PCI Biotech Holding ASA - Fourth Quarter 2010 and preliminary full year 2010 Report

Highlights

- **Completed dose escalation, selected clinical dose, and commenced inclusion of the last patients at selected clinical dose in the PC-A11 Phase I/II study**
- **Planning of the confirmatory Phase II/III study of PC-A11 is proceeding in dialogue with European Medicines Agency (EMA), with the aim to start the study in 2011**
- **Identified additional indications & combination products, and initiated preclinical efficacy studies to select combinations for clinical Proof of Concept studies**
- **Produced and released Amphinex® product of the new formulation sufficient for next clinical trials**

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Operational Review

Progress in development programs

PCI Biotech Holding ASA ("PCI Biotech") is an oncology-focused company developing combination 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.

PC-A11 Head & Neck cancer

PCI Biotech's lead candidate is the combination product PC-A11, i.e. Amphinex® in combination with the generic cytotoxic agent bleomycin. A Phase I/II study of PC-A11 in cancer patients is ongoing at University College Hospital (UCH) in London. The study is a dose escalation study, and the primary objective is to assess the maximum tolerated dose of the new component Amphinex®. Secondary objectives include determination of the antitumour activity of the PC-A11 treatment, as well as pharmacokinetics of the Amphinex® component.

A total of 14 patients were treated in the dose escalation part of the Phase I/II study. Thirteen patients completed the first efficacy assessment and 8 completed the second efficacy assessment (4 weeks and at least 8 weeks after treatment, respectively). The other patients were withdrawn from the study either due to the need of other treatment (4 patients) or poor general performance status (2 patients). Strong response to treatment was seen in all patients, with complete regression of target tumours in 85% (11 of 13) of the patients completing the first assessment and in 5 of the 8 patients completing the second assessment.

Head and Neck Squamos Cell Carcinoma (HNSCC) is the primary target population for further development of PC-A11, and 9 of the 14 patients in the Phase I/II study were HNSCC. Eight of these patients completed the first efficacy assessment and 5 completed the second efficacy assessment. Complete regression of target tumours were seen in 87.5% (7 of 8) of the HNSCC patients completing the first assessment and in 4 of the 5 patients completing the second assessment.

The primary objective of the Phase I/II study, dose limiting toxicity, was reached at the fourth dose level by the appearance of skin photosensitivity and significant ulceration of normal tissue in the

treated areas. Apart from the photosensitivity observed at the fourth dose level, nine serious adverse events have been recorded; however none of these were deemed drug-related by the investigator.

The investigators at University College Hospital (UCH) in London have observed an apparent high specificity for cancer cells using the PCI treatment with PC-A11. Tumours of very different depths have been treated and there seems to be a therapeutic window where mainly the cancer cells are killed by the treatment, leaving the healthy tissue underneath the tumour largely unaffected. This was also confirmed when one patient with a tumour under the skin was effectively treated with superficial illumination without ulceration of the skin.

To complete the Phase I/II study, up to 6 additional patients will be treated at the selected therapeutic dose. Inclusion of these patients started in 2010, and by year end, 2 additional patients had been treated. Due to internal issues at UCH, inclusion of this last patient group was slow in 2010 and will therefore continue in 2011, with the aim to primarily include Head and Neck cancer patients.

In parallel with completion of the ongoing Phase I/II study the company is preparing for a confirmatory Phase II/III study of PC-A11 in Head and Neck cancer patients. The clinical trial applications for the confirmatory Phase II/III study will be based on an interim report of the patients in the four dose groups already completed, and is thus not dependent on the inclusion of the last patients. A Protocol Advisory Board with internationally renowned experts representing all disciplines involved in the treatment of this patient group has been established. The aim is to ensure optimal design of the PC-A11 Phase II/III study and at the same time create awareness of this product in the clinical community. The company also has ongoing discussions with European Medicines Agency (EMA) regarding the study design for this trial and several important questions have already been discussed. Some important questions, such as primary and secondary endpoints, are still up for discussion, and interaction with EMA on the study design will continue in 2011. Number of patients, sites and timelines will be determined after the discussion with EMA is finished.

