PCI Biotech Holding ASA - Fourth Quarter 2011 and preliminary full year 2011 Report

Highlights

- **Completion of Phase I/II study of Amphinex®**
- **Design of Phase II study determined after extensive expert and regulatory consultation**
- **CHMP opinion that Amphinex should be developed as single product rather than a combination pack**
- **CE mark for the PCI 652nm medical laser, with PCI Biotech approved as manufacturer and supplier**
- **Positive pre-clinical efficacy results with 3 widely used cancer drugs: docetaxel, gemcitabine and erlotinib**
- **NOK 10.85 million awarded in BIA grant from The Research Council of Norway**
- **Winner of DNB's 2011 Innovation prize**

* * *

Operational Review

Progress in development programs

PCI Biotech Holding ASA (PCI Biotech) is an oncology-focused company developing products for localised cancer treatment. The products are based on PCI Biotech's patented drug-delivery technology, photochemical internalization (PCI), which can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells.

Amphinex® in combination with bleomycin, Head & Neck cancer

PCI Biotech's lead candidate is the photosensitiser Amphinex® that is developed to be used in combination with the generic cytotoxic agent bleomycin. A Phase I/II study of Amphinex® in combination with bleomycin in cancer patients has been completed at University College Hospital (UCH) in London. The study was a dose escalation study, and the primary objective was to assess the maximum tolerated dose of Amphinex®. Secondary objectives included determination of the antitumour activity of the PCI treatment, as well as pharmacokinetics of Amphinex®.

A total of 19 patients were treated in the Phase I/II study, 14 in the dose escalation part and 5 additional patients at a selected therapeutic dose. Strong response to treatment was seen in all patients. Amphinex® seems to be well tolerated and no serious product related adverse events have been reported, other than photosensitivity.

Next clinical study

Development of Amphinex® in combination with bleomycin will initially be targeted towards patients with recurrent head & neck cancer (H&N) without distant metastases and not suitable for surgery or radiotherapy. This patient population constitutes the majority of the H&N recurrence patients and

approximately 20% of all H&N patients. It has been decided to run a multicentre single arm Phase II study in approximately 70-80 patients. Progression free survival at 6 months is the primary endpoint. Patient inclusion will be in 2012 and 2013. The company has prioritized extensive discussions with the investigators and other H&N cancer experts to optimize the study protocol. Consequently, the final design of the Phase II study has taken somewhat longer than anticipated. Inclusion of the first patient is expected in Q1 2012.

The study will initially run at University College Hospital (UCH) in London, UK, National Center for Tumor Diseases (NCT) in Heidelberg, Germany, Ludwig Maximilian University Munich, Germany, The Netherlands Cancer Institute in Amsterdam, Netherlands and Centre Alexis Vautrin (CAV)-Nancy Université, France, all highly respected cancer institutes. Further hospitals in countries where the study protocol is already approved are being approached and will be considered for site selection in order to ensure rapid patient inclusion.

The possibility to file a Marketing Authorisation Application (MAA) based on the Phase II results will be explored with the EMA if the strong tumour response observed in the Phase I/II study is carried forward in the target patient group of the planned Phase II study.

The lowest dose used in the Phase I/II study has been chosen for further development based on the results of the Phase I/II study and a market assessment. Doses below this level will be studied in an extension study to the Phase I/II trial, to further investigate the therapeutic effect in the lower dose range. The extension study will be performed at University College Hospital (UCH) in London, and will include up to 9 patients. It has taken time to get all necessary approvals to start this study. Inclusion of the first patient is expected in Q1 2012.

Prototyped, produced and received CE marking for the PCI 652nm medical laser

In January 2012, PCI Biotech received CE marking for its PCI 652nm laser as a medical device. PCI Biotech is approved as manufacturer and supplier of the laser. The approvals have been issued by the notifying body NEMKO, Norway.

The laser is specially designed for use with PCI and has 6 channels for simultaneous interstitial illumination and 1 channel for superficial illumination. The laser will be used in the Phase II study of Amphinex®.

