PCI Biotech Holding ASA - First Quarter 2011 Report

Highlights

- **Completed inclusion of patients in the Phase I/II study of PC-A11**
- **Initiated compassionate use of PC-A11 on a named patient basis**
- **Optimal clinical development of PC-A11 in Head & Neck cancer is currently being evaluated, based on feedback from the European Medicines Agency (EMA) and discussions with key opinion leaders**
- **Finalising the initial preclinical efficacy studies to select new product combinations for clinical Proof of Concept studies**

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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 nearing completion 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.

The last patient was included in February 2011, and a total of 19 patients have been treated in the study. Fourteen patients were treated in the dose escalation part of the Phase I/II study and 5 additional patients have been treated at the selected therapeutic dose. Results from the first 14 patients were reported in the Q4 2010 report. Complete results from the last 5 patients will be published as soon as all patients have finished the 3 months follow up.

In parallel with completion of the ongoing Phase I/II study the company is preparing for the next clinical study of PC-A11 in Head and Neck cancer patients. The dialogue with European Medicines Agency (EMA) has been completed, and the optimal clinical development plan for PC-A11 is being planned together with key opinion leaders. Time to marketing approval, market access, pricing, and probability of success are important parameters currently being evaluated..

Based on the feedback from EMA and key opinion leader discussions, the company is planning interactions with the US Food and Drug Administration (FDA). An experienced group of US regulatory consultants has been engaged to support the company through this process.

Other cancer indications
In April 2011, the Norwegian Medicines Agency (NoMA) for the first time approved PC-A11 for compassionate use on a named patient basis at the Norwegian Radium Hospital. NoMA has approved the use of PC-A11 for one specifically named patient with sarcoma cancer. The patient was treated with PC-A11 due to lack of other treatment options.

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 being completed at an internationally renowned 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 performed pre-clinical studies for the use of Photochemical Internalisation (PCI) with bladder instillation of PC-A22, i.e. Amphinex® in combination with the generic cytotoxic agent epirubicin, for treatment of localised bladder cancer. Results from the first pre-clinical studies were reported in the Q2 2010-report. The results were not conclusive and indicated a lack of significant treatment effect at the applied conditions. This has now been confirmed in experimental pre-clinical studies with altered dosing conditions at the Norwegian University of Science and Technology (NTNU) in Trondheim, Norway. No further pre-clinical studies of PC-A22 for treatment of bladder cancer will be performed.

Financial Review

Results 1st Quarter 2011
The company receives grants from Norway and EU and these are shown as revenues. Grants in the quarter were NOK 1.6 million compared with NOK 1.4 million in Q1 2010.

R&D costs in Q1 2011 were NOK 5.0 million, in line with Q1 2010. Costs to external partners and hospitals on pre-clinical and clinical trials have continued to be moderate.

G&A costs in Q1 2011 were NOK 0.6 million compared with NOK 2.2 million in Q1 2010. Costs in 2010 were affected by a significant increase in provision for social security costs related to the share options.

Total operating costs were NOK 5.6 million in Q1 2011, compared with NOK 7.1 million in Q1 2010.

Operating results were NOK -3.2 million in Q1 2011 compared with NOK -5.7 million in Q1 2010.

Net cash flow from operations was NOK -4.5 million in Q1 2011, compared with NOK -3.6 million in Q1 2010. Net cash flow in the quarter was NOK -4.5 million compared with NOK -3.7 million in Q1 2010.

Balance
The company held cash and cash equivalents of NOK 106.3 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 102.5 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 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 in 2011 is to effectively progress PC-A11:
- Complete and report the ongoing clinical study in cancer patients at University College Hospital in London;

- Finalize an optimal clinical development plan for the Head & Neck cancer indication based on feedback from EMA and key opinion leaders, with the aim to start the next clinical study in 2011;
- Initiate regulatory discussions with the Food and Drug Administration (FDA) in the US.

