PCI Biotech Holding ASA - Fourth Quarter 2009 Report

Highlights

- **Successful completion of the second Amphinex® dose group in the clinical study ongoing at University College Hospital (UCH) in London.**
  - **Significant antitumour response reported in all patients.**
  - **No serious drug related adverse reactions have been recorded to date.**

- **Initiated pre-clinical trials for the use of PCI in the treatment of Bladder Cancer**

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Operational Review

Progress in development programs
PCI Biotech Holding ASA is a cancer-focused drug delivery company. The company is developing a patented drug-delivery technology, photochemical internalization (PCI), to enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells.

PCI Biotech has an ongoing phase I/II study of Amphinex® in cancer patients performed at University College Hospital (UCH) in London. The study is a dose escalation study, and the first and second dose levels are now completed and enrolment of patients is well into the third dose group. In the first two dose groups, a total of seven patients have been given a single photochemical internalisation (PCI) treatment of Amphinex® in combination with the cytotoxic agent bleomycin. Strong antitumour response is reported in all patients. One serious adverse event has been recorded, however not deemed drug related by the investigator.

The study can include patients with a range of different cancers and has so far included sarcoma, breast, and head and neck cancer patients. The effectiveness of the PCI treatment seems to be similar across all cancers treated so far, with apparent complete regression of all treated tumours within a few weeks after treatment. These results indicate that the positive pre-clinical results with the PCI technology are transferrable to treatment in humans.

The primary objective of the study is to assess the maximum tolerated dose of Amphinex®, in PCI treatment with bleomycin. Secondary objectives include determination of the antitumour activity of the treatment, as well as the pharmacokinetics of Amphinex®.

PCI Biotech has pre-clinical studies ongoing for the use of Photochemical Internalisation (PCI) in the treatment of Bladder cancer. Bladder cancer is an interesting disease area for the use of the PCI technology. Bladder cancer is the 5th most expensive cancer indication, with the highest average per-patient life-time cost, mainly due to a high recurrence rate. The currently used pharmaceutical treatments have limited effect on recurrence and progression, and there is a large unmet medical need. The bladder is easily accessible for the three

components of the PCI technology: the proprietary photosensitizer Amphinex®, light and a cytotoxic agent.

The studies are being performed at The Norwegian University of Science and Technology (NTNU) in Trondheim, Norway and at Radboud University Nijmegen, Holland. The research at Radboud University is performed at one of the leading urology clinics in Europe under the supervision of Professor Fred Witjes.

PCI Biotech has held several Scientific Advice meetings with European National Health Authorities as well as the European Medicines Agency (EMA) Innovation Task Force. Consistent feedback from the authorities has provided a clear regulatory route to market for PCI-based combination products.

Financial Review

Results 4th Quarter 2009

The company receives grants from Norway and EU. The grants are shown as revenues, and revenues in the quarter were NOK 2.4 million compared with NOK 5.2 million in Q4 2008. The results in Q4 2008 were affected by one off revenues of NOK 3.1 million and one-off costs of NOK 7.8 million due to consolidation effects following the de-merger from Photocure in June 2008. Pro forma revenues without the one-offs were NOK 2.2 million in Q4 2008.

The average number of employees has increased from 4 in Q4 2008 to 9 in Q4 2009 and the company has intensified the R&D on its technology. R&D costs in the fourth quarter were NOK 5.2 million compared with NOK 11.0 million in the fourth quarter 2008. Pro forma R&D costs in Q4 2008 were NOK 5.0 million. Total operating costs were NOK 6.4 million in Q4 2009, compared with NOK 14.4 million in Q4 2008 (pro forma NOK 6.5 million)

Operating results were NOK -4.0 million in Q4 2009 compared with NOK -9.1 million in Q4 2008 (pro forma NOK -4.4 million).

Net cash flow from operations was NOK -3.5 million in Q4 2009, compared with NOK -2.1 million in Q4 2008. Net cash flow in the quarter was NOK -3.5 million compared with NOK -2.2 million in Q4 2008.

Results for the full year 2009

Revenues were NOK 8.6 million for the full year 2009 compared with NOK 7.4 million in 2008. Total costs were NOK 26.3 million in 2009, compared with NOK 19.5 million in 2008.

The cost level in 2009 is affected by an increased activity. R&D costs for the full year 2009 were NOK 19.3 million compared with NOK 14.3 million in 2008. Operating result was NOK -17.7 million for the full year 2009 compared with NOK -12.1 million in 2008.