Regulatory strategy for Amphinex® in Europe

In October PCI Biotech received a response from The Committee for Medicinal Products for Human Use (CHMP) in European Medicines Agency (EMA) about the development of combination packs. It is the CHMP's opinion that Amphinex® should be developed as a single product for use with bleomycin rather than a combination pack with bleomycin for the head & neck cancer indication. The CHMP opinion has provided a clear regulatory development route for Amphinex®, where Amphinex® will be developed as a stand alone agent, used in combination with different cancer drugs.

The opinion has no direct impact on the design of the clinical development programme for head & neck cancer.

It is not yet clear how the US Food and Drug Administration (FDA) will relate to this issue.

Other cancer indications

With the promising results from the completed Phase I/II study at UCH the company has accelerated the process to identify additional cancer indications where the PCI technology could potentially meet a need of improved local cancer control. The pre-clinical studies performed have led to the identification and selection of three additional drugs for further evaluation, i.e. docetaxel, erlotinib and gemcitabine. All three drugs are well established and important tools for the medical oncologists. The indications encompassed by the use of these drugs include large cancer diseases, such as lung, pancreas, prostate, breast and ovarian cancer. Docetaxel and gemcitabine are both widely used generic drugs, while erlotinib (Genentech, OSI Pharmaceuticals, Roche) is still on patent. PCI Biotech aims to start 1-2 clinical Proof of Concept studies during 2012-2013 with Amphinex® used in combination with 1-2 of these drugs.

PCI for vaccination – initiated pre clinical program as part of BIA grant
The Research Council of Norway has awarded PCI Biotech NOK 10.85 million in a BIA (Brukerstyrt Innovasjonsarena) grant for the project "Immunological effects of photochemical internalization – local treatment of cancer with metastasis". The project is planned to run for 3 years, and started during Q3 2011.

The project goal is to document that PCI Biotech's technology photochemical internalization (PCI) induces immunological mechanisms in cancer treatment, and to develop a treatment regime for optimal use of this mechanism. As part of the project, PCI Biotech has initiated a program to investigate the use of PCI with vaccines. The first set of results performed at NTNU in Norway indicates a good technical fit for PCI within this area. The strategy is to establish proof-of-principle for both in vivo and ex vivo vaccination, with early focus on in vivo experiments. Depending on the results, the company may seek partners for further development of PCI for vaccines. The initial experiments will be performed at University Hospital Zürich, Switzerland and results from these initial experiments are expected in 2012.

Financial Review

Results 4th Quarter 2011
The company received grants from Norway and EU and these are shown as revenues. Grants in the quarter were NOK 2.8 million compared with NOK 1.7 million in Q4 2010.

R&D costs in Q4 2011 were NOK 6.9 million compared with NOK 4.3 million in Q4 2010. Costs to external partners and hospitals on pre-clinical and clinical trials were higher in the quarter due to preparations for the Phase II clinical study.

G&A costs in Q4 2011 were NOK 0.7 million compared with NOK 2.5 million in Q4 2010. Costs for provisions for social security costs related to share options were NOK 0.9 million higher in Q4 2010 than in Q4 2011.

Total operating costs were NOK 7.6 million in Q4 2011, compared with NOK 6.8 million in Q4 2010.

Operating results were NOK -4.8 million in Q4 2011 compared with NOK -5.1 million in Q4 2010.

Net cash flow from operations was NOK -3.7 million in Q4 2011, compared with NOK -0.6 million in Q4 2010. Net cash flow in the quarter was NOK -3.7 million compared with NOK -0.6 million in Q4 2010.

Results FY 2011
Total revenues FY 2011 were NOK 7.4 million compared with NOK 10.4 million FY 2010. Total grants were NOK 6.2 million, in line with 2010. Other income was NOK 1.2 million compared with NOK 4.2 million in 2010. Revenues in 2010 were affected by a NOK 4.1 million settlement from an undisclosed supplier following a production error.

R&D costs in 2011 were NOK 22.5 million compared with NOK 20.2 million in 2010. G&A costs in 2011 were NOK 2.3 million compared with NOK 6.5 million in 2010. Costs for provisions for social security costs related to share options were NOK 3.1 million higher in 2010 than in 2011.

