

ANNUAL REPORT 2015
PCI Biotech Holding ASA

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# INTRODUCTION

# ABOUT PCI BIOTECH

PCI Biotech is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange (Axess). The company is developing therapeutic products based on its proprietary photochemical internalization (PCI) technology. Originating from world leading research at the Norwegian Radium Hospital, the PCI technology works by inducing triggered endosomal release and may be used to unlock the true potential of a wide array of therapeutic modalities, such as small molecules, vaccines and nucleic acids.

PCI Biotech's lead candidate is the photosensitiser fimaporfin (Amphinex). A Phase I study of fimaporfin in cancer patients has been completed at University College Hospital in London. Promising early signs of tumour response were seen in all 22 patients and the treatment seemed to be well tolerated, providing the first clinical proof-of-principle of the fimaporfin technology.

PCI Biotech have an extensive collaboration with Norwegian and international hospitals and companies, among others The Norwegian Radium Hospital in Oslo, University Hospital Zürich, Netherlands Cancer Institute Amsterdam and University College London Hospital.

# **OUR TECHNOLOGY**

Both chemotherapies and several novel classes of drugs need free access to the inside of their human target cells, e.g. tumour cells or immune cells, in order to be effective. Unfortunately, many drug substances are by nature encapsulated as they enter the target cell. Once inside the cell, most of the active compound may hence be trapped and therefore unable to attack the tumour or exert other therapeutic effects. Pharmaceutical companies around the world are actively searching for technologies that provide adequate release inside the target cells, in order to exploit the full therapeutic and commercial potential of their products.

PCI Biotech's patented investigational drug fimaporfin is able to unlock the intracellular capsules where the active compounds are trapped. Hence, fimaporfin has the ability to unlock the true potential of new promising classes of cancer therapy, such as immunotherapeutics and RNA therapeutics, as well as established chemotherapies.

Fimaporfin is a light sensitive compound that attach to the capsules inside target cells, where the drug is trapped. When a controlled light source is applied, fimaporfin unlocks the capsules and releases the therapeutic agent.

# LEVERAGING PCI IN THREE DISTINCT AREAS

Recent advancements in cancer therapy are expected to significantly improve the prognosis for millions of patients, not least owing to the development of new classes of drugs, such as immunotherapeutics. The potential of fimaporfin to improve the efficacy of anti-cancer agents has been convincingly shown in well-established preclinical models as well as in clinical trials. Based on these positive findings, PCI Biotech is now developing three parallel programmes:

#### ABOUT INOPERABLE BILE DUCT CANCER AND PCI TREATMENT

PCI Biotech aims at improving the efficacy of well-established chemotherapies. Based on findings from two successful phase I studies in cancer patients, a phase II clinical trial is about to be initiated in extrahepatic bile duct cancer, a rare, but fatal disease with no cure. The market potential (USA and Europe) for an effective treatment of extrahepatic bile duct cancer is estimated up to USD 500 million. As the disease is rare, regulatory authorities are likely to expedite the market approval process, and a market exclusivity period can potentially be secured under the Orphan drug legislation.





#### The Phase Ib/II bile duct cancer study

- Target population: Patients with inoperable extrahepatic bile duct cancer
- Study design: Adaptive Phase Ib/II, open-label, multi-centre study in up to 45 patients, with 5:2 (PCI:control) randomisation in Phase II
- Study objective: Assess the safety and efficacy of a single treatment of fimaporfin (Amphinex) induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine
- Primary endpoint: Progression free survival (PFS) in Phase II

Bile duct cancer originates in the ducts that drain bile from the liver into the small intestine. It is a rare cancer (an orphan disease) without approved chemotherapies and with a limited development pipeline. The annual incidence rate is 1-2 cases per 100,000 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 currently the only potentially curative option for these patients, yet the majority of the tumours are inoperable. Standard treatment for inoperable patients is stenting to keep the bile duct open, followed by chemotherapy. Combination of the chemotherapeutics gemcitabine and cisplatin has 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.

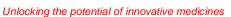
Bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and there is a high need for new drug classes or alternative methods. The most studied and used drug is gemcitabine, which is one of the drugs significantly enhanced by the PCI technology in preclinical studies. Light access for PCI treatment is easy through endoscopic methods used routinely in these patients.

# ABOUT IMMUNOTHERAPY AND THE PCI VACCINATION TECHNOLOGY

PCI Biotech's new vaccination technology have several favourable features for therapeutic cancer vaccines, which is an immunotherapeutic modality in need of improved efficacy. A clinical proof-of-concept trial is currently in planning, to be conducted either by PCI Biotech alone or in collaboration with a partner. PCI Biotech has recently initiated a research collaboration with a therapeutic cancer vaccine company to explore the potential of PCI with a cancer vaccination technology currently in clinical development.

The pharmaceutical industry has long recognised the potential of therapeutic cancer vaccination, i.e. vaccines that treat cancer by inducing or strengthening an immune response. There has been a renewed focus on such vaccines over the past few years, and FDA approved the first such vaccine in 2010. There are however still important unsolved issues and several companies have recently reported failed clinical studies.

Effective induction of cytotoxic immune responses is key to realize the huge potential of therapeutic cancer vaccination, but vaccines often fail to generate the required responses. One of the most important reasons for this is probably insufficient delivery of vaccine antigens to the appropriate processing machinery in target cells. The PCI vaccination technology may solve the issue by effectively enhancing appropriate delivery of vaccine antigens to the target cells in the immune system.





# ABOUT NUCLEIC ACID THERAPEUTICS AND THE PCI DELIVERY TECHNOLOGY

The nucleic acid therapeutics program follows an opportunistic collaborative approach, utilising established preclinical data to enter into research collaborations.

PCI Biotech aims at improving the efficacy of novel nucleic acid based therapies and the PCI delivery technology addresses the main bottleneck in the development of nucleic acid based therapies: sufficient release of the encapsulated therapeutics inside the targeted cells.

PCI Biotech is currently engaged in a research collaboration for delivery of nucleic acid therapeutics with one of the world's largest pharma companies. PCI Biotech is also collaborating with a Nasdaq listed U.S. based company developing siRNA products to augment the efficacy of RNAi therapeutics.

#### **KEY FIGURES**

(In NOK 1,000)	2015	2014
Other income	10 467	7 297
Operating costs	43 096	43 769
Operating results	-32 629	-36 472
Comprehensive income	-31 922	-35 840
Cash & cash equivalents	49 249	15 754
Total liabilities	12 115	11 269
Net cash flow from operations	-32 841	-31 674

# **BOARD OF DIRECTORS REPORT**

#### HIGHLIGHTS

**Fully underwritten rights issue.** PCI Biotech raised 70 million NOK through a fully underwritten rights issue that was completed in February, which enabled PCI Biotech to pursue the preclinical opportunities within immunotherapy and progress the bile duct cancer study.

Promising early signs of efficacy for fimaporfin (Amphinex) in bile duct cancer. Completion of the Phase I part of the Amphinex Phase I/II study in inoperable bile duct cancer patients was achieved through the progression of three dose cohorts (Cohorts 2-4) in 2015. There were no serious safety concerns in any of the dose cohorts in Phase I. Promising early signs of efficacy (tumour response at 6 months) has been provided from Cohort 3 and initial results from Cohort 4 are expected 1H 2016.

**Termination of the ENHANCE study and strategic refocusing.** The study of fimaporfin (Amphinex) in head and neck cancer was terminated in June after a careful re-evaluation of the commercial potential and competitive position. Resources were refocused towards the bile duct cancer study and translation of the preclinical immunotherapy program into the clinic.

**Initiated research collaborations with commercial potential within nucleic acid therapeutics and vaccination.** Two research collaborations have been initiated within nucleic acid therapeutics, with RXi Therapeutics and with an undisclosed top-10 large pharma company. Recently a research collaboration was also initiated with the cancer vaccination company Ultimovacs. All of these are preclinical collaborations with the initial aim to explore synergistic effects of complementary technologies.

**Established a Scientific Advisory Committee with international experts.** The company established a network of internationally renowned scientific advisors, which provided valuable input to the further development of the PCI technology and its development pipeline.

# **BUSINESS AND LOCATION**

PCI Biotech Holding ASA is a cancer focused biopharmaceutical company headquartered in Norway and listed on the Oslo Stock Exchange (Axess) since 2008. The company is developing therapeutic products based on its proprietary photochemical internalisation (PCI) technology, with the lead candidate fimaporfin.

The PCI Biotech group (The Group) comprises PCI Biotech Holding ASA, the wholly owned Norwegian subsidiary PCI Biotech AS and the dormant Icelandic branch PCI Biotech Utibu. PCI Biotech is located at Ullernchausséen 64, Oslo, Norway. Per 31 December 2015 the Group had 10 employees.

#### **OPERATIONS**

# Strategic refocusing

Following a strategic review of the company's assets, the Board of Directors decided in June 2015 to stop the ENHANCE study within head and neck cancer. The competitive landscape for treatment of these patients has and will continue to change in the near future. This will likely result in significantly increased competition for both clinical recruitment and market access, as well as a much higher risk for needing a large phase III study for regulatory approval of fimaporfin (Amphinex) in this indication. The technical complexity and the recent updates on competing products caused the company to reevaluate the competitive ability of fimaporfin in recurrent head and neck cancer. The final close out procedures will continue into 2016.



The company's development resources are refocused towards the clinical bile duct cancer study and the promising immunotherapy opportunities offered by the PCI technology. The new vaccine IP estate within vaccines announced during 2015, provides opportunity to broaden the asset portfolio and translate the vaccination technology into the clinic. Based on the promising preclinical data recently obtained in immunotherapy and with input from the Scientific Advisory Committee (SAC), several options to validate these findings clinically are being explored as part of the strategy going forward.

#### Inoperable bile duct cancer study

The treatment evaluation of the second and the third dose cohort in the phase Ib/II study of Amphinex were completed in 2015. The fourth dose cohort (3 patients) was completed in January 2016. There were no safety concerns at any of these dose levels. Safety is the primary objective of the phase Ib part of the study.

A Cohort Review Committee (CRC) of clinical experts and company representatives evaluates the results and provides recommendation for the continuation of the study, after completion of each dose cohorts. The CRC recommended progression of the study into Phase II at the completion of dose cohort 4. This recommendation was not based on safety findings, but on early promising signs of efficacy in the previous dose cohort (both partial and complete responses), combined with experience from earlier clinical studies with fimaporfin (Amphinex).

Additional patients have been enrolled in the fourth dose cohort in 2016, to gain further experience with the treatment at this dose level before start of Phase II. The Phase II part of the study will be slightly modified to draw on the experiences gained from the Phase Ib part, as well as recommendations from the investigators and PCI Biotech's Scientific Advisory Committee.

Further hospitals in selected European countries are being added in preparation to Phase II. A total of eleven sites are currently open.

#### **Vaccination program**

The preclinical vaccination program in therapeutic cancer vaccination has progressed successfully during 2015, with new promising data presented at several meetings. Preclinical data has convincingly demonstrated that the fimaporfin based PCI vaccination technology not only provide effective cytotoxic T-cell induction, but can also elicit strong enhancement of all other important immune responses. Several options to validate these findings clinically are being explored as part of the strategy going forward.

PCI Biotech received in 2015 a positive international search report and written opinion regarding a patent application on the use of PCI Biotech's proprietary technology 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 vaccination program is supported by a grant from the Research Council of Norway (BIA-program) of up to NOK 12.5 million and the grant is distributed over the course of three years, 2014-2017.

In January 2016, PCI Biotech announced the initiation of a preclinical research collaboration with the Norwegian privately held pharmaceutical company, Ultimovacs AS, developing novel immunotherapy against cancer. The purpose of the collaboration is to utilise the companies' complementary scientific platforms to explore potential synergies. The partnership is governed by a preclinical research collaboration agreement. In brief, the preclinical research collaboration will evaluate technology compatibility and synergy based on preclinical in vivo studies. The companies will evaluate results achieved from this research collaboration and then explore the potential for a further partnership.