Based on the feedback from EMA the company is planning interactions with the US Food and Drug Administration (FDA), and US consultants have been engaged to support the company through this process.

The company also has initiated some new pre-clinical trials of Amphinex® and PC-A11, e g a trial in pet dogs with cancer at the Norwegian School of Veterinary Science (NVH). These trials will provide useful information for the further development of PC-A11.

Other cancer indications
With the promising results from the ongoing Phase I/II study at UCH the company has accelerated the process to identify other cancer indications where the PCI technology could potentially meet a need of improved local cancer control. Pre-clinical studies with selected new product combinations are ongoing at an internationally well known Contract Research Organisation (CRO). The company aims to start 1-2 clinical Proof of Concept studies during 2011/2012. In addition, the company is currently discussing investigator initiated PCI-studies with some investigators.

PCI Biotech has pre-clinical studies ongoing for the use of Photochemical Internalisation (PCI) with PC-A22, i.e. Amphinex® in combination with the generic cytotoxic agent epirubicin, for treatment of bladder cancer. Results from the pre-clinical studies were reported in the Q2 2010-report. The results are not conclusive and indicate a lack of significant treatment effects at the applied conditions. Further experimental pre-clinical studies with altered dosing conditions are being performed at Norwegian University of Science and Technology (NTNU) in Trondheim, Norway. These studies have to be completed before the company can decide whether to proceed with the bladder cancer indication.

Production of Amphinex®
PCI Biotech has developed a new and improved formulation of Amphinex®. Bridging studies between the old and new formulation are completed, and all future clinical trials will be done with the new formulation of Amphinex®.

In 2010, the company invested in production of a large stock of Active Pharmaceutical Ingredients (API) for Amphinex®. 2,000 vials of Amphinex® based on the new formulation were released during

Q4 2010. With these investments, PCI Biotech has enough product to complete the planned Phase II/III study and additional Proof of Concept studies.

Rights Issue

On 23 April 2010, the Board of Directors of 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, being ~50% oversubscribed. 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.

Financial Review

Results 4th Quarter 2010

The company receives grants from Norway and EU and these are shown as revenues. Grants in the quarter were NOK 1.7 million compared with NOK 2.4 million in Q4 2009.

R&D costs in Q4 2010 were NOK 4.3 million, compared with NOK 5.2 million in Q4 2009. Costs to external partners and hospitals on pre-clinical and clinical trials were moderate in the quarter.

G&A costs in Q4 2010 were NOK 2.5 million compared with NOK 1.3 million in Q4 2009. Costs in the quarter were affected by a NOK 0.7 million increase in the provision for social security costs related to the share options. The increased cost of share options is caused by the increase in the share price during the quarter.

Total operating costs were NOK 6.8 million in Q4 2010, compared with NOK 6.4 million in Q4 2009.

Operating results were NOK -5.1 million in Q4 2010 compared with NOK -4.0 million in Q4 2009.

Net cash flow from operations was NOK -0.5 million in Q4 2010, compared with NOK -3.5 million in Q4 2009. Net cash flow in the quarter was NOK -0.5 million compared with NOK -3.5 million in Q4 2009.

Results FY 2010

In July 2010 PCI Biotech settled with and received NOK 4.1 million from an undisclosed supplier following a production error. The received settlement is booked as revenues. Total revenues in year were NOK 10.4 million compared with NOK 8.6 million in the year 2009.

R&D costs in 2010 were NOK 20.2 million, compared with NOK 19.3 million in 2009. G&A costs in 2010 were NOK 6.5 million compared with NOK 7.0 million in 2009.

Operating results were NOK -16.2 million in 2010 compared with NOK -17.7 million in 2009.

Net cash flow from operations was NOK -8.3 million in 2010, compared with NOK -14.2 million in 2009. Net cash flow was NOK 75.0 million compared with NOK -14.3 million 2009. Cash flow in 2010 was affected by net proceeds from the rights issue of NOK 83.3 million.