Total costs were NOK 24.4 million in 2011, compared with NOK 26.7 million in 2010.

Operating results were NOK -17.1 million in 2011 compared with NOK -16.2 million in 2010.

Net cash flow from operations was NOK -15.7 million in 2011, compared with NOK -8.3 million in 2010. Net cash flow was NOK -15.7 million compared with NOK 75.0 million in 2010. Cash flow in 2010 was affected by net proceeds from a rights issue of NOK 83.3 million.

Balance
The company held cash and cash equivalents of NOK 95.1 million at the end of the year. Total equity was NOK 92.5 million compared with NOK 105.4 million at the end of 2010. The change in equity reflects the loss in the period.

Outlook
PCI Biotech will continue to focus on the clinical development of Amphinex® in combination with bleomycin and other drugs for localised cancer treatment, based on the company's unique drug delivery platform.

The main priority is to effectively develop Amphinex in combination with bleomycin. The main focus in 2012 is to start and secure a rapid patient inclusion in the Phase II clinical study in head & neck cancer patients

A second priority is to progress the development of Amphinex® in combination with 1-2 of the newly identified cancer drugs and initiate clinical proof of concept studies in 2012/2013.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Note	Q4 2011	Q4 2010	01.01-31.12 2011	01.01-31.12 2010
Other Income		**2 765**	**1 741**	**7 423**	**10 444**
Research and development expenses		6 913	4 344	22 226	20 185
General and administrative expenses		667	2 488	2 273	6 502
Operating costs		**7 580**	**6 832**	**24 499**	**26 687**
OPERATING RESULT		**(4 815)**	**(5 091)**	**(17 076)**	**(16 243)**
Financial income and expenses					
Financial income		896	972	3 350	2 308
Financial expenses		(20)	(11)	(23)	(5)
Net financial result		**876**	**961**	**3 327**	**2 303**
ORDINARY PROFIT BEFORE TAXES		**(3 939)**	**(4 130)**	**(13 749)**	**(13 940)**
Tax on ordinary result	10	0	0	0	0
Net profit/loss	4	**(3 939)**	**(4 130)**	**(13 749)**	**(13 940)**
Other comprehensive income		0	0	0	0
Comprehensive income		**(3 939)**	**(4 130)**	**(13 749)**	**(13 940)**

BALANCE SHEET

(In NOK '000)	Note	31.12.2011	31.12.2010
Fixed and Intangible Assets			
Intangible assets	8	0	0
Operating assets	9	17	78
Total fixed and intangible assets		**17**	**78**
Current Assets			
Short term receivables	7	5 033	3 649
Cash & cash equivalents		95 115	110 814
Total current assets		**100 148**	**114 463**
Total assets		**100 165**	**114 541**
Shareholders equity and liabilities			
Shareholders equity			
Paid in capital	12	189 148	188 477
Other reserves		-96 615	-83 054
Total equity	11	**92 533**	**105 423**
Trade debtors		2 168	2 047
Other short term debt		5 464	7 071
Total short term debt		**7 632**	**9 118**
Total debt		7 632	9 118
Total shareholders equity and liabilities		**100 165**	**114 541**

CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	Note	Paid in capital	Other paid in capital/ reserves	Retained earnings	Total
Balance at 1 January 2009		**16 249**	**88 451**	**-55 399**	**49 301**
Share option scheme	12	-	791	-	791
Write down of reserves		-	-88 036	88 036	-
Comprehensive income in the period		-	-	-15 015	-15 015
Balance at 31 December 2009		**16 249**	**1 206**	**17 622**	**35 077**
Issue of shares, net of share issue cost	12	6 750	76 524	-	83 274
Share option scheme	11	-	1 012	-	1 012
Comprehensive income in the period		-	-	-13 940	-13 940
Balance at 31 December 2010		**22 999**	**78 742**	**3 682**	**105 423**
Share option scheme	11	-	861	-	861
Comprehensive income in the period		-	-	-13 749	-13 749
Balance at 31 December 2011		**22 999**	**79 603**	**-10 067**	**92 533**

