose cohort has been initiated.
- In January 2015 PCI Biotech announced a successful Investigational New Drug (IND) application review for Amphinex. The IND is a clearance by the United States Food and Drug Administration (FDA) to include patients in the USA in PCI Biotech's phase II clinical programme for Amphinex.
- A fully underwritten rights issue of NOK 70 million was completed 12 February 2015.

# Post closing events

 Initiation of a pre-clinical research collaboration with RXi Pharmaceuticals (NASDAQ: RXII), an American biotechnology company focused on discovering and developing innovative therapeutics, that address high-unmet medical needs primarily in the area of dermatology and ophthalmology. The partnership is governed by a pre-clinical research collaboration agreement.

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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<sup>®</sup> 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 Q1 2015

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.

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

In January 2015 PCI Biotech announced a successful Investigational New Drug (IND) application 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.

The company is actively working to further accelerate patient inclusion. A total number of 10 sites in selected European countries are now open.

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.

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. Finalisation of the PoC part of the study will depend on the number of light dose cohorts needed.

#### 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.



# Amphinex in combination with gemcitabine for 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 in 2014. In this indication Amphinex will be used in combination with the generic cytotoxic agent gemcitabine.

#### Events in Q1 2015

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. The primary objective of phase I, is to determine a maximum tolerable dose.

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 cohort (cohort number three) in accordance with the study protocol. Enrolment for the next dose cohort has been initiated.

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 nine sites in selected European countries are now open.

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.

A Cohort Review Committee of clinical experts and company representatives has been established to evaluate and provide recommendation for the continuation of the phase I part of study between cohorts. 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.

Surgery is the only current curative option for these patients, yet the majority of the tumours are inoperable. Inoperable patients are treated with stenting to keep the bile duct open and with chemotherapy. Combination of the chemotherapeutics gemcitabine and cisplatin has shown promising results and has become standard treatment in some countries, but there is still a need for better treatments to increase overall survival and quality of life. Bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and new drug classes or alternative methods are needed. The most studied and used drug is gemcitabine, which is one of the identified drugs that are



significantly enhanced by PCI in preclinical studies. Light access is easy through the endoscopic methods that are routinely used in the treatment of this disease.

#### 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 Q1 2015

The company has presented new data at several vaccine- and partnering-meetings during Q1 2015.

In March 2015 PCI Biotech announced that it has received a positive international search report and written opinion regarding a patent application, on the use of PCI Biotech's proprietary technology photochemical internalization (PCI) in vaccination and immunotherapy. The patent application covers the use of the PCI technology in combination with a very important group of immune enhancing substances and may give PCI Biotech at least 20 years broad protection for the use of the PCI technology with many of the therapeutic cancer vaccines that are under development.

The company has in support and expansion of the work of PCI for vaccination 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" for the period 2014-2017. 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.

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.

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 for the emerging immunotherapy market. 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.

#### 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

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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. One of the most important reasons for this is probably 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.

#### Events in Q1 2015 and beyond

The first agreement showing potential commercial future opportunities for PCI Biotech was signed within the field of macromolecules in April 2015. The agreement is a pre-clinical research collaboration with RXi Pharmaceuticals (NASDAQ: RXII), an American biotechnology company focused on discovering and developing innovative therapeutics, that address high-unmet medical needs primarily in the area of dermatology and ophthalmology. The partnership is governed by a pre-clinical research collaboration agreement.

Initially, the purpose of the pre-clinical research collaboration is to utilize the companies' complementary scientific platforms to explore potential synergies.

In brief the pre-clinical research collaboration will evaluate technology compatibility based on in vitro and in vivo studies. The costs related to the research collaboration will be covered by each company separately. The companies will evaluate results achieved from this research collaboration and then explore the potential for a closer collaboration.

Both companies will retain exclusive ownership rights to existing registered intellectual property. However, any inventions arising from the collaboration will be jointly owned by the companies.



# **Financial Review**

### Income Statement Results 1<sup>st</sup> Quarter (Q1) 2015

Other income in the quarter was NOK 2.6 million compared with NOK 2.0 million in Q1 2014. The company received Norwegian grants and tax incentive scheme (SkatteFUNN) and these are disclosed as other income. The increase is due to a generally increased level both within of grants and the tax incentive scheme.

R&D costs in Q1 2015 were NOK 9.4 million compared with NOK 10.0 million in Q1 2014. The reduction compared to Q1 2014 is due to lower activity within CMC and equipment. G&A costs in Q1 2015 were NOK 0.9 million compared with NOK 1.4 million in Q1 2014.