Balance

The company held cash and cash equivalents of NOK 110.8 million at the end of the year. A large proportion of the cash equivalents is placed in Norwegian money market funds with approximately 3 months maturity. Total equity was NOK 105.4 million compared with NOK 35.1 million at the end of 2009. The change in equity reflects the loss in the period and NOK 83.3 million in net proceeds from the rights issue completed in June 2010.

Outlook

PCI Biotech will continue to focus on clinical studies for PC-A11 and the development of new combination products with Amphinex® for localised cancer treatment, based on the company's unique drug delivery platform.

The priority is to effectively progress PC-A11:

- Complete the ongoing Phase I/II clinical study at University College Hospital in London,
- Complete formal scientific advice process with the European Medicines Agency (EMA) and initiate regulatory discussions with the Food and Drug Administration (FDA) in the US,
- Initiate a Phase II/III study in head & neck cancer patients in 2011

A second priority is to complete the preclinical efficacy studies of newly identified product combinations and indications, and initiate further clinical proof of concept studies in 2011/12 based on the results of these studies.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Q4 2010	Q4 2009	01.01-31.12 2010	01.01-31.12 2009
Other Income	**1 741**	**2 395**	**10 444**	**8 612**
Research and development expenses	4 344	5 150	20 185	19 319
General and administrative expenses	2 488	1 263	6 502	6 979
Operating costs	**6 832**	**6 413**	**26 687**	**26 298**
OPERATING RESULT	**(5 091)**	**(4 018)**	**(16 243)**	**(17 685)**
Financial income and expenses				
Financial income	972	437	2 308	2 838
Financial expenses	(11)	(24)	(5)	(167)
Net financial result	**961**	**413**	**2 303**	**2 671**
ORDINARY PROFIT BEFORE TAXES	**(4 130)**	**(3 605)**	**(13 940)**	**(15 015)**
Tax on ordinary result	0	0	0	0
Net profit/loss	**(4 130)**	**(3 605)**	**(13 940)**	**(15 015)**
Other comprehensive income	0	0	0	0
Comprehensive income	**(4 130)**	**(3 605)**	**(13 940)**	**(15 015)**

BALANCE SHEET

(In NOK '000)	Note	31.12.2010	31.12.2009
Fixed and Intangible Assets			
Intangible assets	8	0	27
Operating assets	9	78	153
Total fixed and intangible assets		**78**	**181**
Current Assets			
Short term receivables	7	3 649	5 017
Cash & cash equivalents		110 814	35 823
Total current assets		**114 463**	**40 840**
Total assets		**114 541**	**41 021**
Shareholders equity and liabilities			
Shareholders equity			
Paid in capital	12	188 477	105 108
Other reserves		-83 054	-70 031
Total equity	11	**105 423**	**35 077**
Trade debtors		2 047	2 557
Other short term debt		7 071	3 387
Total short term debt		**9 118**	**5 944**
Total debt		9 118	5 944
Total shareholders equity and liabilities		**114 541**	**41 021**

CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	**Paid in capital**	**Other paid in capital/ reserves**	**Retained earnings**	**Total**
Balance at 1. January 2008	**323**	**20 120**	**-15 203**	**5 240**
Establishment of Group	884	27 912	-28 821	-25
Capitalization issue	6 042	-6 042	-	-
Share issue	9 000	51 000	-	60 000
Share issue - costs		-4 954	-	-4 954
Share option scheme	-	415	-	415
Comprehensive income in the period	-	-	-11 375	-11 375
Balance at 31 December 2008	**16 249**	**88 451**	**-55 399**	**49 301**
Balance at 31 December 2008	16 249	88 451	-55 399	49 301
Changes in acounting principles		-	-	-
Balance at 1 January 2009	**16 249**	**88 451**	**-55 399**	**49 301**
Share option scheme	-	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	6 750	76 524	-	83 274
Share option scheme	-	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**