CASH FLOW

(In NOK '000)	Note	Q4 2011	Q4 2010	01.01-31.12 2011	01.01-31.12 2010
Ordinary profit before taxes		-3 939	-4 130	-13 749	-13 940
Depreciation, Amortization and Write Off		12	17	61	102
Share options		190	317	861	1 012
Net financials		-876	-961	3 327	2 303
Changes in working capital		54	3 225	-2 872	4 543
Cash flow from operations		-4 559	-1 532	-12 372	-5 980
Net financials		876	961	-3 327	-2 303
Taxes paid		-	-	-	-
Net cash flow from operations		-3 683	-571	-15 699	-8 283
Cash flow from investments					
Purchase of tangible assets		-	-	-	-
Purchase of intangible assets		-	-	-	-
Net cash flow from investments		-	-	-	-
Cash flow from financial activities					
Net proceeds from share issues	12	-	-	-	83 274
Net cash flow from financial activities		-	-	-	83 274
Net change in cash during the period		-3 683	-571	-15 699	74 991
Cash and cash equivalents at the beginning of the period		98 798	111 385	110 814	35 823
Cash and cash equivalents at the end of the period		95 115	110 814	95 115	110 814

Selected explanatory notes:

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA, the 100 percent owned subsidiary PCI Biotech AS and the Islandic Branch PCI Biotech Utibu. PCI Biotech AS was a subsidiary of Photocure ASA until June 2008. The company is headquartered at Lysaker, Norway.

PCI Biotech has developed a unique and patented photochemical drug delivery technology for use in cancer therapy and other diseases. The company collaborates closely with The Norwegian Radium Hospital in Oslo, Norway and receives substantial funding on several projects from the Norwegian Research Council, Innovation Norway and the EU. The company has an extensive international collaboration network with recognised drug delivery expert groups. PhotoChemical Internalisation (PCI) is a technology for light-directed drug delivery by triggered endosomal release and was developed to introduce therapeutic molecules in a biologically active form specifically into diseased cells.

The PCI technology has potential to improve the effect both of existing drugs and new classes of drugs, such as gene therapy and other therapies based on nanotechnology or on biotechnological principles. The company's objective is to prove the clinical usefulness of the technology with different drugs and subsequently license out the technology to partners for further development and marketing. Revenues will be generated at the time of partnering and onwards from up-front payments, milestone payments and royalties from licensees. PCI Biotech focuses on the development of technology and products for the delivery of marketed drugs and drugs in development. During the third quarter 2009, the first cancer patients received treatment in a Phase I/II trial with the patented lead candidate Amphinex® in combination with the cytotoxic agent bleomycin (PC-A11). The trial was completed at University College Hospital (UCH) in London during Q2 2011. The study has primarily enrolled patients with Head & Neck cancer, a disease with local control issues that the PCI technology could potentially contribute to solve.

The PCI Biotech shares have been listed on the Oslo Axess since 18 June 2008 under the ticker PCIB.

2. Basis of presentation

These Interim Financial Statements should be read in conjunction with the Consolidated Financial Statements for the year ended 31 December 2010 (hereafter 'the Annual Financial Statements'), as they provide an update of previously reported information. They were approved for issue by the Board of Directors on 28 February 2011. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the Interim Financial Statements is consistent with the Annual Financial Statements. The interim report has not been subject to an audit. The board of directors approved the interim condensed financial information on 6 February 2012. The Annual Accounts for 2011 will be approved at the Annual General Meeting on 25 April 2012.

3. Summary of significant accounting policies

The accounting policies applied and the presentation of the interim condensed consolidated financial information is consistent with the consolidated financial statements for the year ended 31 December 2010.

The new standards, interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2011 and that could affect the PCI Biotech are discussed in accounting policies, part 3, to the consolidated financial statements for 2010. In the 2010 financial statements, PCI Biotech made evaluations that none of these are expected to have significant effect for PCI Biotech.