Total operating costs were NOK 10.3 million in Q1 2015 compared with NOK 11.4 million in Q1 2014.

Operating results were NOK -7.7 million in Q1 2015 compared with NOK -9.4 million in Q1 2014.

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

Short term receivables have increased at the end of Q1 2015 compared to Q1 and year-end 2014, due to timing differences and a generally increased level of grants and SkatteFUNN in 2015. Other short term debt has increased at the end of Q1 2015 compared to Q1 2014, due to increased R&D activities during 2014.

The company held cash and cash equivalents of NOK 71.8 million at the end of Q1 2015 compared with NOK 38.4 million at the end of Q1 2014. Total equity was NOK 66.8 million at the end of Q1 2015 compared with NOK 34.7 million at the end of Q1 2014. Both the increase in cash and equity are due to the capital increase finalised in Q1 2015. In addition the change in equity reflects the loss in the period and a net positive equity effect from the share option scheme of NOK 0.7 million in Q1 2015 (NOK 0.6 million in Q1 2014).

Cash flow from operations was NOK -8.6 million in Q1 2015, compared with NOK -8.3 million in Q1 2014. Net proceeds from the capital increase in Q1 2015 were NOK 64.6 million, leading to a positive net cash flow of NOK 56.1 million in Q1 2015. Net cash flow was NOK -8.2 million in Q1 2014.

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 were NOK 64.6 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.

The Chairman Erling Øverland, one of the Directors Theresa Comiskey Olsen and her related parties and the CEO Per Walday participated in the rights issue with their pro-rata share. The Chairman, Erling Øverland, also contributed to the underwriting syndicate and underwritten NOK 378 062 of the rights issue. The Chairman made all transactions through the company Trifolium AS, which is fully owned by Erling Øverland and his wife.



### **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 2015. See Note 6 for full disclosure of related party transactions.

In Q1 2015 there has been related party transactions regarding the capital increase finalised during the quarter and subsequent events. These related party transactions are disclosed in this interim report under the cash flow review and post-closing events.

### **Risks and uncertainty factors for 2015**

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 2014. The most important risks the company is exposed to for 2015 are associated with progress and performance of R&D programs.

#### Post-closing events

The share capital increase of 174 000 new shares resolved by the Board of Directors following the employee share option exercise on 27 April 2015, was completed 28 April 2015 and the new shares were tradeable on the Oslo Stock Exchange (Axess) from that day. The capital increase will result in net proceeds of approximately NOK 0.8 million.

PCI Biotech's new 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.

In relation to the above mentioned capital increase, the primary insider and CEO, Per Walday, exercised 60 000 options, corresponding to 60 000 shares at a strike price of NOK 4.78. Thereafter he transferred 60 000 rights to receive shares resulting from the exercise of options to a third party. Following the transfer of rights he entered into an agreement to use the whole compensation, net of tax, from the transfer of rights to purchase shares and he purchased a total number of 17 647 shares at a price of NOK 11.40 per share. After this the primary insider, Per Walday, holds a portfolio of 40 519 shares and 126 000 unexercised options, corresponding to 80 000 unexercised options at a strike price of NOK 14.07, 16 000 unexercised options at a strike price of NOK 27.38 and 30 000 unexercised options at a strike price of NOK 27.54.

Other employees exercised 114 000 options and transferred a total of 90 000 rights to a third party and have in total purchased 26 470 shares at a price of NOK 11.40 per share for the net compensation after tax.

As part of the employee share option program, the Board of Directors of PCI Biotech Holding ASA has awarded a total of 93 500 options to key employees on 20 April 2015. Each option gives the right to subscribe for or acquire one share per option (after PCI Biotech Holding ASA's choice), at a strike price of NOK 12.53, equal to the volume weighted average price (VWAP) for the last 5 days of trade prior to the grant date. The options can be exercised with 1/3 of the options after one year, further 1/3 after two years and the last third after three years. The options are lapsing in Q3 2020.

Out of these options, 20 000 options were allotted to primary insider and CFO, Ronny Skuggedal. In addition, Ronny Skuggedal, has purchased 10 000 shares at a price of NOK 11.40 per share. After this, Ronny Skuggedal, holds a portfolio of 10 000 shares and 60 000 unexercised options in the company, corresponding to 40 000 unexercised options at a strike price of NOK 13.78 and 20 000 unexercised options at a strike price of NOK 12.53.

