PCI Biotech Holding ASA - Third Quarter 2010 Report

Highlights

- **Successful completion of the fourth dose group in the Amphinex® study with continued strong tumour response. Further dose escalation is not needed.**
- **Received initial feedback from European Medicines Agency (EMA) regarding the study design for the next clinical trial for PC-A11. Based on this initial feedback, the company continues the preparations for a confirmatory Phase II/III study.**
- **Initiated pre-clinical studies to identify new cancer indications for the PCI technology**

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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 has an ongoing Phase I/II study of the combination product PC-A11, i.e. Amphinex® in combination with the generic cytotoxic agent bleomycin, in cancer patients at University College Hospital (UCH) in London. The study is a dose escalation study, and treatment of the patients at the fourth dose level was completed during Q3. The clinical results from the previous dose groups were confirmed also at the fourth dose level, with strong tumour response in all three patients and complete clinical regression of treated tumours observed in two of the patients within a few weeks of treatment.

Significant photosensitivity in normal skin, as well as ulceration of treated areas, were observed in patients at the fourth dose level. The primary objective of the phase I/II study, i.e. dose-limiting toxicity, is thus reached and no further dose escalation is necessary. The ulceration of treated target areas at the fourth dose level has complicated the evaluation of tumour response, but it was concluded that complete clinical regression was achieved in two of the patients. Strong tumour response was reported also in the third patient, but tumour recurrence was observed at the three months follow-up visit.

A total of 14 patients have been treated with PC-A11 across the four completed dose levels. Complete clinical regression of all treated tumours was observed within a few weeks of treatment in 12 of the patients, although one of the 12 patients had tumour recurrence at the three months follow-up visit. One patient died of the underlying disease before level of clinical regression could be assessed and another patient was difficult to assess due to extensive ulceration and was classified as partial response. Patients with osteosarcoma (1) and squamous cell carcinoma (9) of the Head & Neck, adenocarcinoma of the breast (3), and malignant skin adnexal tumour (1) have been included and the effectiveness of the PCI treatment with PC-A11 seems to be similar across all cancers treated so far. The PCI technology could therefore potentially be used for local treatment of several different cancers.

Apart from the photosensitivity observed at the fourth dose level, seven serious adverse events have been recorded; however six of these are not deemed drug-related by the investigator (assessment of seventh pending).

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.

The primary objective of the current study is to assess the maximum tolerated dose of the new component Amphinex® in the PC-A11 product. Secondary objectives include determination of the antitumour activity of the PC-A11 treatment, as well as pharmacokinetics of the Amphinex® component.

To complete the study, 6 additional patients will be treated at the selected therapeutic dose. Inclusion of these patients is expected to be completed in 2010.

Preparation for the next clinical study for PC-A11 is progressing according to plan. The company has received initial feedback from European Medicines Agency (EMA) regarding the study design for the next clinical trial for PC-A11. Based on this initial feedback, the company continues the preparations for a confirmatory Phase II/III study. A final response from EMA is expected in Q4 2010. Based on the initial 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 the process.

PC-A22 Bladder cancer
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 have been received during Q2 and Q3, and as reported in the Q2-report, the results are not conclusive and indicate a lack of significant treatment effects at the applied conditions. Some further experimental pre-clinical studies with altered dosing conditions are required before the company can decide whether to proceed with the bladder cancer indication. These pre-clinical studies are being performed at The Norwegian University of Science and Technology (NTNU) in Trondheim, Norway.

Other cancer indications
With the very promising results from the ongoing Phase I/II study at UCH and the strengthened cash situation, the company has decided to accelerate the process to identify other cancer indications where the PCI technology could potentially meet a need of improved local cancer control. International advisors have been engaged to assess the data from interviews with key opinion leaders and provide market analyses of the opportunities.

Pre-clinical studies within selected indications will be completed as soon as possible with the aim to start 1-2 clinical Proof of Concept studies during 2011/2012. A well known, international Contract Research Organization (CRO) has been selected and the pre-clinical studies are initiated.

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®.

During 1H 2010, the company invested in production of a large stock of Active Pharmaceutical Ingredients (API) for Amphinex®. Formulation of 2,000 vials of Amphinex® based on the new formulation has been done during Q3 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 3rd Quarter 2010

The company receives grants from Norway and EU. The grants are shown as revenues, and grants in the quarter were NOK 1.4 million compared with NOK 2.8 million in Q3 2009. 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 the quarter were NOK 5.6 million compared with NOK 2.8 million in Q3 2009.