4. Earnings per share

Earnings per share:

	Q4 2011	Q4 2010	FY 2011	FY 2010
Result allocated to shareholders (in NOK '000)	(3 939)	(4 130)	(13 749)	(13 940)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666	6 609
Earnings per share (NOK per share)	-0,51	-0,54	-1,79	-2,11

Diluted earnings per share:

	Q4 2011	Q4 2010	FY 2011	FY 2010
Result allocated to shareholders (in NOK '000)	(3 939)	(4 130)	(13 749)	(13 940)
Weighted average of outstanding shares (in '000)	8 389	8 307	8 389	7 136
Earnings per share (NOK per share)	-0,51	-0,54	-1,79	-2,11

Weighted average of outstanding diluted shares is weighted number of average shares adjusted with share options. Earning per share is not affected by the dilution if negative results in the period.

5. Segment information

The company reports only one segment.

The Company's revenues are not influenced by any cyclicality of operations.

6. Related party transactions

PCI Biotech is relying on services provided by third parties, included related parties, as a result of its organisational set-up. PCI Biotech considers that its business relationship with Radiumhospitalets Forskningsstiftelse and legal services provided by Board member Theresa Comiskey Olsen represents related party transactions. The following table shows the extent of such transactions in the reported periods (all figures in NOK '000):

Purchase of services	Q4 2011	Q4 2010	FY 2011	FY 2010
Radiumhospitalets Forskningsstiftelse	470	994	1 947	2 427
Theresa Comiskey Olsen	17	17	92	92

At the end of the quarter, PCI Biotech held NOK 297,000 in short term debt to Radiumhospitalets Forskningsstiftelse and NOK 21,000 to Theresa Comiskey Olsen.

7. Credit risk, foreign currency risk and interest risk

Credit risk

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

Maturity profile on receivables as per 31 December:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	352			352
Other receivables	4 681	-	-	4 681
Total receivables	**5 033**	**-**	**-**	**5 033**

Foreign currency risk
PCI Biotech has transactional currency exposure arising from sales and purchases in currencies other than the functional currency (NOK). PCI Biotech has not implemented any hedging strategy to reduce currency risk.

Interest risk
PCI Biotech has no interest bearing debt. At year end, NOK 87 million of the cash was placed at a fixed interest account of 3.3% p.a. The fixed interest matures 15 February 2012.

8. Intangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2011	2010	2011	2010
Carrying value at the beginning of the period	**-**	**-**	**-**	**27**
Additions				-
Amortization in the period				-27
Carrying value at the end of the period	**-**	**-**	**-**	**-**

9. Tangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2011	2010	2011	2010
Carrying value at the beginning of the period	**29**	**95**	**78**	**153**
Additions				
Depreciation in the period	-12	-17	-61	-75
Carrying value at the end of the period	**17**	**78**	**17**	**78**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 32.7 million in non-capitalised deferred tax assets.

11. Share options

No share options have been granted in 2011.

Costs related to the share options granted in 2008, 2009 and 2010 were NOK 0.2 million in the fourth quarter and NOK 0.9 million in 2011.

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

Expiry date	Exercise price in NOK per share	Number of shares 31.12.2011	30.09.2010
2013 - Q4	19.02	255 000	255 000
2014 - Q4	6.47	234 000	234 000
2015 - Q4	37.24	115 000	0
Total		**604 000**	**489 000**

12. Rights Issue

On 23 April 2010, the Board of Directors PCI Biotech Holding ASA proposed to strengthen the company's equity by NOK 90 million through a rights issue of 2,250,000 shares with pre-emptive subscription rights for existing shareholders. The rights issue was guaranteed fully subscribed. The subscription price in the rights issue was NOK 40 per share. The rights issue was approved in an extraordinary general meeting on 18 May 2010 and was completed during May and June. The rights issue was registered in Companies Registry on 21 June 2010.

Gross proceeds from the rights issue were NOK 90 million. Net proceeds were NOK 83.3 million.

The share capital was increased with NOK 6,750,000 distributed on 2,250,000 new shares. The new share capital is NOK 22,999,170, divided into 7,666,390 shares, each with a par value of NOK 3. One share provides for the right to cast one vote at the general meeting.

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

To the best of PCI Biotech's knowledge, there have been no events subsequent to the end of the reported interim period that would influence the financial statements included in this report.