# **Nucleic acid delivery**

PCI Biotech has two active research collaborations within nucleic acid therapeutics. A collaboration with an undisclosed top-10 pharma company, with the aim to evaluate synergistic effects of PCI with their nucleic acid therapeutics technology was signed in September 2015. The research agreement covers evaluation of technology compatibility and synergy based on in vitro studies. The pharma company, which is one of the global leaders in nucleic acid therapeutics, will fund the research collaboration. The companies will evaluate the data generated in this research collaboration and based on this explore the potential for a further partnership. The original evaluation period spans over 9 months, but may be further extended.

The other collaborative research program is with RXi Pharmaceuticals, signed in April 2015, with the aim to explore potential synergies between the companies' complementary PCI technology and siRNA platform. RXi Pharmaceuticals (NASDAQ: RXII), is 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.

#### **Scientific Advisory Committee established**

PCI Biotech has strengthened the organisation by appointing internationally renowned experts to inaugural Scientific Advisory Committee (SAC). The SAC will serve as a strategic resource to PCI Biotech as it continues to develop promising therapeutic applications based on the proprietary PCI technology platform. The committee includes experts in immunology, oncology, translational research and early clinical development. More information about the members of PCI Biotech's scientific advisory committee can be found on the company's website.

#### **Business development**

The first agreements showing potential for future commercial opportunities are signed in 2015 (and 2016) and all three active research collaborations can be important milestones to progress PCI Biotech into a commercial phase.

PCI Biotech believe that the PCI technology has the potential to play a role in the realization of several new therapeutic modalities, including cancer immunotherapy and mRNA therapeutics and the signed agreements shows that external companies share this view. Business development activities regarding the bile duct cancer program will be ramped up, as further relevant data are received during phase II.

PCI Biotech will continue the business development activities, to build on the proven ability to initiate new research collaboration and explore the business opportunities present in the active collaborations.

PCI Biotech's strategy is to prioritise commercialisation through agreements with external partners. The company envisages establishing partnership based on data from the phase II part of the ongoing clinical study. The strategy within PCI vaccination includes clinical validation of the platform and potential products within the expanded patent estate in immunotherapy. Within nucleic acids PCI Biotech's strategy is to utilise the available preclinical results to enter into early partnership agreements for further development and use of the PCI technology.

# 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 from 2014 and onwards.

# Organisation

<u>The Board of Directors</u> – Theresa Comiskey Olsen and Kjell Stenberg ended their terms as board members and were replaced by Christina Herder and Hans Peter Bøhn at the general assembly 12 May 2015. The Board of Directors consist of Erling Øverland (Chairman), Hilde H. Steineger, Christina Herder, Kjetil Taskén and Hans Peter Bøhn.





The Chairman of the Board, Erling Øverland, has notified PCI Biotech Holding ASA's Nomination Committee and Board of Directors that he does not wish to be candidate for re-election as Board Chairman of PCI Biotech Holding ASA at the next ordinary general meeting, in May 2016. Erling Øverland has served as the Chairman of the Board since October 2008.

<u>Employees</u> - The Group had 10 employees at the end of 2015 (2014: 11). Company's management team consists of Per Walday, CEO, Ronny Skuggedal, CFO, Anders Høgset CSO, Kristin Eivindvik PD and Gaël L'Hévéder CBDO.

The parent company has no employees. The Group mainly uses external suppliers for manufacturing, research and development and regulatory work.

The working environment is considered good. No accidents or injuries were reported in 2015 or 2014. Absence due to illness was 40 days, approximately 1.6% in 2015 (2014: 31 days, approximately 1.4%).

PCI Biotech's goal is to be a workplace with equality between women and men, and any discrimination is not accepted. The company has traditionally recruited from environments where women and men are fairly evenly represented. As at 11 April 2016 the company has 40% female representation in the board of directors and 20% in the senior management team. Out of 10 employees in 2015, 6 of them were women. The working time and remuneration arrangements in the company are regardless of gender.

Tone Otterhaug has been appointed as Clinical Science Director, starting from 1<sup>st</sup> January 2016. Tone has a Master in Pharmacy and a PhD in Immunology from the University of Oslo, Norway. She brings with her 10 years of experience in big pharma and biotech, mainly within clinical development in oncology.

#### **New location at Oslo Cancer Cluster Innovation Park**

PCI Biotech has signed a lease agreement for offices at the Oslo Cancer Cluster Innovation Park, running from 1 January 2016. The new office location enables PCI Biotech to further develop and capitalise on the close cooperation with the Norwegian Radium Hospital where the PCI technology originated.

# **FINANCIAL POSITION**

The Group has no revenue, but receives grants from different public sources such as the Norwegian Research Council and "SkatteFUNN". These grants are disclosed as other operating income. Other operating income for 2015 was NOK 10.5 million compared to 7.3 million in 2014. The increase is due to increases in grants from both the Research Council of Norway and "SkatteFUNN". There was no income in the parent company in 2015 or 2014.

Total operating expenses were NOK 43.1 million in 2015 (2014: NOK 43.8 million). Expenditure on research activities is recognised as an expense in the period in which it was incurred. The Group has no development expenditure that qualifies for recognition as an asset under IAS 38 and all research expenses are charged through the profit and loss statement, in line with previous years. Research and development costs amounted to NOK 38.8 million in 2015 (2014: NOK 39.3). The decrease is mainly due to lower activity level in the clinical trials. Other operating (general and administration) expenses were NOK 4.3 million (2014: NOK 4.4 million). The parent company had in 2015 other operating expenses of NOK 2.7 million (2014: NOK 3.0 million).

Operating result in 2015 was NOK -32.6 million (2014: NOK -36.5 million) for the Group and the improved operating result is due to increased public grants and reduced operating expenses. Operating result for the parent company was NOK -2.7 million (2014: NOK -3.0 million).

Net financial results for the Group were NOK 0.7 million in 2015 (2014: NOK 0.6 million). In 2015 the parent company wrote down NOK 50 million of an intercompany loan to the fully owned subsidiary PCI



Biotech AS, charged as a financial expense. The subsidiary is dependent on financing support from the parent company. In addition, the parent company made an impairment assessment of the investment in subsidiary, resulting in a write down of NOK 102.8 million, charged as a financial expense, based on an observable fair value of the group at Oslo Stock Exchange (Axess) at year-end 2015.

PCI Biotech Holding ASA finalised a rights issue of 7,000,000 new shares in February 2015, increasing the share capital of the company with NOK 21,000,000. Net proceeds from the rights issue was NOK 64.6 million. In addition, a rights issue of 174,000 shares following the exercise of employee share options was finalised in April 2015, with net proceeds of NOK 0.8 million.

Equity in the wholly owned subsidiary PCI Biotech AS was NOK 27.8 million at the end of 2015 (2014: NOK 8.2 million). The equity in PCI Biotech AS was increased in 2015 by NOK 50 million, through a capital increase from PCI Biotech Holding ASA.

The Board of Directors proposes that the loss in the parent company of NOK 152.7 million is covered by NOK 63.4 million from other paid-in capital and NOK 89.3 million from share premium. The total equity of the parent company PCI Biotech Holding ASA amounts to NOK 76.1 million (2014: NOK 161.7 million), giving an equity ratio of 98.9% (2014: 99.3%).

Total assets of the Group at the end of 2015 were NOK 56.4 million (2014: NOK 20.4 million). The increase is due to net proceeds from the rights issue resolved in February 2015, offset by cash spending during the year. Total assets in parent were NOK 76.9 million (2014: NOK 162.9). The decrease in total assets is due to write down of assets, offset by net proceeds from the rights issue.

PCI Biotech does not recognize deferred tax assets in the balance sheet, due to uncertainty as to when the company actually will accrue a payable tax liability. Unrecognized deferred tax assets at the end of 2015 are NOK 62.7 million (2014: NOK 57.0).

Net cash flow from operating activities of the Group amounted to NOK -32.8 million in 2015 (2014: NOK -31.7 million) and to NOK -2.7 million for 2015 (2014: NOK -2.9 million) for the parent. Net change in cash and cash equivalents for the Group was NOK 33.5 million in 2015 (2014: NOK -30.9 million) and NOK 8.8 million for the parent (2014: NOK 0.4 million), both impacted by net proceeds from the rights issue.

The Group's cash and cash equivalents at the end of 2015 were NOK 49.2 million (2014: NOK 15.8 million) and NOK 10.9 million for the parent (2014: NOK 2.1 million). The Group employs a prudent investment strategy for its cash and cash equivalents. The return on the company's cash and cash equivalents depends on the general level of interest rates in the money market, and thus vary over time. All cash and cash equivalents were placed as bank deposits at the end of 2015.

# **RISK AND RISK MANAGEMENT**

# **Operational Risk and Risk Management**

There are great risks in the business of developing medical drugs, both related to regulatory affairs and market risk. The development may fail at any stage of the process, due to safety considerations or lack of clinical results. It is not possible to predict with certainty whether and when PCI Biotech will be able to submit applications to regulatory authorities in the relevant markets. Moreover, one can not be sure that PCI Biotech will receive the marketing authorizations to commercialize the products. Regulatory approval may be denied, suspended or limited.

To handle the inherent risks in the industry, and to comply with national and international regulations, PCI Biotech has implemented a process to identify, analyse and manage the key risks for the company, including the character of the relevant insurance policies.

The Group does not pollute the external environment.

#### **Financial Risk and Risk Management**

The Group's activities are exposed to certain financial risks including currency risk, interest rate risk and liquidity risk. The risk is however of such character that the Group has chosen not to put in place any measures to mitigate the potential unpredictability of the financial markets, except a prudent strategy regarding interest rate risk.

PCI Biotech's most important future sources of financing is revenue related to any licensing and collaboration agreements, government grants and equity issues. The equity capital market is used as a source of liquidity when appropriate and conditions within this market are competitive. PCI Biotech has no external debt with financial covenants or any long term debt.

<u>Currency risk -</u> The Group's expenses and revenues are incurred in multiple currencies. The Group is therefore exposed to fluctuations in exchange rates. The risks are assessed on a regular basis. PCI Biotech is currently not using any financial hedging instruments.

<u>Interest rate risk - PCI</u> Biotech has no interest-bearing debt and interest risks are mainly related to the Group's holdings of cash and cash equivalents. The company's strategy is to take very low risk on the company's cash. The company's assets are invested in short term money market instruments or placed in bank deposits.

<u>Liquidity Risk</u> - One of the main objectives of PCI Biotech's financial policy is to ensure that the Group has sufficient financial flexibility in the short and long term to achieve strategic and operational objectives. PCI Biotech's goal is at least to have sufficient cash to cover the known capital need over the next 12 months, as well as a strategic reserve. The Group monitors the cash flows in the short and long term perspective. Cash burn rate depends mainly on the level of activity in the clinical and preclinical programs and the activity levels are adjustable without substantial long term commitments.

# **GOING CONCERN**

In accordance with § 3-3a of the Norwegian Accounting Act (NAA) it is confirmed that the conditions for assuming that the Group will continue as a going concern are present and that the financial statements have been prepared on the basis of this assumption. The Board of Directors refers to the document on corporate governance in the annual report relating to corporate governance (NAA § 3-3b) and corporate social responsibility (NAA § 3-3c).



# SUBSEQUENT EVENTS

In January 2016 a preclinical research collaboration with Ultimovacs AS was initiated, please see section "Vaccination program" under "Operations" for further information. In the bile duct cancer program, the Cohort Review Committee (CRC) recommended progression of the study into Phase II, at the completion of dose cohort 4 in January 2016, please see section "Inoperable bile duct cancer study" under "Operations" for further information.

There have been no other events since year-end 2015 which is of material significance to the financial statements as of 31 December 2015.