A second priority is to complete the preclinical evaluation 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)	Note	Q1 2011	Q1 2010	01.01-31.12 2010
Other Income		**1 560**	**1 362**	**10 444**
Research and development expenses		5 012	4 856	20 185
General and administrative expenses		587	2 222	6 502
Operating costs		**5 599**	**7 078**	**26 687**
OPERATING RESULT		**(4 039)**	**(5 716)**	**(16 243)**
Financial income and expenses				
Financial income		854	188	2 308
Financial expenses		(13)	0	(5)
Net financial result		**841**	**188**	**2 303**
ORDINARY PROFIT BEFORE TAXES		**(3 198)**	**(5 528)**	**(13 940)**
Tax on ordinary result	10	0	0	0
Net profit/loss	4	**(3 198)**	**(5 528)**	**(13 940)**
Other comprehensive income		0	0	0
Comprehensive income		**(3 198)**	**(5 528)**	**(13 940)**

BALANCE SHEET

(In NOK '000)	Note	31.03.2011	31.03.2010	31.12.2010
Fixed and Intangible Assets				
Intangible assets	8	0	13	0
Operating assets	9	60	134	78
Total fixed and intangible assets		**60**	**147**	**78**
Current Assets				
Short term receivables	7	3 955	4 507	3 649
Cash & cash equivalents		106 274	32 171	110 814
Total current assets		**110 229**	**36 678**	**114 463**
Total assets		**110 289**	**36 825**	**114 541**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital	12	188 757	105 108	188 477
Other reserves		-86 253	-75 280	-83 054
Total equity	11	**102 504**	**29 828**	**105 423**
Trade debtors		560	518	2 047
Other short term debt		7 225	6 479	7 071
Total short term debt		**7 785**	**6 997**	**9 118**
Total debt		7 785	6 997	9 118
Total shareholders equity and liabilities		**110 289**	**36 825**	**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	-	280	-	280
Comprehensive income in the period		-	-	-3 198	-3 198
Balance at 31 March 2011		**22 999**	**79 022**	**484**	**102 504**

CASH FLOW

(In NOK '000)	Note	Q1 2011	Q1 2010	01.01-31.12 2010
Ordinary profit before taxes		-3 198	-5 528	-13 940
Depreciation, Amortization and Write Off		17	33	102
Share options		280	280	1 012
Net financials		-841	-188	2 303
Changes in working capital		-1 639	1 563	4 543
Cash flow from operations		-5 381	-3 840	-5 980
Net financials		841	188	-2 303
Taxes paid		-	-	-
Net cash flow from operations		-4 540	-3 652	-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		-4 540	-3 652	74 991
Cash and cash equivalents at the beginning of the period		110 814	35 823	35 823
Cash and cash equivalents at the end of the period		106 274	32 171	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 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 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 9 May 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 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:

	Q1 2011	Q1 2010	FY 2010
Result allocated to shareholders (in NOK '000)	(3 198)	(5 528)	(13 940)
Weighted average of outstanding shares (in '000)	7 666	7 666	6 609
Earnings per share (NOK per share)	-0,42	-0,72	-2,11

Diluted earnings per share:

	Q1 2011	Q1 2010	FY 2010
Result allocated to shareholders (in NOK '000)	(3 198)	(5 528)	(13 940)
Weighted average of outstanding shares (in '000)	8 389	8 307	7 136
Earnings per share (NOK per share)	-0,42	-0,72	-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	Q1 2011	Q1 2010	FY 2010
Radiumhospitalets Forskningsstiftelse	312	1 016	2 427
Theresa Comiskey Olsen	17	12	92

At the end of the quarter, PCI Biotech held NOK 212,000 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 Q1 2011.

Maturity profile on receivables as per 31 March:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	3 955	-	-	3 955
Total receivables	**3 955**	**-**	**-**	**3 955**

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:

	First quarter	
	2011	**2010**
Carrying value at the beginning of the period	**-**	**27**
Additions		-
Amortization in the period	-	-14
Carrying value at the end of the period	**-**	**13**

9. Tangible assets

Changes in value:

	First quarter	
	2011	**2010**
Carrying value at the beginning of the period	**78**	**173**
Additions		-
Depreciation in the period	-17	-20
Carrying value at the end of the period	**60**	**153**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 29.8 million in non-capitalised deferred tax assets.

11. Share options

No share options were granted in Q1 2011.

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.

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.