PCI Biotech has previously reported an initial rejection, from the Norwegian tax authorities (Skatt Øst), of extension of advance registration for VAT (Value Added Tax) for the future periods 2015-2016. PCI Biotech's formal appeal is settled in favour of PCI Biotech and the company is now advance registered for VAT throughout 2016.



Except for the above and events disclosed in Note 11 in this Q1 2015 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. Within vaccines and macromolecules PCI Biotech's strategy is to use the currently available 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.

The main priorities with available funds are to:

- 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, 11 May 2015

Erling Øverland Chairman Theresa Comiskey Olsen

Hilde H. Steineger

Kjetil Taskén

Kjell Stenberg

Per Walday CEO



# CONDENSED INTERIM CONSOLIDATED FINANCIAL INFORMATION

# PROFIT AND LOSS

(In NOK 1,000) Note	Q1 2015	Q1 2014	01.01 - 31.12 2014
Other Income 5	2 614	1 967	7 297
Research and development8General and administrativeOperating costs	9 442 882 <b>10 324</b>	9 959 1 417 <b>11 376</b>	39 341 4 428 <b>43 769</b>
Operating results	-7 710	-9 409	-36 472
Financial income and costs Financial income	55	283	812
Net financial result	<b>59</b>	-122 161	<b>632</b>
Ordinary profit before taxes	-7 655	-9 248	-35 840
Tax on ordinary result9Net profit/loss4	0 -7 655	0 <b>-9 248</b>	0 <b>-35 840</b>
Other comprehensive income Comprehensive income	0 <b>-7 655</b>	0 <b>-9 248</b>	0 <b>-35 840</b>

# BALANCE SHEET

(In NOK 1,000) Not	e	31.03	31.03	31.12
		2015	2014	2014
Fixed and intangible assets				
Operating assets		13	17	14
Total fixed and intangible assets		13	17	14
Current assets				
Short term receivables	7	6 154	4 586	4 614
Cash & cash equivalents	7	71 835	38 433	15 754
Total current assets		77 989	43 020	20 368
Total assets		78 002	43 037	20 382
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		169 911	99 911	99 911
Other reserves		-103 086	-65 195	-90 797
Total equity 7	0	66 825	34 716	9 114
Trade debtors		1 779	1 648	2 586
Other short term debt		9 398	6 673	8 682
Total debt		11 184	8 321	11 269
Total shareholders equity and liabilities		78 002	43 037	20 382



# CHANGE IN SHAREHOLDERS EQUITY

(In NOK '000)	Paid in capital	Share premium	Other paid in capital	Retained earnings	Total
Balance at 31 December 2013	23 179	76 732	-	-56 515	43 396
Share option scheme	-	-	568	-	568
Comprehensive income in the period	-	-	-	-9 248	-9 248
Balance at 31 March 2014	23 179	76 732	568	-65 762	34 716
Share option scheme	-	-	990	-	990
Comprehensive income in the period	-	-	-	-26 592	-26 592
Allocation	-	-	-1 558	1 558	-
Balance at 31 December 2014	23 179	76 732	0	-90 796	9 114
Capital increase	21 000	43 646	-	-	64 646
Share option scheme	-	-	720	-	720
Comprehensive income in the period	-	-	-	-7 655	-7 655
Balance at 31 March 2015	44 179	120 378	720	-98 451	66 825

# CASH FLOW

(In NOK '000)	Q1 2015	Q1 2014	01.01-31.12 2014
Ordinary profit before taxes	-7 655	-9 248	-35 840
Depreciation, Amortization and Write Off	1	1	4
Share options	720	568	1 558
Net financials	-55	-161	-632
Changes in working capital	-1 631	517	3 436
Cash flow from operations	-8 620	-8 323	-31 473
Net financials	55	161	632
Taxes paid	-	-	-
Net cash flow from operations	-8 565	-8 162	-30 841
Cash flow from investments			
Purchase of tangible assets	-	-	-
Net cash flow from investments	-	-	-
Cash flow from financial activities			
Net proceeds from share issues	64 646	-	-
Net cash flow from financial activities	64 646	-	-
Net change in cash during the period	56 081	-8 162	-30 841
Cash and cash equivalents at the beginning of the period	15 754	46 595	46 595
Cash and cash equivalents at the end of the period	71 835	38 433	15 754



# 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 2014 (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 23 March 2015. 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 11 May 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 2014.