Net cash flow from operations was NOK - 14.2 million for the full year 2009, compared with NOK -8.5 million in 2008. Net cash flow was NOK -14.3 million compared with NOK 46.4 million in 2008. Cash flow in 2008 was affected by net proceeds from a share issue of NOK 55 million.

Balance

The company held cash and cash equivalents of NOK 35.8 million at the end of 2009. A large proportion of the cash equivalents is placed in Norwegian money market funds with

approximately 3 months maturity. Total equity was NOK 35.1 million compared with NOK 49.3 million at the end of 2008. The change in equity reflects the loss in the period.

Outlook

PCI Biotech will continue to focus on the development of combination products with Amphinex® based on the company's unique drug delivery platform.

The priority is to complete the ongoing clinical study at University College Hospital in London, as well as complete pre-clinical studies performed in various cancers, including bladder. Further clinical studies are planned to be initiated by the end of 2011 based on the results of these studies.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Note	Q4 2009	Q4 2008	01.01-31.12 2009	01.01-31.12 2008
Other Income		**2 395**	**5 235**	**8 612**	**7 367**
Research and development expenses		5 150	10 995	19 319	14 323
General and administrative expenses		1 263	3 369	6 979	5 182
Operating costs		**6 413**	**14 364**	**26 298**	**19 505**
OPERATING RESULT		**(4 018)**	**(9 129)**	**(17 686)**	**(12 138)**
Financial income and expenses					
Financial income		437	759	2 838	992
Financial expenses		(24)	(74)	(167)	(229)
Net financial result		**413**	**685**	**2 671**	**763**
ORDINARY PROFIT BEFORE TAXES		**(3 605)**	**(8 444)**	**(15 015)**	**(11 375)**
Tax on ordinary result	10	0	0	0	0
Net profit/loss	4	**(3 605)**	**(8 444)**	**(15 015)**	**(11 375)**
Other comprehensive income		0	0	0	0
Comprehensive income		**(3 605)**	**(8 444)**	**(15 015)**	**(11 375)**

BALANCE SHEET

(In NOK '000)	Note	31.12.2009	31.12.2008
Fixed and Intangible Assets			
Intangible assets	8	27	76
Operating assets	9	153	120
Total fixed and intangible assets		**181**	**196**
Current Assets			
Short term receivables	7	5 017	4 238
Cash & cash equivalents		35 823	50 142
Total current assets		**40 840**	**54 380**
Total assets		**41 021**	**54 576**
Shareholders equity and liabilities			
Shareholders equity			
Paid in capital		105 108	104 700
Other reserves		-70 031	-55 399
Total equity	11	**35 077**	**49 301**
Trade debtors		2 557	2 728
Other short term debt		3 387	2 547
Total short term debt		**5 944**	**5 275**
Total debt		5 944	5 275
Total shareholders equity and liabilities		**41 021**	**54 576**

CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	Paid in capital	Other paid in capital/ reserves	Translation differences	Retained earnings	Total
Balance at 31 December 2007	323	20 120	-	-15 203	5 240
Changes in acounting principles	-	-		-	-
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**
Issue of shares, net of share issue cost	-	-	-	-	-
Share option scheme	-	791	-	-	791
Translation difference	-	-	-	-	-
Comprehensive income in the period	-	-	-	-15 015	-15 015
Balance at 31 December 2009	**16 249**	**89 242**	**-**	**-70 414**	**35 077**

CASH FLOW

(In NOK '000)	Q4 2009	Q4 2008	01.01-31.12 2009	01.01-31.12 2008
Ordinary profit before taxes	-3 605	-8 444	-15 015	-11 375
Depreciation, Amortization and Write Off	34	21	128	71
Share options	245	275	791	415
Changes in pension funds	-	-	-	24
Other changes	-	-	-	-49
Net financials	-776	-685	-2 258	-763
Changes in working capital	-168	6 069	-110	2 433
Cash flow from operations	-4 270	-2 764	-16 464	-9 244
Net financials	776	685	2 258	763
Taxes paid	-	-	-	-
Net cash flow from operations	-3 494	-2 079	-14 206	-8 481
Cash flow from investments				
Purchase of tangible assets	-	-72	-107	-
Purchase of intangible assets	-	-	-6	-122
Net cash flow from investments	-	-72	-113	-122
Cash flow from financial activities				
Net proceeds from share issues	-	-	-	55 046
Net cash flow from financial activities	-	-	-	55 046
Net change in cash during the period	-3 494	-2 151	-14 319	46 443
Cash and cash equivalents at the beginning of the period	39 317	52 293	50 142	3 699
Cash and cash equivalents at the end of the period	35 823	50 142	35 823	50 142

Selected explanatory notes:

Nature of operation

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA and the 100 percent owned subsidiary PCI Biotech AS. 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 with their drugs. 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 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 2008 (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 26 February 2009. 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. This is the Company's seventh interim report presented in accordance with IAS 34. The same accounting principles have been applied for all reported periods in this report. The board of directors approved the interim condensed financial information on 18 February 2010.