# **OUTLOOK**

PCI Biotech's lead project is clinical development of fimaporfin (Amphinex) in combination with gemcitabine for treatment of inoperable bile duct cancer; an orphan disease with high unmet medical need. The company will also maintain the high activity level in development and licensing of PCI as a versatile and innovative platform.

The main priorities are to:

- Effectively progress the proof of concept study for inoperable bile duct cancer treatment with fimaporfin and gemcitabine;
- Solidify a robust vaccination IP estate and further strengthen the promising preclinical results;
- Translate the promising vaccination results to the clinical setting;
- Alliance management and partnering activities across all commercially interesting areas for the PCI platform.

The Board of Directors emphasise that there are generally considerable uncertainty and risks associated with forward looking statements.

Oslo, 11 April 2016
Board of Directors and Chief Executive Officer,
PCI Biotech Holding ASA

Erling Øverland Chairman	Hilde H. Steineger
Christina Herder	Kjetil Taskén
Hans Peter Bøhn	Per Walday CEO



# RESPONSIBILITY STATEMENT FROM THE BOARD OF DIRECTORS AND CEO 2015

We confirm that the financial statements for the period 1 January to 31 December 2015, to the best of our knowledge, have been prepared in accordance with IFRS and that the accounts give a true and fair view of the assets, liabilities, financial position and results of operations, and that the information in the report includes a fair review of the development, performance and position of the Company and the Group, together with a description of the principal risks and uncertainties the company faces.

Oslo, 11 April 2016 Board of Directors and Chief Executive Officer, PCI Biotech Holding ASA

Erling Øverland Chairman	Hilde H. Steineger
Christina Herder	Kjetil Taskén
Hans Peter Bøhn	Per Walday CFO

# ANNUAL STATEMENT ON CORPORATE GOVERNANCE POLICY AND CORPORATE SOCIAL RESPONSIBILITY POLICY

# PCI Biotech Holding ASA emphasises good corporate governance

The Norwegian Code of Practice for corporate governance is a guideline for listed companies to help regulate the division of roles between shareholders, the board of directors and executive management more comprehensively than is required by legislation.

PCI Biotech Holding ASA ("PCI Biotech" or "The Company") bases its policy for corporate governance on the Norwegian Code of Practice of 30 October 2014. Adherence to the code of practice is implemented on the basis of a "comply or explain principle".

The Board of Directors and management has resolved as a main principle to follow the recommendations of the Norwegian Corporate Governance Code to the extent not considered unreasonable due to the company size and stage of development. Explanations are provided of non-conformance to the code if not fully implemented. PCI Biotech's compliance with the Code is described in this report and section numbers refer to the Code's chapters.

# 1. Implementation and reporting on corporate governance and social responsibility

PCI Biotech acknowledges the division of roles between shareholders, the Board of Directors and the executive management team. PCI Biotech has implemented a sound corporate governance and social responsibility policy. The statement of compliance with the Code is presented in the Company's annual report and website. The Company ensures that the policy is adopted by holding regular Board of Directors' meetings which the executive management team attends to present strategic, operational and financial matters.

# 1.1 Corporate governance

PCI Biotech adhere to the code of practice for corporate governance. The company has to date four deviations from the code and these are further explained under section 1.2, 6, 9 and 11.

Guidelines on corporate governance can be found in the Company's annual report and website. Corporate values are established with the purpose to establish a healthy corporate culture and preserve the Company's integrity by helping employees to comply with standards of good business conduct. Furthermore, the values are intended to be a tool for self-assessment and for further development of the Company's identity. The corporate values are important foundations for PCI Biotech's corporate governance. Ethical guidelines are also established and these guidelines are based on the corporate values.

# 1.2 Corporate social responsibility

PCI Biotech is a Norwegian based company focusing on research and development within the field of cancer treatment. The PCI Biotech Group consists of 10 employees and the core competencies are possessed by these employees, while the group's other resources in research and development are purchased from public and private research institutions across Europe.

As of today, the Group has no sales or supply of services and a limited complexity in operations. The Group has established guidelines, policies, procedures and standards in accordance with internal control policies for comparable businesses of similar size, complexity and industry to fight corruption. This means that the group requires its directors and employees to demonstrate high ethical standards in business and interpersonal relationships. Other principles followed are prevention through awareness-raising activities, limitation of opportunities, high detection risk of and zero tolerance for corruption.

The Group has established its own quality control system in line with authorities' requirements within the activities that the Group operates, both in terms of production and storage of pharmaceutical products and medical devices, and in connection with preclinical and clinical studies. The quality





control procedures are based on the relevant activities in relation to the different phases of operation and the development of procedures are thus a continuous and systematic process. The group is concerned that staff have appropriate training and experience in their areas and staff are regularly updated within their fields.

The group is concerned with human rights, labour rights and social issues. The Group's management conducts regular performance reviews and internal evaluations. The group adapts according to Norwegian law within the area. The Group's subcontractors are mainly public and private European research institutions. Clinical research is subject to strict government regulation of human rights and social conditions in all the countries where the research and development work is carried out. The Group therefore considers that human rights, labour rights and social issues are well taken care of, both internally and among its subcontractors.

The Group has not identified any material issues based on the corporate social responsibility procedures performed in 2015. The implementation of further detailed specific goals, strategies or action plans related to CSR, beyond the ones described above, has not yet been prioritized, but will be developed along with the continuous development of PCI Biotech's operations.

Non-conformance with the recommendation: The Group's operations are of such character that it does not significantly affect the environment and the Group therefore believes it is not appropriate to establish specific guidelines, policies, procedures and standards in this area, but environmental issues are included in the ethical guidelines.

# 1.3. Ethical guidelines

The ethical guidelines encompass the following elements; core values, compliance with laws and regulations, working environment, interaction with different stakeholders, intragroup transactions, employees loyalty, conflicts of interest, confidentiality, environment, accounting, financial reporting, trading of Company shares, other employee activities and compliance with the ethical guidelines.

# 2. Business

The objective and purpose for PCI Biotech's business are clearly defined in the articles of association. "The Company's business activities shall include cancer treatment and drug delivery based on the PCI technology and other related activities, including participation in other companies with similar activities through equity, loan or by issue of guarantees." The Company's articles of association are available at the Company's website and the Company's goals and strategy are available in the annual report.

#### 3. Equity and dividends

PCI Biotech's equity as of 31 December 2015 was NOK 44.3 million, which corresponds to an equity ratio of 78.5%. The equity ratio is regularly assessed in light of the Company's goals, strategy and risk profile and the equity is assessed as satisfactory given the Group's strategy, objectives and risk profile.

To date the Company has not distributed any dividends and this dividend policy will apply as long as PCI Biotech is in a research and development phase.

The Board of Directors has no general authorization to issue shares. The Board of Directors has been authorised by the Company's General Assembly to increase the share capital by exercise of stock options granted to key employees. The authorisation was granted for two years in 2014, and applies to 13 May 2016.

# 4. Equal treatment of shareholders and related party transactions

PCI Biotech has only one class of shares and all shares have equal rights. Each share carries one vote.

The Board of Directors and management are committed to treat all shareholders equally. The Company had no transactions in own shares during 2015. The Group had regular business transactions with two related parties in 2015.



In the event of the Board of Directors resolving to issue new shares and waive the pre-emptive rights of existing shareholders, the Board of Directors intends to comply with the recommendation of the Norwegian Code of Practice for Corporate Governance that the justification for such waiver is noted in the Stock Exchange announcement relating to such a share issue.

The Norwegian Radium Hospital Research Foundation owns 9.1% of PCI Biotech at year-end 2015. PCI Biotech has extensive cooperation with the Norwegian Radium Hospital. The cooperation is regulated through signed agreements and it is the Board of Director's and management's opinion that the contracts are based on "arm's length" principles.

Theresa Comiskey Olsen was a Director of PCI Biotech until she ended her term in May 2015. The Group acquires legal services from Theresa Comiskey Olsen, and she received separate remuneration beyond regular Director remuneration for legal services rendered. It is the Board of Director's and management's opinion that the agreement for these legal services is based on "arm's length" principles.

Please refer to Note 19 Related party transactions to the financial statements 2015 where information regarding related party transactions are disclosed.

All material transactions between the Group and shareholders, directors, management or close associates of such parties are valuated independently by a third party. Directors and members of the executive management are obliged to notify the Board of Director's of any direct or indirect material interest in any transaction entered into by the Group.

#### 5. Freely negotiable shares

The shares in PCI Biotech are freely negotiable with no form of restriction and no restrictions regarding transferability are included in the Company's articles of association.

# 6. General Meetings

The Board of Director's facilitate that as many shareholders as possible may exercise their rights by participating at the General Meeting and that the General Meeting is an effective forum for both the views of shareholders and the Board of Director's.

The Chairman, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) are present at the Annual General Meeting, along with representatives from the Nomination Committee and the group auditor.

Shareholders who are unable to participate themselves may vote by proxy and a person can also be appointed to vote for the shareholders as a proxy.

Notice of the meeting and relevant documents, including the proposal of the nomination committee, are made available on the company website three weeks in advance of the meeting. Notice of the meeting is sent to all shareholders individually, or to their depository banks, three weeks in advance of the meeting. The meeting notice include information regarding shareholders' rights, guidelines for registering and voting at the meeting. The company provides information on the procedure for representation at the meeting through proxy, nominations of a person to vote on behalf of the shareholders and to the extent possible prepare a form which allows separate voting instructions for each matter.

Non-conformance with the recommendation: PCI Biotech is a small company and has encouraged directors to attend the General Meeting, but has for both cost and convenience reasons so far not required all directors to attend. The recommendation to implement routines to ensure an independent chairing of the meeting has not been implemented.



#### 7. Nomination Committee

The requirement for a Nomination Committee and its guidelines follows from the articles of association. The Nomination Committee's duties are to propose candidates for election to the Board of Directors and to propose remuneration. The Nomination Committee is required to justify its recommendations and encouraged to interact with shareholders, the Board of Directors and the Chief Executive Officer (CEO) in its work. The Nomination Committee's members, including the chairman, are elected by the General Meeting for two years at a time, unless otherwise resolved by the General Meeting. The Nomination Committee shall consist of minimum two members who shall be shareholders or representatives for the shareholders. The remuneration to the members of the Nomination Committee is determined by the General Meeting.

The Nomination Committee consist of Kjetil Hestdal (Chairman), Erik Must and Anders Tuv. It is possible to contact the Nomination Committee through the Company's website.

#### 8. Board of Directors, composition and independence

The Board of Directors is composed to ensure that the Board of Directors can operate independently, attend the common interest for all shareholders and the Company's need for expertise, capacity and diversity. The members and the Chairman of the Board of Directors are elected for one year terms by the General Meeting. The Board of Directors is presented on the company website. All board members are considered to be independent from the Company's day-to-day management, main shareholders and material business connections. All board members are encouraged to be shareholders and their shareholdings are disclosed in the Annual Report.

#### 9. Work of the Board of Directors

It is the responsibility of the Board of Directors to ensure that the Company has a well functioning internal control environment in accordance with the regulations that apply to its activities. The Board of Directors adopts an annual plan for its work, which includes objectives, strategy and implementation. The Board of Directors evaluates its performance and expertise annually. The Company has not established a separate Audit Committee in accordance with the exemption in the Norwegian Public Limited Liability Companies Act. The Company has not established a separate Remuneration Committee. The Board of Directors in its entirety serves as an Audit and Remuneration Committee.

The Board conducted twelve meetings in 2015. Board members had the following attendance at these meetings:

Erling Øverland, 12/12 Kjetil Taskén, 12/12 Christina Herder 6/6 Hans Peter Bøhn 6/6 Theresa Comiskey Olsen, 5/6 Hilde H. Steineger, 11/12 Kjell G. Stenberg 5/6

Theresa Comiskey Olsen and Kjell G. Stenberg ended their terms as Directors in May 2015. Christina Herder and Hans Peter Bøhn were elected as new Directors at the Annual General Meeting on 12th May 2015 and both attended all Board of Directors meetings after that date.