R&D costs in Q3 2010 were NOK 4.6 million, compared with NOK 5.1 million in Q3 2009. Costs to external partners and hospitals on pre-clinical and clinical trials were moderate in the quarter.

G&A costs in Q3 2010 were NOK -0.1 million compared with NOK 1.8 million in Q3 2009. Costs in the quarter were affected by a NOK 0.9 million reduction in the provision for social security costs related to the share options. The reduced cost of share options is caused by the decrease in the share price during the quarter.

Total operating costs were NOK 4.5 million in Q3 2010, compared with NOK 6.9 million in Q3 2009.

Operating results were NOK 1.0 million in Q3 2010 compared with NOK -4.1 million in Q3 2009.

Net cash flow from operations was NOK -1.8 million in Q3 2010, compared with NOK -2.5 million in Q3 2009. Net cash flow in the quarter was NOK -1.9 million compared with NOK -2.5 million in Q3 2009.

Results YTD 2010

Revenues were NOK 8.7 million YTD 2010 compared with NOK 6.2 million YTD 2009. Total costs were NOK 19.9 million YTD 2010, in line with YTD 2009.

R&D costs YTD 2010 were NOK 15.8 million, compared with NOK 14.2 million YTD 2009. G&A costs YTD 2010 were NOK 4.0 million compared with NOK 5.7 million YTD 2009.

Operating results were NOK -11.2 million YTD 2010 compared with NOK -13.7 million YTD 2009.

Net cash flow from operations was NOK -7.7 million YTD 2010, compared with NOK -10.7 million YTD 2009. Net cash flow was NOK 75.6 million compared with NOK -10.8 million YTD 2009. Cash flow YTD 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 111.4 million at the end of the quarter. A large proportion of the cash equivalents is placed in Norwegian money market funds with approximately 3 months maturity. Total equity was NOK 109.2 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 in 2010,
- Complete formal scientific advice process with the European Medicines Agency (EMA) in 2010 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 identify new product combinations and indications, and perform pre-clinical studies in various identified cancers. Further clinical studies are planned to be initiated in 2011/12 based on the results of these studies.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Q3 2010	Q3 2009	01.01-30.09 2010	01.01-30.09 2009	01.01-31.12 2009
Other Income	**5 552**	**2 778**	**8 703**	**6 217**	**8 612**
Research and development expenses	4 642	5 110	15 841	14 169	19 319
General and administrative expenses	(120)	1 770	4 014	5 716	6 979
Operating costs	**4 522**	**6 880**	**19 855**	**19 885**	**26 298**
OPERATING RESULT	**1 030**	**(4 102)**	**(11 152)**	**(13 667)**	**(17 686)**
Financial income and expenses					
Financial income	993	785	1 346	2 401	2 838
Financial expenses	(82)	(9)	(4)	(143)	(167)
Net financial result	**911**	**776**	**1 342**	**2 258**	**2 671**
ORDINARY PROFIT BEFORE TAXES	**1 941**	**(3 326)**	**(9 810)**	**(11 410)**	**(15 015)**
Tax on ordinary result	0	0	0	0	0
Net profit/loss	**1 941**	**(3 326)**	**(9 810)**	**(11 410)**	**(15 015)**
Other comprehensive income	0	0	0	0	0
Comprehensive income	**1 941**	**(3 326)**	**(9 810)**	**(11 410)**	**(15 015)**

BALANCE SHEET

(In NOK '000)	Note	30.09.2010	30.09.2009	31.12.2009
Fixed and Intangible Assets				
Intangible assets	8	0	41	27
Operating assets	9	95	173	153
Total fixed and intangible assets		**95**	**214**	**181**
Current Assets				
Short term receivables	7	5 127	4 675	5 017
Cash & cash equivalents		111 385	39 317	35 823
Total current assets		**116 512**	**43 992**	**40 840**
Total assets		**116 607**	**44 206**	**41 021**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital	12	188 477	105 108	105 108
Other reserves		-79 241	-66 671	-70 031
Total equity	11	**109 236**	**38 437**	**35 077**
Trade debtors		1 271	2 177	2 557
Other short term debt		6 100	3 592	3 387
Total short term debt		**7 371**	**5 769**	**5 944**
Total debt		7 371	5 769	5 944
Total shareholders equity and liabilities		**116 607**	**44 206**	**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	-	695	-	695
Comprehensive income in the period	-	-	-9 810	-9 810
Balance at 30 September 2010	**22 999**	**78 425**	**7 812**	**109 236**