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 2008.

New accounting developments
Management has evaluated the accounting policies according to IFRS and information about new development in IFRS.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2009.

- IAS 1 (revised), 'Presentation of financial statements'.
- IFRS 8, 'Operating segments'. IFRS 8 replaces IAS 14, 'Segment reporting'.

The following new standards, amendments to standards and interpretations are mandatory for the first time for the financial year beginning 1 January 2009, but are not currently relevant for PCI Biotech:

- IAS 23 (amendment), 'Borrowing costs'.
- IFRS 2 (amendment), 'Share-based payment'.
- IAS 32 (amendment), 'Financial instruments: Presentation'.
- IFRIC 13, 'Customer loyalty programmes'.
- IFRIC 15, 'Agreements for the construction of real estate'.
- IFRIC 16, 'Hedges of a net investment in a foreign operation'.
- IAS 39 (amendment), 'Financial instruments: Recognition and measurement'.

The following new standards, amendments to standards and interpretations have been issued, but are not effective for the financial year beginning 1 January 2009 and have not been early adopted:

- IFRS 3 (revised), 'Business combinations' and consequential amendments to IAS 27, 'Consolidated and separate financial statements', IAS 28, 'Investments in associates' and IAS 31, 'Interests in joint ventures',
- IFRIC 17, 'Distributions of non-cash assets to owners', effective for annual periods beginning on or after 1 July 2009.
  IFRIC 18, 'Transfers of assets from customers', effective for transfers of assets received on or after 1 July 2009.

4. Earnings per share

Earnings per share:

	Q4 2009	Q4 2008	FY 2009	FY 2008
Result allocated to shareholders (in NOK '000)	(3 605)	(8 444)	(15 015)	(11 375)
Weighted average of outstanding shares (in '000)	5 416	5 416	5 416	4 031
Earnings per share (NOK per share)	-0,67	-1,56	-2,77	-2,82

Diluted earnings per share:

	Q4 2009	Q4 2008	FY 2009	FY 2008
Result allocated to shareholders (in NOK '000)	(3 605)	(8 444)	(15 015)	(11 375)
Weighted average of outstanding shares (in '000)	5 828	5 416	5 905	4 031
Earnings per share (NOK per share)	-0,67	-1,56	-2,77	-2,82

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 2009	Q4 2008	FY 2009	FY 2008
Radiumhospitalets Forskningsstiftelse	1 016	397	2 757	1 364
Theresa Comiskey Olsen	12	-	50	-
Photocure ASA	52	171	423	474

At the end of the quarter, PCI Biotech held NOK 694,000 in short term debt to Radiumhospitalets Forskningsstiftelse and NOK 10,000 in short term debt to Photocure ASA.

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 2009.

Maturity profile on receivables as per 31 December:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	5 017	-	-	5 017
Total receivables	**5 017**	**-**	**-**	**5 017**

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	
	2009	2008	2009	2008
Carrying value at the beginning of the period	**41**	**90**	**76**	**130**
Additions	-	-	6	-
Amortization in the period	-14	-14	-55	-54
Carrying value at the end of the period	**27**	**76**	**27**	**76**

9. Tangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2009	2008	2009	2008
Carrying value at the beginning of the period	**173**	**55**	**119**	**14**
Additions	-	72	107	122
Depreciation in the period	-20	-7	-73	-16
Carrying value at the end of the period	**153**	**120**	**153**	**120**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 23.1 million in non-capitalised deferred tax assets.

11. Share options

No share options were granted in the fourth quarter.

In the second quarter, a total of 234,000 share options were granted to five employees with an exercise price of NOK 6.80 per share, equal to the average price of the 5 latest days with trading prior to the General Meeting in April 2009.

The fair value of options granted in Q2 determined using the Black-Sholes valuation model was NOK 675,000. The significant inputs into the model were a share price of NOK 6.80 at the grant date, volatility of 82.5%, dividend yield 0%, an expected option life of three years and an annual risk free rate of 3.25%.

Costs related to the share options were NOK 0.2 million in the fourth quarter.

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 31.12.2009	31.12.2008
2013 - Q3	20,00	255 000	210 000
2014 - Q3	6,80	234 000	0

12. 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.