Non-conformance with the recommendation: PCI Biotech has not established separate Audit and Remuneration Committees. The Board of Directors believes that this is most appropriate given the Company's current size and complexity. The Board of Directors will, depending on the Company's performance, consider appointing a separate Audit and Remuneration Committee.

# 10. Risk management and internal control

It is the responsibility of the Board of Directors to ensure that the Company has sound internal controls and systems for risk management that are appropriate in relation to the extent and nature of the Company's activities. Significant risks include strategic risks, financial risks, liquidity risks and operational risks including risks related to development of products. The internal control systems also include company values, code of ethics and corporate social responsibility. The Company's significant risk areas and internal control systems are assessed on an on-going basis and at least once a year by the Board of Directors.



The Company presents its financial statements in accordance with IFRS, and procedures have been established to ensure compliance with IFRS interim and annual reporting requirements. The Company's management, the Chief Executive Officer (CEO) and Chief Financial Officer (CFO) is responsible for preparing the financial statements, and financial reports are approved by the Board of Directors prior to publication. Management regularly reports to the Board of Directors on progress in the development of the PCI technology and the Group's financial situation.

There are established procedures for handling inside information applicable to all employees and insiders reflecting the guidelines of the Oslo Stock Exchange.

Please also refer to The Board of Directors report, for a description of relevant risk factors.

#### 11. Remuneration of the Board of Directors

The General Meeting determines the remuneration to the Board of Directors based on a proposal from the Nomination Committee. Remuneration reflects the Board of Directors responsibility, expertise, time commitment and the business complexity. The remuneration is not linked to the Company's performance, and no share options are granted to Directors.

Non-conformance with the recommendation: The Director, Theresa Comiskey Olsen, rendered in 2015 some legal services to the Company, and she is remunerated separately for these services, while she served as Director. The Board of Directors are informed about the services, and these related party transactions are disclosed in the interim and annual reports.

#### 12. Remuneration of the executive management

The Board of Directors has adopted guidelines for remuneration to the Company's executive management and the guidelines are presented to the general meeting. Performance-related remuneration is linked to long term value creation for shareholders and is based on quantifiable factors that can be influenced by the executive management. It is established a limit for the performance related remuneration. A share option scheme is part of the remuneration policy and the scheme is approved by the general meeting.

Remuneration to the executive management, Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Scientific Officer (CSO), Chief Business Development Officer (CBDO) and Project Director (PD) are disclosed in the annual report.

#### 13. Information and communication

The Company's guidelines for reporting of financial and other information is based on transparency and takes into account the requirement for equal treatment of all participants in the securities market. The Company is committed to report financial results and other relevant information on an accurate and timely basis. The Company publishes a financial calendar on an annual basis, including dates for release of interim and annual reports and dates for general meetings. All press releases and stock exchange notifications are posted on the Company's website at the same time as it is released.

#### 14. Take-overs

The Board of Directors endorses the principles concerning equal treatment of all shareholders. In the event of a take-over bid, it is obliged to act in accordance with the requirements of Norwegian law and in accordance with the applicable principles for good corporate governance. Transaction that in fact is a business disposal shall be approved by a General Meeting.

#### 15. Auditor

Ernst & Young AS (EY) is the appointed auditor of PCI Biotech.

The auditor shall annually in writing confirm to the Board of Directors that he/she satisfies established requirements for independence and objectivity. The auditor participates at least one Board of Directors meeting per year, where he/she present auditors plan for the audit, the assessment of the Company's internal control and participate during the approval of the annual accounts. The auditor has a minimum



of one meeting per year with the Board of Directors without the presence of the Executive Management. The Board of Directors has established separate guidelines for use of non-audit services. Fees paid to the external auditor for audit and non-audit services are reported in the Company's Annual Report, which are, in turn, approved by the annual general meeting.



# PCI Biotech Holding ASA – financial statement

# STATEMENT OF COMPREHENSIVE INCOME For the year ended 31 December 2015

(1.1 - 31.12)

Р	arent			Gro	up
2014	2015	(figures in NOK 1,000)	Note	2015	2014
-	-	Other income	1,2	10 467	7 297
-	-	Total income		10 467	7 297
-	-	Research and development	3	38 844	39 341
2 996	2 748	General and administrative	3,4	4 252	4 428
2 996	2 748	Total operating expenses	3, 4, 5, 6,19	43 096	43 769
-2 996	-2 748	Operating results		-32 629	-36 472
2 092	2 824	Financial income	7	867	812
30 001	152 781	Financial expenses	7	160	180
-27 908	-149 956	Net financial results		707	632
-30 904	-152 704	Ordinary result before taxes		-31 922	-35 840
-	_	Tax on ordinary result	8	-	-
-30 904	-152 704	Net loss for the year		-31 922	-35 840
		Other comprehensive income, net of income tax			
-	-	Items that will not be reclassified to income statement		-	-
-	-	Items that subsequently may be reclassified to income statement		-	-
-30 904	-152 704	Total comprehensive income for the year		-31 922	-35 840
		Loss per share basic and diluted (figures in NOK)	9	-2.29	-4.64



# **BALANCE SHEET** for the year ended 31 December 2015

	Parent			G	roup
2014	2015	ASSETS (figures in NOK 1,000)	Note	2015	2014
		Non-current assets		40	4.4
-	-	Property, plant and equipment	10	10	14
160 758	59 602	Shares in subsidiary	11	-	-
160 758	59 602	Total non-current assets		10	14
		Current assets			
_	6 355	Receivables from group companies		-	-
9	24	Other short term receivables	14	7 139	4 614
9	6 379	Total receivables	13	7 139	4 614
2 082	10 913	Cash and cash equivalents	13, 15	49 249	15 754
2 091	17 292	Total current assets		56 389	20 368
162 849	76 894	Total assets		56 399	20 382



# **BALANCE SHEET** for the year ended 31 December 2015

	Parent			Gr	oup
2014	2015	EQUITY AND LIABILITIES	Note	2015	2014
		(figures in NOK 1.000)			
		Equity			
23 179	44 701	Share capital	16	44 701	23 179
76 732	31 363	Share premium		120 678	76 732
61 765	-	Other paid-in capital		-	-
-	-	Retained earnings		-121 094	-90 796
161 677	76 064	Total equity	4,19	44 284	9 114
		Liabilities			
		Current liabilities			
43	28	Trade accounts payable		3 371	2 586
84	87	Public duties payables		956	1 163
369	-	Other current liabilities, group companies		-	-
676	715	Other current liabilities	18	7 788	7 518
1 172	830	Total current liabilities	12,17	12 115	11 269
1 172	830	Total liabilities	13	12 115	11 269
162 849	76 894	Total equity and liabilities		56 399	20 382

Oslo, 11 April 2016 Board of Directors and Chief executive Officer, PCI Biotech Holding ASA

Erling Øverland <i>Chairman</i>	Christina Herder	Hilde H. Steineger
Kjetil Taskén	Hans Peter Bøhn	Per Walday CEO



# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY for the year ended 31 December 2015

(attributable to the equity holders of the parent)

(figures in NOK 1,000)	Note	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
Equity at 31 December 2013	16	23 179	76 732	0	-56 515	43 396
Share-based payments		-	-	1 558	-	1 558
Total comprehensive income		-	-	-	-35 840	-35 840
Allocation		-	-	-1 558	1 558	0
Equity at 31 December 2014	16	23 179	76 732	0	-90 796	9 114
Capital increase		21 522	43 946	-	-	65 468
Share-based payments		-	-	1 624	-	1 624
Total comprehensive income		-	-	-	-31 922	-31 922
Allocation		-	-	-1 624	1 624	0
Equity at 31 December 2015	16	44 701	120 678	0	-121 094	44 284

# STATEMENT OF CHANGES IN EQUITY – PARENT for the year ended 31 December 2015

(figures in NOK 1,000)	Note	Share capital	Share premium	Other paid-in capital	Retained earnings	Total equity
<b>Equity at 31 December 2013</b>	16	23 179	76 732	91 112	0	191 023
Share-based payments in						
subsidiary		-	-	1 558	-	1 558
Total comprehensive income		-	-	-30 904	-	-30 904
Equity at 31 December 2014	16	23 179	76 732	61 765	0	161 677
Capital increase		21 522	43 946	-	-	65 468
Share-based payments in						
subsidiary		-	-	1 624	-	1 624
Total comprehensive income		-	-89 315	-63 389	-	-152 704
Equity at 31 December 2015	16	44 701	31 363	0	0	76 064



# **CASH FLOW STATEMENT** for the year ended 31 December 2015

	Parent	(figures in NOK 1,000)		Gro	oup
2014	2015		Note	2015	2014
-30 904	-152 704	Ordinary profit before tax		-31 922	-35 840
-	-	Depreciation and amortisation	3,10	4	4
30 000	152 781	Write downs	7	-	-
-	-	Share-based payments	4	1 624	1 558
-2 092	-2 824	Interest income	7	-867	-812
-4	-15	Changes in accounts receivables		-2 525	1 509
18	-15	Changes in accounts payables		785	-1 474
41	42	Changes in other net operating assets and liabilities		60	3 382
-2 941	-2 736	Cash flow from operating activities		-32 841	-31 674
1 211	-56 726	Net proceeds from intragroup interest-bearing debt		_	
2 092	2 824	Interest income received	7	867	812
	-53 902	Net cash flow from investing activities	,	<b>867</b>	812
3 303	-33 302	Net cash now from investing activities		007	012
0	65 469	Net proceeds from issue of new equity	16	65 469	0
0	65 469	Net cash flow from financing activities		65 469	0
362	8 831	Net changes in cash and cash equivalents		33 495	-30 862
1 720	2 082	Cash and cash equivalents at 1 January		15 754	46 595
2 082	10 913	Cash and cash equivalents at 31 December	15	49 249	15 754

# PCI BIOTECH HOLDING ASA – ACCOUNTING PRINCIPLES 2015

# 1. Corporate information

The annual accounts for 2015 for PCI Biotech Holding ASA (the Company) and the consolidated financial statement (the Group or PCI Biotech) were approved for publication by the Board of Directors on 11<sup>th</sup> April 2016.

PCI Biotech Holding ASA is a public listed company domiciled in Norway. The business of the Group is associated with research and development of pharmaceutical products and related technical equipment. The Company is listed on the Oslo Axess and the registered office address is Ullernchausséen. N-0379 Oslo.

#### 2. Significant accounting policies

#### 2.1 Basis of preparation

The Group and the Company's annual accounts are prepared in accordance with International Financial Reporting Standards (IFRS) as specified by the International Accounting Standards Board and implemented by the EU as per 31 December 2015.

The annual accounts for the Group and the Company have been prepared on the basis of historical cost. The financial income statement is presented by function of expense.

NOK (Norwegian kroner) is the functional currency for all companies within the Group. In the absence of any statement to the contrary, all financial information is reported in whole thousands. As a result of rounding adjustments, the figures in the financial statements may not add up to the totals.

#### 2.2 Basis of consolidation

The consolidated accounts include the overall financial results and overall financial position when the parent company PCI Biotech Holding ASA, the fully owned subsidiary PCI Biotech AS and the dormant Icelandic branch PCI Biotech Utibu are presented as a single economic entity. The subsidiary and the branch are fully consolidated. The consolidated financial statements are prepared using uniform accounting policies for similar transactions and events under similar circumstances. Intercompany transactions and balances, including internal profits and unrealized gains and losses, are eliminated. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

#### 2.3 Summary of significant accounting policies

# a) Current versus non-current classification

The Group presents assets and liabilities in statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realised or intended to sold or consumed in normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realised within twelve months after the reporting period

#### Or

 Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading



It is due to be settled within twelve months after the reporting period

Or

• There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

#### b) Fair value measurement

The Group measures financial instruments, at fair value at each balance sheet date. Fair value related disclosures for financial instruments, are summarised in the following notes:

• Financial instruments (including those carried at amortised cost) Note 12, 14 and 15.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place in the principal market for the asset or liability.