CASH FLOW

(In NOK '000)	**Q3 2010**	**Q3 2009**	**01.01-30.09 2010**	**01.01-30.09 2009**	**01.01-31.12 2009**
Ordinary profit before taxes	1 941	-3 326	-9 810	-11 410	-15 015
Depreciation, Amortization and Write Off	19	33	85	94	128
Share options	135	232	695	546	791
Net financials	-911	-776	1 342	-2 258	-2 258
Changes in working capital	-3 940	552	1 318	58	-110
Cash flow from operations	-2 756	-3 285	-6 370	-12 970	-16 464
Net financials	911	776	-1 342	2 258	2 258
Taxes paid	-	-	-	-	-
Net cash flow from operations	-1 845	-2 509	-7 712	-10 712	-14 206
Cash flow from investments					
Purchase of tangible assets	-	-	-	-107	-107
Purchase of intangible assets	-	-	-	-6	-6
Net cash flow from investments	-	-	-	-113	-113
Cash flow from financial activities					
Net proceeds from share issues	-95	-	83 274	-	-
Net cash flow from financial activities	-95	-	83 274	-	-
Net change in cash during the period	-1 940	-2 509	75 562	-10 825	-14 319
Cash and cash equivalents at the beginning of the period	113 325	41 826	35 823	50 142	50 142
Cash and cash equivalents at the end of the period	111 385	39 317	111 385	39 317	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 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. 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 25 October 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 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 the nine months of 2010, as no acquisitions were made and no holdings in subsidiaries bought or sold.

4. Earnings per share

Earnings per share:

	Q3 2010	Q3 2009	FY 2010	FY 2009	FY 2009
Result allocated to shareholders (in NOK '000)	1 941	(3 326)	(9 810)	(11 410)	(15 015)
Weighted average of outstanding shares (in '000)	7 666	5 416	6 252	5 416	5 416
Earnings per share (NOK per share)	0,25	-0,61	-1,57	-2,11	-2,77

	Q3 2010	Q3 2009	FY 2010	FY 2009	FY 2009
Result allocated to shareholders (in NOK '000)	1 941	(3 326)	(9 810)	(11 410)	(15 015)
Weighted average of outstanding shares (in '000)	8 155	5 433	6 017	6 740	5 416
Earnings per share (NOK per share)	0,25	-0,61	-1,57	-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	Q3 2010	Q3 2009	FY 2010	FY 2009	FY 2009
Radiumhospitalets Forskningsstiftelse	140	398	1 433	1 741	2 757
Theresa Comiskey Olsen	18	1	75	38	50
Photocure ASA	-	83	31	371	423

At the end of the quarter, PCI Biotech held NOK 140,000 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 Q3 2010.

Maturity profile on receivables as per 30 September:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	5 127	-	-	5 127
Total receivables	**5 127**	**-**	**-**	**5 127**

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:

	Third quarter		1.1 - 30.09	
	2010	2009	2010	2009
Carrying value at the beginning of the period	-	55	27	76
Additions		-		6
Amortization in the period	-	-14	-27	-41
Carrying value at the end of the period	-	41	-	41

9. Tangible assets

Changes in value:

	Third quarter		1.1 - 30.09	
	2010	2009	2010	2009
Carrying value at the beginning of the period	114	192	153	119
Additions		-		107
Depreciation in the period	-19	-19	-58	-53
Carrying value at the end of the period	95	173	95	173

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 25.9 million in non-capitalised deferred tax assets.

11. Share options

No share options were granted in the first nine months of 2010.

In the second quarter 2009, 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 2009 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 0.1 million in the third quarter and NOK 0.7 million in the first nine months of 2010.

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

	Exercise price in NOK per	Number of shares	
Expiry date	share	30.09.2010	30.09.2009
2013 - Q3	19,02	255 000	255 000
2014 - Q3	6,47	234 000	234 000

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.

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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.