The new standards, interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2015 and that could affect the PCI Biotech are discussed in accounting policies, part 4, to the consolidated financial statements for 2014. In the 2014 financial statements, PCI Biotech made evaluations that *IFRS 2 Share-based Payment* and *IFRS 8 Operating Segments* are expected to have an impact for PCI Biotech.



### 4. Earnings per share

Earnings per share:			
	Q1 2015	Q1 2014	FY 2014
Result allocated to shareholders (in NOK '000)	(7 655)	(9 248)	(35 840
Weighted average of outstanding shares (in '000)	11 226	7 726	7 726
Earnings per share (NOK per share)	-0,68	-1,20	-4,64
Diluted earnings per share:			
	Q1 2015	Q1 2014	FY 2014
Result allocated to shareholders (in NOK '000)	(7.655)	(9 248)	(35 840

 Result allocated to shareholders (in NOK '000)
 (7 655)
 (9 248)
 (35 840)

 Weighted average of outstanding shares (in '000)
 11 400
 8 195
 8 179

 Earnings per share (NOK per share)
 -0,68
 -1,20
 -4,64

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	Q1 2015	Q1 2014	FY 2014
The Norwegian Radium Hospital Research Foundation	868	586	2 698
Theresa Comiskey Olsen	16	30	104

At the end of the quarter, PCI Biotech had NOK 696 thousand in short term debt to The Norwegian Radium Hospital Research Foundation and no 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 Q1 2015.



Maturity profile on receivables as per 31 March 2015 (all figures in '000 NOK):

		Less than 3	3 to 12	
	Not due	months	months	Total
Trade receivables	-	-	-	-
Other receivables	6 154	-	-	6 154
Total receivables	6 154	-	0	6 154

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

	Q1 2015	Q1 2014	FY 2014
Clinical studies	4 103	3 724	19 267
Pre-clinical studies	2 714	2 880	10 745
CMC and equipment	1 274	2 050	5 396
Patents	1 350	1 305	3 933
Other costs	0	0	0
Total	9 442	9 959	39 341

## 9. Deferred tax and deferred tax assets

At the end of the quarter, the group held NOK 60.3 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	31.03.2015	31.12.2014
2015 - Q2	4.78	174 000	174 000
2015 - Q3	27.54	90 000	90 000
2016 - Q3	14.07	170 000	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
Total		645 500	645 500

The exercise prices have been adjusted in Q1 2015 according to the employee share option agreements, due to the capital increase resolved in the quarter.

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

PCI Biotech has previously reported an initial rejection, from the Norwegian tax authorities (Skatt Øst), of extension of advance registration for VAT (Value Added Tax) for the future periods 2015-2016. PCI Biotech's formal appeal is now settled in favour of PCI Biotech and the company is advance registered for VAT throughout 2016.

A rights issue of 174 000 new shares, following the exercise of employee share options was finalised in April 2015. The primary insider and CEO, Per Walday, exercised 60 000 options, corresponding to 60 000 shares at a strike price of NOK 4.78. Thereafter he transferred 60 000 rights to receive shares resulting from the exercise of options to a third party. Following the transfer of rights he entered into an agreement to use the whole compensation, net of tax, from the transfer of rights to purchase shares and a total number of 17 647 shares at a price of NOK 11.40 per share was purchased.

As part of the employee share option program, the Board of Directors of PCI Biotech Holding ASA has awarded a total of 93 500 options to key employees on 20 April 2015, at a strike price of NOK 12.53. Out of these options, 20 000 options were allotted to primary insider and CFO, Ronny Skuggedal. In addition Ronny Skuggedal has purchased a total number of 10 000 shares with a share price of NOK 11.40 per share.

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

#### 12. 10 largest shareholders at the end of the reporting period

10 largest shareholders per 31 March 2015	No. of shares	Ownership in %
FONDSAVANSE AS	2 049 138	13,9
PHOTOCURE ASA	1 483 339	10,1
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 359 853	9,2
STOREBRAND VEKST JPMORGAN EUROPE LTD	1 201 592	8,2
MP PENSJON PK	899 408	6,1
VICAMA AS	743 288	5,1
KLP AKSJE NORGE VPF	670 095	4,6
KOMMUNAL LANDSPENSJON	628 858	4,3
BERGEN KOMMUNALE PENSJONSKASSE	350 000	2,4
HOLBERG NORGE VERDIPAPIRFONDET	283 696	1,9
Total 10 largest shareholders	<u>9 669 267</u>	<u>65,7</u>
Others	5 057 123	34,3
Total	14 726 390	100,0