# c) Government grants

Government grants are disclosed under revenue as other income, see note 1 for further information. Government grants are recognised where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognised as income in equal amounts over the expected useful life of the related asset.

### d) Taxes

#### Current income tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognised directly in equity is recognised in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

#### Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognised for all taxable temporary differences.

Deferred tax assets are recognised for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised.



The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are re-assessed at each reporting date and are recognised to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognised outside profit or loss is recognised outside profit or loss. Deferred tax items are recognised in correlation to the underlying transaction either in OCI or directly in equity. Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

# e) Foreign currencies

The Group's consolidated financial statements are presented in NOK, which is also the parent company's functional currency.

#### Transactions and balances

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

#### Cash dividend distribution to equity holders of the parent f)

The Company recognises a liability to make cash distributions to equity holders of the parent when the distribution is authorised and the distribution is no longer at the discretion of the Company. As per the corporate laws in Norway, a distribution is authorised when it is approved by the shareholders. A corresponding amount is recognised directly in equity.

#### g) Property, plant and equipment

Tangible fixed assets are recognized at cost less deductions for accumulated depreciation and writedowns. Tangible fixed assets are depreciated over the expected useful life of the assets taking any residual value into consideration. Costs accrued for major replacements and upgrades of tangible fixed assets are added to cost if it is probable that the costs will generate future economic benefits for the Group and if the costs can be reliably measured. Ordinary maintenance is expensed as incurred.

Tangible fixed assets are depreciated on a straight-line basis over the estimated useful life of the asset as follows:

- Production and test equipment 5 years
- Furniture and equipment 3-5 years

### h) <u>Leases</u>

The determination of whether an arrangement is (or contains) a lease is based on the substance of the arrangement at the inception of the lease. The arrangement is, or contains, a lease if fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset or assets, even if that right is not explicitly specified in an arrangement.

#### Group as a lessee

A lease is classified at the inception date as a finance lease or an operating lease.



Operating lease payments are recognised as an operating expense in the statement of profit or loss on a straight-line basis over the lease term.

#### i) Intangible assets - Research and development costs

Research costs are expensed as incurred. Development expenditures on an individual project are recognised as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that the asset will be available for use or sale
- · Its intention to complete and its ability and intention to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortisation and accumulated impairment losses. Amortisation of the asset begins when development is complete and the asset is available for use. It is amortised over the period of expected future benefit. Amortisation is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

# j) Financial instruments - initial recognition and subsequent measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

#### k) Financial assets

#### Initial recognition and measurement

Financial assets are classified, at initial recognition, as financial assets at fair value through profit or loss, loans and receivables, held-to-maturity investments, AFS financial assets, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. All financial assets are recognised initially at fair value plus, in the case of financial assets not recorded at fair value through profit or loss, transaction costs that are attributable to the acquisition of the financial asset. Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the market place (regular way trades) are recognised on the trade date, i.e., the date that the Group commits to purchase or sell the asset.

#### Subsequent measurement

For purposes of subsequent measurement financial assets are classified in four categories:

- Financial assets at fair value through profit or loss
- Loans and receivables
- Held-to-maturity investments
- AFS financial assets

#### Receivables

Receivables (short-term) is the most relevant category to the Group and no other categories are relevant for 2014 and 2015. Receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial measurement, such financial assets, with no stated interest rates, are subsequently measured at face-value (non-discounted contractual payments) as long as the discounted cash-flow effect is immaterial. The discounting effect is often considered immaterial based on the low face-value and limited duration. All receivables are accounted for according to this principle in 2014 and 2015. This category generally applies to trade and other receivables. For more information on receivables, refer to Note 14 and Note 19.

#### Impairment of financial assets

Further disclosures relating to impairment of financial assets are also provided in the following notes:



- Financial Risk, credit risk Note 12
- Receivables Note 14
- Financial income and expenses Note 7
- Related parties transactions Note 19

The Group assesses, at each reporting date, whether there is objective evidence that a financial asset or a group of financial assets is impaired.

#### Financial assets carried at amortised cost

Assets are individually assessed for impairment. The amount of any impairment loss identified is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows. The present value of the estimated future cash flows is discounted at the financial asset's original effective interest rate.

#### Financial liabilities

#### Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as loans and borrowings and payables, as appropriate. All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs. The Group's other financial liabilities include trade and other payables.

#### m) Derivative financial instruments and hedge accounting

The Group has not used derivative financial instruments, such as forward currency contracts, to hedge its foreign currency risks during 2014 or 2015.

# n) Impairment of non-financial assets

Further disclosures relating to impairment of non-financial assets are also provided in the following notes:

Property, plant and equipment Note 10

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. When the carrying amount of an asset exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

#### o) Cash and short-term deposits

Cash and short-term deposits in the statement of financial position comprise cash at banks and short-term deposits with a maturity of three months or less, which are subject to an insignificant risk of changes in value. For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash and short-term deposits, as defined above, net of outstanding bank overdrafts as they are considered an integral part of the Group's cash management.

#### p) Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

# q) Pensions and other post-employment benefits

PCI Biotech AS has an agreement with a life assurance company concerning contribution-based pensions for employees. Contributions, ranging from 7% to 12,5% of the employee's ordinary salary up to 12 times the basic amount (G) of the Norwegian National Insurance scheme, are paid into the



employee's contribution account with the life assurance company. The Company's payment of contributions is expensed in the period it is accrued. Any prepayments made to the contribution fund are recognized in the balance sheet.

#### r) Share-based payments

Employees (including senior management) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions).

#### Equity-settled transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using the Black-Scholes valuation model. That cost is recognised, together with a corresponding increase in other capital reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognised for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognised as at the beginning and end of that period and is recognised in employee benefits expense. See Note 4 for further information.

No expense is recognised for awards that do not ultimately vest, except for equity-settled transactions for which vesting are conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied. When the terms of an equity-settled award are modified, the minimum expense recognised is the expense had the terms had not been modified, if the original terms of the award are met. An additional expense is recognised for any modification that increases the total fair value of the share-based payment transaction, or is otherwise beneficial to the employee as measured at the date of modification. The dilutive effect of outstanding options is reflected as additional share dilution in the computation of diluted earnings per share, further details are given in Note 9.

#### s) License costs

Agreements with external parties concerning access to technology in the form of license agreements and agreements that allow the use of patented technology are expensed when they occur according to the agreement and are disclosed as "Research and development expenses" in the income statement.

#### t) Investment in subsidiary

Shares and investments with the aim of long-term ownership are disclosed in the balance sheet as long-term investments and are valued at the lower of cost and fair value. Write-downs for permanent declines in value are made on the basis of individual evaluations. Any realized and unrealized profits/losses and any write-downs related to these investments will be booked in the income statement as financial items.

#### u) Segment reporting

Segments are reported similarly as the internal reporting to the Group's senior decision makers. Senior decision makers are defined as the Group's management group. The Group has only one segment. See Note 2 for further information.

# v) Cash-flow statement

The cash flow statement has been prepared in accordance with the indirect method. Cash and cash equivalents consists of cash, bank deposits and other current investments like money market funds.



#### w) Events after the balance sheet date

New information regarding the Group's financial position on the balance sheet date has been taken into account in the annual accounts. Events after the balance sheet date that do not affect the Group's financial position on the balance sheet date, but which will affect the Group's financial position in the future, are reported if they are significant.

# x) Contingent liabilities and assets

Contingent liabilities are defined as:

- Possible liabilities as a result of earlier events where their existence depends on future events;
- Liabilities that is not included because it is not probable that they will lead to an outflow of resources from the Group;
- Liabilities that cannot be measured with sufficient reliability.

Contingent liabilities are not included in the annual accounts. Notes on significant contingent liabilities are provided, with the exception of contingent liabilities with little probability of occurring. Contingent assets are not included in the annual accounts, but are reported in cases in which there is a certain likelihood of their resulting in a benefit to the Group.

# y) Changes in accounting policies and disclosures

New and amended standards and interpretations

The Group applied no new or amended standards and interpretations for the first time effective for annual periods beginning on or after 1 January 2015.

One amendment that has an impact on the Group's financial position, performance and/or disclosures was applied for the first time effective for annual periods beginning on 1 January 2014 and is described below:

# Annual Improvements 2010-2012 Cycle

In the 2010-2012 annual improvements cycle, the IASB issued seven amendments to six standards, which included an amendment to IFRS 13 Fair Value Measurement. The amendment to IFRS 13 is effective immediately and, thus, for periods beginning at 1 January 2014, and it clarifies in the Basis for Conclusions that short-term receivables and payables with no stated interest rates can be measured at invoice amounts when the effect of discounting is immaterial. The Group has implemented this amendment with an immaterial effect due to low value and duration on short-term receivables and payables from 1 January 2014.

#### 3. Significant accounting judgments, estimates and assumptions

The preparation of the Group's consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Other disclosures relating to the Group's exposure to risks and uncertainties includes:

Financial risk management and policies Note 12

#### **Judgments**

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognised in the consolidated financial statements:



- The fair value of employee options is calculated according to the Black-Scholes method. This method involves the use of estimates and discretionary judgment, as described in more detail in Note 4. The allocation of options to employees of subsidiary is made directly from the parent company and the financial presentation is correspondingly reported in the subsidiary.
- The Group has not recognized a deferred tax asset related to carry forward losses, as described in more detail in Note 8.
- Regarding development of pharmaceuticals and medical equipment the Group cannot render probable future earnings large enough to justify recognising development costs in the balance sheet before marketing approval has been obtained. Own development costs are therefore recognized as an expense as incurred until national market approval for the product and indication has been obtained. Any further development of the product after marketing approval has been obtained and market launch completed will be recognized in the balance sheet to the extent that this involves significant changes to the product, which is considered likely will generate future financial benefits.

PCI Biotech Holding ASA has in its separate financial statement performed an assessment of the carrying amount of the subsidiary PCI Biotech AS, see Note 7 and 11 for further information.

#### 4. Standards issued, but not yet effective

The standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are disclosed below. The Group intends to adopt these standards, if applicable, when they become effective. Only standards and interpretations that are expected to have an impact on the Group's financial position, performance, and/or disclosures are included.

Annual Improvements to IFRSs (2010 – 2012). These improvements are effective for annual periods beginning from 1 July 2014 and endorsed by EU for annual periods beginning from 1 Feb 2015 and are expected to have an impact on the Group.

They include *Amendment to IAS 24 Key management personnel*. The amendment clarifies that a management entity – an entity that provides key management personnel services – is a related party subject to the related party disclosures. In addition, an entity that uses a management entity is required to disclose the expenses incurred for management services. This amendment is already implemented by the Group and parent and disclosed in the annual accounts for 2014 and 2015.

*IFRS 15 Revenue from contract with customers* establishes a comprehensive framework for determining whether, how much and when revenue is recognized. IFRS 15 is effective for annual reporting periods beginning on or after 1 January 2018. At current stage of operations IFRS 15 is not expected to have an impact on the Group's financial position, performance, and/or disclosures.

*IFRS 16 Leases* specifies how to recognise, measure, present and disclose leases. IFRS 16 is effective for annual reporting periods beginning on or after 1 January 2018. At current stage of operations IFRS 16 is not expected to have an impact on the Group's financial position, performance, and/or disclosures.



# PCI BIOTECH HOLDING ASA - NOTES FINANCIAL STATEMENT 2015

# 1 OTHER INCOME

(figures in NOK 1,000)	Grou	р
	2015	2014
Grants from the Research Council of Norway	5 425	4 105
Tax incentive scheme - SkatteFUNN	4 982	3 174
Other income	60	0
Total other income	10 467	7 279

#### 2 OPERATING SEGMENTS

The group has only one operating segment, which is research and development. PCI Biotech develop products for clinical markets, based on its proprietary technology, to transport molecules into living cells. The company had mainly external costs within research and development in 2015 and 2014. The group expects that development costs will be covered by future revenues from products under development.