CASH FLOW

(In NOK '000)	**Q4 2010**	**Q4 2009**	**01.01-31.12 2010**	**01.01-31.12 2009**
Ordinary profit before taxes	-4 130	-3 605	-13 940	-15 015
Depreciation, Amortization and Write Off	17	34	102	128
Share options	317	245	1 012	791
Net financials	-961	-413	2 303	-2 258
Changes in working capital	3 225	-168	4 543	-110
Cash flow from operations	-1 532	-3 907	-5 980	-16 464
Net financials	961	413	-2 303	2 258
Taxes paid	-	-	-	-
Net cash flow from operations	-571	-3 494	-8 283	-14 206
Cash flow from investments				
Purchase of tangible assets	-	-	-	-107
Purchase of intangible assets	-	-	-	-6
Net cash flow from investments	-	-	-	-113
Cash flow from financial activities				
Net proceeds from share issues		-	83 274	-
Net cash flow from financial activities	-	-	83 274	-
Net change in cash during the period	-571	-3 494	74 991	-14 319
Cash and cash equivalents at the beginning of the period	111 385	39 317	35 823	50 142
Cash and cash equivalents at the end of the period	110 814	35 823	110 814	35 823

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 both the Norwegian Research Council 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 combination product PC-A11, which contains the patented lead candidate Amphinex®. The trial is performed at University College Hospital (UCH) in London. The study is primarily enrolling 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 2009 (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 22 March 2010. 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 7 February 2011.

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 2009.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2010:

IFRS 3 – Business Combinations (revised)
IAS 27 – Consolidated and Separate Financial Statements (revised)

The amendments to IFRS 3 and IAS 27 did not affect the consolidated accounts for 2010, as no acquisitions were made and no holdings in subsidiaries bought or sold.

4. Earnings per share

Earnings per share:

	Q4 2010	Q4 2009	FY 2010	FY 2009
Result allocated to shareholders (in NOK '000)	(4 130)	(3 605)	(13 940)	(15 015)
Weighted average of outstanding shares (in '000)	7 666	5 416	6 609	5 416
Earnings per share (NOK per share)	-0,54	-0,67	-2,11	-2,77

	Q4 2010	Q4 2009	FY 2010	FY 2009
Result allocated to shareholders (in NOK '000)	(4 130)	(3 605)	(13 940)	(15 015)
Weighted average of outstanding shares (in '000)	8 307	5 828	7 136	5 905
Earnings per share (NOK per share)	-0,54	-0,67	-2,11	-2,77

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, Photocure ASA 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 2010	Q4 2009	FY 2010	FY 2009
Radiumhospitalets Forskningsstiftelse	994	1 016	2 427	2 757
Theresa Comiskey Olsen	17	12	92	50
Photocure ASA	-	52	31	423

At the end of the quarter, PCI Biotech held NOK 453,000 in short term debt to Radiumhospitalets Forskningsstiftelse.

7. Credit risk and foreign currency 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 Q4 2010.

Maturity profile on receivables as per 31 December:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	3 649	-	-	3 649
Total receivables	**3 649**	**-**	**-**	**3 649**

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.

8. Intangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2010	2009	2010	2009
Carrying value at the beginning of the period	**-**	**41**	**27**	**76**
Additions		-		6
Amortization in the period	-	-14	-27	-55
Carrying value at the end of the period	**-**	**27**	**-**	**27**

9. Tangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2010	2009	2010	2009
Carrying value at the beginning of the period	**95**	**173**	**153**	**119**
Additions		-		107
Depreciation in the period	-17	-20	-75	-73
Carrying value at the end of the period	**78**	**153**	**78**	**153**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 27.1 million in non-capitalised deferred tax assets.

11. Share options

In the fourth quarter 2010, a total of 115,000 share options were granted to five employees with an exercise price of NOK 37.24 per share, equal to the average price of the 5 latest days prior to allocation.

The fair value of options granted in Q4 2010 determined using the Black-Sholes valuation model was NOK 2,276,000. The significant inputs into the model were a share price of NOK 37.24 at the grant date, volatility of 103%, dividend yield 0%, an expected option life of three years and an annual risk free rate of 3.00%.

Costs related to the share options were NOK 0.3 million in the fourth quarter and NOK 1.0 million in the year 2010.

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 31.12.2010	31.12.2009
2013 - Q3	19.02	255 000	255 000
2014 - Q3	6.47	234 000	234 000
2015 - Q3	37.24	115 000	0

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 was 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 on the financial statements included in this report.