# 3 STATEMENT OF COMPREHENSIVE INCOME ACCORDING TO CLASSIFICATION AND R&D EXPENSES BY CATEGORY

Operating costs according to classification.

(figures in NOK 1,000)		Group		Par	ent
	Note	2015	2014	2015	2014
Salary expenses	4	15 306	14 846	981	896
R&D exclusive salary / other operating expens	ses	20 282	20 415	0	0
Depreciation and amortisation	10	4	4	0	0
Other operating expenses		7 503	8 504	1 767	2 100
Total operating expenses		43 096	43 769	2 748	2 996
Specification of other operating expenses					
		2015	2014	2015	2014
Travel expenses		767	1 367	56	77
Patent, legal and other fees		3 973	4 715	997	1 430
Other expenses		2 763	2 422	714	593
Total other operating expenses		7 503	8 504	1 767	2 100

# R&D expenses by category:

2015	2014
17 808	19 267
11 876	10 745
4 941	5 396
4 220	3 933
0	0
38 844	39 341
	17 808 11 876 4 941 4 220



#### 4 SALARY EXPENSES AND OTHER REMUNERATION

(figures in NOK 1,000)		Gro	up	Par	ent
		2015	2014	2015	2014
Wages and Board of Directors remunera	ation	11 338	11 373	860	790
Social security contributions		1 491	1 193	121	106
Share-based payments		1 624	1 558	0	0
Pension costs	5	727	652	0	0
Other expenses		127	70	0	0
Total salary expenses		15 306	14 846	981	896
No. of full-time equivalent positions		10,5	12,0	0	0

# **Share based payments**

The general vesting term in the employee share option scheme is three years, with one third vested each year. The options expire five years from grant date. All options will lapse immediately upon the event that the employee's employment with the company are terminated. Each option gives the right to subscribe for or acquire one share upon PCI Biotech Holding ASA's choice.

The general meeting held 13 May 2014 authorized the Board of Directors to grant the employees with a total of 739,000 options and the authorisation applies for two years. A total of 565.000 options are outstanding at year-end 2015 (2014: 645.500). In April 2015 a total of 174.000 options were exercised and subscribed for and the authorisation from the general meeting is fully utilised.

In February 2015 a share issue was completed and the strike price for outstanding share options were adjusted in accordance with the share option program agreement and the fair value assessments were adjusted accordingly, leading to a total increase of share based payment expenses of MNOK 0.6, where MNOK 0.4 are charged through the P&L in 2015 and MNOK 0.2 are amortised over the remaining lifetime for the relevant options.

As part of the employee share option program, the Board of Directors of PCI Biotech Holding ASA awarded a total of 183.500 options to key employees in 2015. 73.500 options were awarded on 20 April 2015, at a strike price of NOK 12.53. In August 2015 a total of 90.000 options expired. 27 November 2015 the Board of Directors awarded a total of 110.000 options, at a strike price of NOK 5.21. The Board of Directors have not been granted any options. See note 19 Related party transactions for further information.

The P&L effect resulted from the share option program for 2015 were a net cost of NOK 1.6 million (2014: NOK 1.6 million).



Share options outstanding at the end of the period have the following expiry date and exercise prices: **Exercise** 

	price in NOK			
Expiry date	per share	Number of shares		
		2015	2014	
2015 - Q2	4.78	-	174 000	
2015 - Q3	27.54	-	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	
2020 - Q3	12.53	73 500	-	
2020 - Q3	5.21	110 000	-	
Sum		565 000	645 500	

All options granted to employees, average exercise price and transactions during the year is listed below:

	2	015	2014	
	Number	Average exercise price in NOK per share	Number	Average exercise price in NOK per share
Outstanding at the beginning of the vear	645 500	20.65	645 500	20.65
Granted during the year	183 500	8.14	0	0.00
Lapsed during the year	0	0.00	0	0.00
Exercised during the year	174 000	4.78	0	0.00
Expired during the year	90 000	27.54	0	0.00
Outstanding at year end	565 000	14.23	645 500	20.65
Exercisable options at year end	339 833	17.51	533 333	19.97

Exercise price and average remaining lifetime for outstanding options per year-end:

Number of options 2015 / 2014	Exercise price in NOK per share	Average remaining lifetim (years)	
		2015	2014
0 / 174 000	4.78	-	0.4
0 / 90 000	27.54	-	0.7
170 000 / 170 000	14.07	0.7	1.7
86 500 / 86 500	27.38	1.7	2.7
85 000 / 85 000	14.52	2.7	3.7
40 000 / 40 000	13.78	2.7	3.7
73 500 / 0	12.53	4.7	-
110 000 / 0	5.21	4.7	-



# Valuation method for fair value assessment of options granted

The Black-Scholes method is used for fair value assessment of the options at grant date. Volatility is calculated based on PCI Biotech's own stock market price. The exercise price is set at market terms, equal to the average volume weighted share price last five days of trade prior to grant date (5 days VWAP), and no premium for the options are paid. The risk free interest rate is based on Norwegian 3-5 years government bond yield. Each option program is calculated separately with actual exercise price and lifetime for the program. The table below shows the input values used in the model.

Fair value for options granted in 2015 were NOK 1.1 million. No options were granted in 2014. The fair value estimated at grant date is amortised over the vesting period of three years.

Options granted in 2015	April 2015	November 2015
Number of options	73 500	110 000
Dividend	0,00	0,00
Historical volatility (%)	86 %	86 %
Risk free interest (%)	1.02 %	0.87 %
Expected lifetime (years)	5	5

# **5 PENSION EXPENSES**

Pensions expenses for the year:

(figures in NOK 1,000)	Group	
	2015	2014
Total pension cost from contribution schemes	727	651

# 6 AUDITORS FEE

	Group		Parent		
(figures in NOK 1,000 ex. VAT)	2015	2014	2015	2014	
Statutory audit	108	108	57	54	
Other assurance services	55	20	35	0	
Tax and VAT advising services	36	0_	0	0	
Total	199	128	92	54	

### 7 FINANCIAL INCOME AND EXPENSES

(figures in NOK 1,000)	Group		Parent	
	2015	2014	2015	2014
Interest income	867	812	196	2
Interest income group	0	0	2 628	2 090
Total financial income	867	812	2 824	2 092
Interest expense	0	0	0	1
Other financial expense	160	180	152 781	30 000
Total financial expense	160	180	152 781	30 001

The other financial expense of NOK 152.8 million in Parent is related to a financial write-down of intercompany receivables from the subsidiary PCI Biotech AS of NOK 50 million (2014: NOK 30 million) and a financial write-down of NOK 102.8 million related to investment in PCI Biotech AS. The impairment assessment is based on the observable market value at Oslo Stock Exchange (Axess) at year-end 2015.



# 8 TAX

(figures in NOK 1,000)

	Group		Pare	ent
	2015	2014	2015	2014
Loss before tax	-31 922	-35 840	-152 704	-30 904
Expected nominal rate of tax (27%)	-8 619	-9 677	-41 230	-8 344
Permanent differences charged through P&L	-869	-859	41 251	8 100
Deferred tax asset not recognised in the balance sheet	9 487	10 536	-21	244
Total tax expense for the year	0	0	0	0

Specification of basis for deferred tax asset / liability				
Tax effect of temporary differences:	Group		Parent	
	2015	2014	2015	2014
Fixed assets	-17	-23	0	0
Receivables	0	0	0	0
Carry forward loss	-62 656	-56 972	-4 867	-3 830
Total tax asset (25% for 2015 / 27% for 2014)	-62 672	-56 994	-4 867	-3 830
Deferred tax asset not recognised	62 672	56 994	4 867	3 830
Deferred tax asset recognised in the balance sheet	0	0	0	0

The group and parent have no history of taxable profits and deferred tax assets are therefore valued to NOK 0 in the balance sheet. Deferred tax asset not recognised in the balance sheet amounts to NOK 62.7 million (2014: NOK 57.0 million) at group level. The carry forward loss has no time limit according to current tax legislations.

#### 9 EARNINGS PER SHARE

Earnings per share (diluted earnings per share) are calculated on the basis of the financial result after tax for the year (financial result after tax for the year adjusted for dilutive effects) divided by a weighted average number of shares outstanding over the year (weighted average number of outstanding shares over the year adjusted for dilutive effects). Dilution effect is weighted number of outstanding share options which are in-the-money during the year. Accretive effects are not taken into consideration. Earnings per share is not affected by the dilution effect if negative results in the period.

Earnings per share	2015	2014
Weighted average number of shares (in '000)	13 967	7 726
Dilution effect (in '000)	58	453
Weighted average number of shares fully diluted (in '000)	14 025	8 179
Net loss for the year	-31 922	-35 840
Earnings per share (NOK per share)	-2.29	-4.64
Diluted earnings per share (NOK per share)	-2.29	-4.64



#### 10 FIXED AND INTANGIBLE ASSETS

(figures in NOK 1,000)	Group		
	Software	Equipment	Total
Acquisition cost per 31 December 2013	168	314	482
Additions in 2014	0	0	0
Disposals and scrapping during 2014	0	0	0
Acquisition cost per 31 December 2014	168	314	482
Additions in 2015	0	0	0
Disposals and scrapping during 2015	0	0	0
Acquisition cost per 31 December 2015	168	314	482
Accumulated depreciation per 31 December 2013	168	296	464
Ordinary depreciation 2014	0	4	4
Disposals in 2014	0	0	0
Accumulated depreciation per 31 December 2014	168	300	468
Ordinary depreciation 2015	0	4	4
Disposals in 2015	0	0	0
Accumulated depreciation per 31 December 2015	168	304	472
Book value per 31 December 2014	0	14	14
Book value per 31 December 2015	0	10	10
Leasing expenses	2015	2014	
Leasing office premises	663	650	
Total leasing expenses	663	650	

The group leased premises at Strandveien 55, Lysaker Bærum until year-end 2015. The lease runs to 31 Dec 2015, with an option for extension for three more years. The lease option was not exercised. Amounts of minimum lease payment for non-cancellable operating leases is NOK 0 million per year-end 2015. (2014: NOK 0.7 million).

PCI Biotech has entered into a new lease agreement with Oslo Cancer Cluster Incubator, Ullernchausséen 64 Oslo, from 2016. The lease runs to 31 Dec 2018, with an option for extension for three more years. The lease including all costs is NOK 0.7 million per annum. The lease agreement is subject to annual adjustment according to changes in the consumer price index from 2017. Amounts of minimum lease payment for non-cancellable operating leases is NOK 2.1 million per year-end 2015.



#### 11 SHARES IN SUBSIDIARY

	Year of	Share capital	Equity participation and share of	Carrying amount (NOK	Equity (NOK	Financial result 2015 (NOK
Company	acquisition	of company	voting rights	thousand)	thousand)	thousand)
PCI Biotech AS, Oslo, Norway	2008	3 879 120	100 %	59 602	27 813	-31 999

In 2014 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 29 676 740, totalling to NOK 30 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 30 millions by PCI Biotech Holding ASA.

In 2015 the share capital of PCI Biotech AS was increased by NOK 323 260, with a share premium of NOK 49 676 740, totalling to NOK 50 000 000. The share capital was increased by a contribution in kind of intercompany balances of NOK 50 millions by PCI Biotech Holding ASA.

The carrying amount is assessed in accordance with the observable market value of PCI Biotech at Oslo Stock Exchange (Axess) per year-end 2015.

#### 12 FINANCIAL RISK

This note describes the group's various financial risks and the management of these. In addition, numerical tables for risk associated with financial risks are also presented.

# (I) Organisation of financial risk management

PCI Biotech has an international business operation and is exposed to currency risk, interest risk, liquidity risk and credit risk. The group has not utilised any derivatives or other financial instruments to reduce these risks during the accounting period. The responsibility for managing financial risk is at group level. The risk associated with centralised activities such as financing, interest rate and currency management is managed at group level. In addition, the group manages the risks associated with the business processes. The financial risk management is monitored by the Board of Directors.

#### Centralised risk management

PCI Biotech has a centralised risk management policy. The most important tasks within risk management are to ensure the group's financial freedom to act both in a short- and long term perspective, and to monitor and manage financial risk in cooperation with the individual units in the group. The finance department maintains dialogue with the company's bankers and carries out any necessary hedging transactions in regard to interest rates and currencies. Any permits required for borrowing and entering into derivative framework agreements are given on an annual basis by the Board of Directors. A hedging-oriented view forms the basis for risk management of the finance department's positions so that all transactions with financial instruments have a counter item in an underlying commercial hedging requirement.

# Financial risk

This section describes the most important risk factors within each business area and the management of these. In this context, financial risk is understood as risk associated with financial instruments. These can either be hedging instruments for underlying risk or be considered themselves as a source of risk. Market risk is not hedged with financial instruments.

### Research and development activities

PCI Biotech carries out research and development for new innovative medical products based on the company's patented technology. The currency risk in research and development is limited to the purchase of services, primarily related to clinical and pre-clinical studies. Foreign currency risk associated with purchase of goods and services are foremost related to transactions in EUR and GBP. Foreign currency exposure associated with research and development is not normally hedged.



# (II) Classes of financial risk Interest rate risk

PCI Biotech does not have any interest-bearing debt, and the group's interest rate risk is primarily associated with the group's cash positions and cash equivalents. This risk is managed at group level. The main strategy is to diversify the risk and invest in cash deposits with fixed or spot interest rates or money market funds with low risk, high liquidity and short duration.

#### Liquidity risk

One of the most important objectives of PCI Biotech's finance policy is to ensure that the group has financial freedom to act in the short and long-term in order to attain strategic and operational goals. PCI Biotech shall have sufficient funds to cover known capital requirements during the forthcoming 12 month period in addition to a strategic reserve. Cash flow in research and development depends mainly on the activity level of the clinical programmes. The finance department monitors the cash flows in a short- and long term perspective. PCI Biotech's most important source of finance are future royalty and milestones associated with licence agreements, government grants and the capital market. The capital market is used as a source of liquidity when this is appropriate and the conditions in these markets are competitive. The finance department continually evaluate other sources of financing. PCI Biotech does not have any debt agreements with key business ratio requirements (covenants).

#### Credit risk

The group 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 group's exposure to bad debts is not significant and therefore no bad debt provision has been recognised during 2015 or 2014. The following table shows an overview of the maturity structure of the group's financial obligations, based on non-discounted contractual payments.

Group (figures in NOK 1,000)	Remaining period				
	Less than 1 month	1-3 months	3-12 months	1-5 years	Total
31.12.2015					
Trade accounts payables	3 371	0	0	0	3 371
Public duties payables	729	0	226	0	956
Other current liabilities	349	1 351	6 088	0	7 788
31.12.2014					
Trade accounts payables	2 586	0	0	0	2 586
Public duties payables	773	0	390	0	1 163
Other current liabilities	1 550	966	5 002	0	7 518

Parent (figures in NOK 1,000)		Remai	ning perio	d	
	Less than 1 month	1-3 months	3-12 months	1-5 years	Total
31.12.2015					
Trade accounts payables	28	0	0	0	28
Public duties payables	0	0	87	0	87
Other current liabilities	0	0	715	0	715
31.12.2014					
Trade accounts payables	43	0	0	0	43
Other current liabilities, group companies	0	0	369	0	369
Public duties payables	0	0	84	0	84
Other current liabilities	0	0	676	0	676



# Foreign currency risk

As NOK is the group's functional currency, PCI Biotech is exposed to foreign currency risk associated with the group's foreign net exchange rate exposure.

PCI Biotech strives as far as possible to achieve the lowest possible net currency exposure. The group's expenses and revenues accrue in various currencies, primarily EUR, GBP, USD, SEK and NOK. PCI Biotech is therefore exposed to fluctuations in foreign exchange rates. The company evaluates whether measures should be taken to reduce the foreign currency risk through hedging for significant transactions.

The following table details the group's sensitivity to potential changes in the foreign currency exchange rate, with all other factors constant. The calculation assumes an equal change against all relevant foreign currencies. The effect on earnings comes from changes in the value of monetary items.

	Changes in exchange rates	Effect on operating result	
		Parent	Group
2015	+/- 10 %	0	+/- 1 823
2014	+/- 10 %	0	+/- 2 067

# 13 CLASSIFICATION OF FINANCIAL ASSETS AND LIABILITIES

		Group	
31.12.2015	Lending and receivables	Other financials liabilities	Total
Assets			_
Other current receivables	7 139	0	7 139
Cash and cash equivalents	49 249	0	49 249
TOTAL FINANCIAL ASSETS	56 388	0	56 388
<b>Liabilities</b> Trade accounts payables		0.074	
Public duties payables	0	3 371	3 371
Other current liabilities	0	956	956
Other current habilities	0	7 788	7 788
TOTAL FINANCIAL LIABILITIES	0	12 115	12 115
31.12.2014	Lending and receivables	Other financials liabilities	Total
Assets			
Other current receivables	4 614	0	4 614
Cash and cash equivalents	15 754	0	15 754
TOTAL FINANCIAL ASSETS	20 368	0	20 368



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Liabilities			
Trade accounts payables	0	2 586	2 586
Public duties payables	0	1 163	1 163
Other current liabilities	0	7 518	7 518
TOTAL FINANCIAL LIABILITIES	0	11 268	11 268
-		Parent	
31.12.2015	Lending and	Other financials	
	receivables	liabilities	Total
Assets			
Group receivables	6 355	0	6 355
Other current receivables	24	0	24
Cash and cash equivalents	10 913	0	10 913
TOTAL FINANCIAL ASSETS	17 292	0	17 292
Liabilities			
Trade accounts payables	0	28	28
Public duties payables	0	87	87
Other current liabilities	0	715	715
TOTAL FINANCIAL LIABILITIES	0	830	830
31.12.2014	l anding and	Other financials	
	Lending and receivables	liabilities	Total
Assets			
Other current receivables	9	0	9
Cash and cash equivalents	2 082	0	2 082
TOTAL FINANCIAL ASSETS			
	2 091	0	2 091
	2 091	0	2 091
Liabilities			
Liabilities Trade accounts payables	0	43	43
Liabilities Trade accounts payables Public duties payables		43 84	43 84
Liabilities Trade accounts payables Public duties payables Group payables	0 0 0	43 84 369	43 84 369
Liabilities Trade accounts payables Public duties payables	0	43 84	43 84



#### 14 RECEIVABLES BY YEAR END

Figures based on non-discounted contractual payments.

# Other current receivables - specification

(Figures in NOK 1,000)	Group		Parent	
- · ·	2015	2014	2015	2014
Recognised not received government grants	6 506	4 249	0	0
Prepaid payables	193	109	0	0
VAT receivables	440	256	24	9
Total other receivables	7 139	4 614	24	9

No bad debt provision recognised at year-end 2015 or 2014.

# 15 CASH AND CASH EQUIVALENTS BY YEAR END

(Figures in NOK 1,000)	Group		Parent	
	2015	2014	2015	2014
Cash and cash equivalents, restricted (1)	561	572	0	0
Cash and cash equivalents, non-restricted	48 688	15 182	10 913	2 082
Sum	49 249	15 754	10 913	2 082

<sup>(1)</sup> Restricted cash and cash equivalents are security for the employees' tax and a bank deposit of NOK 50 thousand.

At year-end 2015 and 2014 the cash and cash equivalents are all deposits in regular bank accounts in NOK, EUR and GBP.

# 16 SHARE CAPITAL

The registered share capital in PCI Biotech Holding ASA:

	No. of shares	Nominal value per share in NOK	Share capital in NOK
Share capital as per 31.12.2013	7 726 390	3,00	23 179 170
Share issue in 2014	-	-	-
Share capital as per 31.12.2014	7 726 390	3,00	23 179 170
Share issues in 2015	7 174 000	3,00	21 522 000
Share capital as per 31.12.2015	14 900 390	3,00	44 701 170

All shares have equal voting rights and otherwise have equal rights in the company and one share represents one voting right.

Ordinary shares are classified as equity and only one class of shares exists. Expenses that are directly attributable to the issue of ordinary shares are included in the accounts as a reduction of equity.

A fully underwritten rights issue of NOK 70 million was completed 12 February 2015. 7 000 000 new shares were issued in the rights issue, increasing the share capital of the company with NOK 21 000 000. Through the rights issue, PCI Biotech received gross proceeds in the amount of NOK 70 million and net proceeds of NOK 64.6 million. The transaction cost includes a guarantee fee of 3.0%.

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.

In addition, a rights issue of 174.000 new shares (nominal value per share NOK 3), following the exercise of employee share options was finalised in April 2015.

Following the completion of the rights issue transactions the share capital is NOK 44.701.170 divided by 14.900.390 shares, each with a nominal value of NOK 3.00.

# **Ownership structure**

The largest shareholders of PCI Biotech Holding ASA as per 31.12.2015:

The largest shareholders of the Biotesia Holding 7.67 that per emiliar		Ownership
	Number of shares	in %
FONDSAVANSE AS	2 149 138	14,42 %
PHOTOCURE ASA	1 483 339	9,96 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE	1 359 853	9,13 %
STOREBRAND VEKST JPMORGAN EUROPE LTD	1 257 815	8,44 %
MP PENSJON PK	899 408	6,04 %
VICAMA AS	743 288	4,99 %
VERDIPAPIRFONDET KLP	670 095	4,50 %
KOMMUNAL LANDSPENSJON	628 858	4,22 %
BERGEN KOMMUNALE PENSJON	350 000	2,35 %
LGJ INVEST AS	250 487	1,68 %
CATILINA INVEST AS	175 253	1,18 %
ARNE LOEN AS	174 733	1,17 %
HOLBERG NORGE VERDIPAPIRFONDET	170 320	1,14 %
RUL AS	144 918	0,97 %
PONGO AS	137 207	0,92 %
ERRYCO INVEST AS	132 642	0,89 %
BIRK VENTURE AS	125 000	0,84 %
MYNA AS	125 000	0,84 %
BAKKER DIRK THEODOOR	124 240	0,83 %
BASILI IRENE WAAGE	123 277	0,83 %
Total 20 largest shareholders	11 224 871	75,33 %
Total other shareholders	3 675 519	24,67 %
Total number of shares	14 900 390	100 %



Shares owned, directly or indirectly, by members of the board and their personally related parties per 31.12.2015 and per 31.12.2014:

		No. of shares		
Name	Position	2015	2014	
Erling Øverland, including Trifolium AS	Chairman	61 945	32 500	
Kjetil Tasken	Board member	0	0	
Hans Peter Bøhn	Board member	50 000	NA	
Christina Herder	Board member	0	0	
Hilde H. Steineger	Board member	0	0	
Theresa Comiskey Olsen	Former board member	NA	27 193	
Kjell G. Stenberg	Former board member	NA	0	
Per Walday	CEO	44 019	12 000	
Ronny Skuggedal	CFO	15 000	0	
Anders Høgset	CSO	47 977	28 424	
Gaël L'Hévéder	CBDO	10 000	0	
Kristin Eivindvik	PD	13 235	0	
Total number of shares		242 176	100 117	

Ronny Skuggedal (CFO) and Gaël L'Hévéder (CBDO) acquired shares in the market during 2015. Per Walday (CEO) and Anders Høgset (CSO) increased their holdings of shares in 2015 through the rights issue in February 2015 and by exercising employee share options in April 2015. Kristin Eivindvik (PD) increased her holdings of shares by exercising employee share options in April 2015.

# 17 FINANCING STRUCTURE

The group had no external interest bearing debt as of 31.12.2015 or 31.12.2014.

#### 18 OTHER CURRENT LIABILITIES BY YEAR END

(Figures in NOK 1,000)	Group		Paren	t
	2015	2014	2015	2014
Accruals for incurred external R&D expenses	5 166	3 651	0	0
Accruals for various remuneration items	2 174	2 061	615	593
Other accruals	449	1 807	100	84
Total other current liabilities	7 788	7 518	715	676



# 19 RELATED PARTIES TRANSACTIONS

Figures for remuneration are expensed amounts in the financial year. (Figures in NOK 1,000)

	Board remuneration	Salary	Bonus	Other benefits*	Pension benefits	Total
Senior executives 2015						
Per Walday, CEO	0	1 545	93	404	88	2 129
Ronny Skuggedal, CFO	0	1 006	65	18	71	1 160
Anders Høgset, CSO	0	959	83	308	76	1 426
Gaël L'Hévéder, CBDO	0	1 477	50	4	102	1 633
Kristin Eivindvik, PD	0	939	22	306	82	1 349
Total senior executives remuneration	0	5 925	313	1 042	419	7 697

<sup>\*</sup> Other benefits include salary benefits in relation to exercise of share options in 2015.

	Board		_		Pension	
Board of Directors 2015	remuneration	Salary	Bonus	benefits	benefits	Total
Erling Øverland, Chairman	235	0	0	0	0	235
Kjetil Tasken	143	0	0	0	0	143
Theresa Comiskey Olsen**	143	0	0	17*	0	160
Kjell G. Stenberg**	143	0	0	0	0	143
Hilde H. Steineger	143	0	0	0	0	143
Hans Peter Bøhn***	0	0	0	0	0	0
Christina Herder ***	0	0	0	0	0	0
Total remuneration	807	5 925	313	1 059	419	8 521

<sup>\*</sup>Legal services ex VAT up to Comiskey Olsen ended the term as board member in May 2015.

<sup>\*\*\*</sup>joined the Board of Directors in 2015.

	Board	Other		Pension		
	remuneration	Salary	<b>Bonus</b>	benefits	benefits	Total
Senior executives 2014						
Per Walday, CEO	0	1 501	90	18	79	1 688
Ronny Skuggedal, CFO	0	901	15	18	63	998
Total senior executives remuneration	0	2 402	105	36	142	2 685

	Board remuneration	Salary	Bonus	Other benefits	Pension benefits	Total
Board of Directors 2014						
Erling Øverland, Chairman	220	0	0	0	0	220
Kjetil Tasken	135	0	0	0	0	135
Else Krüger-Hagen						
(left the Board of Directors in 2014)	135	0	0	0	0	135
Theresa Comiskey Olsen	135	0	0	104*	0	239
Kjell G. Stenberg	135	0	0	0	0	135
Hilde H. Steineger						
(joined the Board of Directors in 2014)	0	0	0	0	0	0
Total remuneration	760	2 402	105	140	142	3 549

<sup>\*</sup> Legal services ex VAT

PCI Biotech's policy as regards the determination of salary and other remuneration to senior executives is to have market based remuneration and provide other benefits that are competitive in

<sup>\*\*</sup>left the Board of Directors in 2015.



employment for senior executives. It is important to attract the required expertise and experience to create value and contribute to the mutual interests between owners and senior executives. The performance-based remuneration shall be linked to value creation for shareholders or long term performance of the company.

The main principles for remuneration of the company's senior executives are as follows:

- Salaries are reviewed annually
- Bonuses are calculated on the basis of goals for the company established by the Board of Directors and achievement of personal goals. The company's Chief Executive Officer (CEO) has a bonus agreement for up to 25% of annual salary, other senior executives have bonus agreements of up to 15% of annual salary.
- Senior executives, and other key employees, participate in the company's share option incentive program
- Senior executives participate in the company's general pension scheme

Bonuses for senior executives are calculated on the basis of the company's financial results and development, and achievement of personal goals.

The senior executives participate in the company pension plan that is a defined contribution plan which entails payment of 7% to 12,5% of the employee's annual salary up to 12 times the basic National Insurance amount (G). The pension scheme also covers in the event of disability.

The CEO is entitled to six months' notice and has an agreement of additional 6 months salary on certain terms. There are no agreements beyond the statutory requirements for other senior executives.

Senior executives have not received any remuneration or financial benefits from other companies in the group other than those shown above. It is not given additional remuneration for special services outside the normal functions of a senior executive.

There are no loans or pledges to senior executives, board of directors, employees or other persons in elected corporate bodies.

Senior executive's shareholdings in PCI Biotech Holding ASA are disclosed in note 16 Share capital. Allocation, exercise and holdings of share options for senior executives in 2015 are presented in the table below:

	Total holdings 31.12.					holdings	Average exercise price in
Senior executives	2014	Allocated	Lapsed	<b>Exercised</b>	Expired	2015	NOK
Per Walday,							
CEO	186 000	9 000	0	60 000	30 000	105 000	15.34
Ronny Skuggedal,							
CFO	40 000	26 000	0	0	0	66 000	12.62
Anders Høgset,							
CSO	136 000	6 000	0	45 000	20 000	77 000	15.28
Kristin Eivindvik,							
PD	76 000	13 500	0	45 000	20 000	24 500	16.96
Gaël L'Hévéder,							
CBDO	70 000	21 000	0	0	0	91 000	13.58
Sum	508 000	75 500	0	150 000	70 000	363 500	





#### Related parties:

#### The Norwegian Radium Hospital Research Foundation:

PCI Biotech has a long-standing research relationship with the Norwegian Radium Hospital Research Foundation (RF), which is affiliated to the Norwegian Radium Hospital (NRH), now named Rikshospitalet-Radiumhospitalet Helseforetak (RR-HF). Some of PCI Biotech's main patents were filed by the NRH and later transferred to PCI Biotech. Under the terms of research agreements with RF from 2002 and 2007 and later amendments, the PCI Biotech supports the RF with research and development funding, and gets rights of use and an option on certain conditions to acquire the new technologies developed by the RF.

PCI Biotech has a right of first refusal to purchase from the RF, completely or in part, any new technology within the field of Photochemical Internalization. If PCI Biotech is not interested in purchasing such technology at the terms offered, RF can offer the technology to a third party. An offer to a third party cannot be at terms inferior to those offered to PCI Biotech, and PCI Biotech has the right to perform an independent assessment of any agreement entered into between RF and a third party, to ensure that RF has offered no more favourable terms to the third party than those previously rejected by PCI Biotech. If the terms are found more favourable, PCI Biotech may request that the agreement between RF and the third party is to be cancelled.

The group has for delivery of R&D services, related to the described agreements, paid NOK 3.5 million on commercial terms to RF in 2015 (2014: NOK 2.7 million). As of 31.12.2015 the group had account payables of NOK 1.1 million to RF (2014: NOK 0.6 million).

#### PCI Biotech AS:

PCI Biotech AS is a fully owned subsidiary of the parent company in the group, PCI Biotech Holding ASA. The parent company has no employees. The group operations are managed through the fully owned subsidiary PCI Biotech AS that has a management service agreement with the parent company, including services like management, offices, finance and investor relation functions for the group. All transactions are performed at market terms.

The parent company has been charged for operations according to the service agreement of NOK 1.0 million in 2015 (2014: NOK 1.4 million). The parent company has charged PCI Biotech AS interest expenses for intercompany loans of NOK 2.6 million during 2015 (2014: NOK 2.1 million). Net current receivables from PCI Biotech AS at year-end 2015 were NOK 6.4 million (2014: net current liabilities of NOK 0.4 million). During 2015 PCI Biotech Holding ASA has recognised a write down of NOK 50 million in an intercompany loan to PCI Biotech AS. The same intercompany loan has been utilised as contribution in kind from PCI Biotech Holding ASA in a capital increase in PCI Biotech AS during 2015.

#### **Board of Directors:**

PCI Biotech AS acquires legal services from Theresa Comiskey Olsen, who ended the term as board member in May 2015. Total cost for these services up to May 2015 was NOK 17 thousand for 2015 (2014: NOK 104 thousand). At year-end 2015 PCI Biotech AS has no open balances with Comiskey Olsen (2014: NOK 8 thousand).

In relation to the rights issue resolved in February 2015 the Chairman contributed to the underwriting syndicate and underwrote NOK 378 thousand with a guarantee fee of 3.0%.

#### 20 SUBSEQUENT EVENTS

In January 2016 a preclinical research collaboration with Ultimovacs AS was initiated. In the bile duct cancer program, the Cohort Review Committee (CRC) recommended progression of the study into Phase II, at the completion of dose cohort 4 in January 2016. Please see Board of Directors report for further information. PCI Biotech is not aware of other post-closing events, which could materially influence this financial statement.



# **AUDITORS REPORT**



Statsautoriserte revisorer Ernst & Young AS

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To the Annual Shareholders' Meeting of PCI Biotech Holding ASA

#### **AUDITOR'S REPORT**

#### Report on the financial statements

We have audited the accompanying financial statements of PCI Biotech Holding ASA, comprising the financial statements for the Parent Company and the Group. The financial statements of the Parent Company and the Group comprise balance sheet as at 31 December 2015, the statements of comprehensive income, cash flows and changes in equity for the year then ended as well as a summary of significant accounting policies and other explanatory information.

The Board of Directors' and Chief Executive Officer's responsibility for the financial statements

The Board of Directors and Chief Executive Officer are responsible for the preparation and fair
presentation of these financial statements in accordance with the International Financial Reporting
Standards as adopted by the EU, and for such internal control as the Board of Directors and Chief
Executive Officer determine is necessary to enable the preparation of financial statements that are free
from material misstatement, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including International Standards on Auditing. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion on the financial statements for the Parent Company and the Group.

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#### Opinion

In our opinion, the financial statements of PCI Biotech Holding ASA have been prepared in accordance with laws and regulations and present fairly, in all material respects, the financial position of the Parent Company and the Group as at 31 December 2015 and their financial performance and cash flows for the year then ended in accordance with the International Financial Reporting Standards as adopted by the EU.

#### Report on other legal and regulatory requirements

Opinion on the Board of Directors' report and on the statements on corporate governance and corporate social responsibility

Based on our audit of the financial statements as described above, it is our opinion that the information presented in the Directors' report and in the statements on corporate governance and corporate social responsibility concerning the financial statements, the going concern assumption and the proposal for the allocation of the result is consistent with the financial statements and complies with the law and regulations.

# Opinion on registration and documentation

Based on our audit of the financial statements as described above, and control procedures we have considered necessary in accordance with the International Standard on Assurance Engagements (ISAE) 3000, «Assurance Engagements Other than Audits or Reviews of Historical Financial Information», it is our opinion that the Board of Directors and Chief Executive Officer have fulfilled their duty to ensure that the Company's accounting information is properly recorded and documented as required by law and generally accepted bookkeeping practice in Norway.

Oslo, 11 April 2016 ERNST & YOUNG AS

Per-pyvind Borge-Hansen

State Authorised Public Accountant (Norway)

A member film of Error & Young Classo Control

# OTHER INFORMATION

# **DEFINITIONS AND GLOSSARY**

PCI: Photochemical internalization SAC: Scientific Advisory Committee

ENHANCE: Name of PCI Biotech's Phase II head & neck study

PFS: Progression free survival

FDA: US Food and Drug Administration R&D: Research and development

In vitro: Studies performed with cells or biological molecules studied outside their normal biological

context; for example proteins are examined in solution, or cells in artificial culture medium.

In vivo: Studies in which the effects of various biological entities are tested on whole,

living organisms usually animals.

# **FINANCIAL CALENDAR**

First quarter 2016 report
Ordinary general meeting 2016
Presentation of first half year 2016
Third quarter 2016 report

3 May 2016 19 May 2016 30 August 2016 22 November 2016

#### **INVESTOR CONTACT**

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#### FORWARD LOOKING STATEMENTS

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

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