PCI Biotech Holding ASA - First Quarter 2012 Report

Highlights

- **Completed all preparations necessary to include patients in the Phase II study in head & neck cancer patients. Screening for patients started at two hospitals**
- **Started inclusion of patients in the Phase I/II extension study of Amphinex®**
- **Process to initiate a Proof of Concept study in 2012 in an additional cancer indication is progressing according to plan**
- **Project to investigate PCI used with vaccines is progressing according to plan**
- **Strengthened the organization by hiring Director Regulatory Affairs and Clinical Trial Manager**

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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. A total of 19 patients were treated in this study and 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.

Phase II study in head & neck cancer patients

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.

During the quarter, all preparations necessary to start inclusion of patients were completed. The National Center for Tumor Diseases (NCT), University Hospital Heidelberg, and Ludwig Maximilian University Munich, Germany, have started the screening of patients.

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 accelerate patient inclusion.

The Phase II study has been submitted to National Institute for Health Research Cancer Research Network (NCRN) in the UK for review and adoption. The NCRN Industry Trials Adoption Panel fully adopted the study, based on objective criteria regarding the potential therapeutic benefit, study design, investigator interest and infrastructure considerations. NCRN will offer support to PCI Biotech through its Local Research Network in UK for site identification, selection, set-up and recruitment monitoring.

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 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 are being 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 is being performed at University College Hospital (UCH) in London, and will include up to 9 patients. During the quarter, two patients have been treated in the extension study.

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. Docetaxel and gemcitabine are both widely used generic drugs, while erlotinib (Genentech, OSI Pharmaceuticals, Roche) is still on patent. The process to start the first Proof of Concept (PoC) studies in 2012 and 2013 is progressing according to plan.

PCI for vaccination
The company has ongoing a project 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. The project is progressing according to plan and results from the initial experiments are expected in 2012.

Strengthening the organisation
PCI Biotech has established a core team of highly competent people. All employees have long industry expertise within their respective areas of responsibility. To further strengthen the organization, a Director Regulatory Affairs and a Clinical Trial Manager have been employed.

Lucy Wabakken is employed as Director Regulatory Affairs. Lucy holds a Cand. Pharm degree from the University of Oslo. She has more than 20 years of regulatory experience from Nycomed Pharma, and her last position in Nycomed Pharma was as Director International Regulatory Affairs.

Lena Finnesand is employed as Clinical Trial Manager. She holds a Master of Science in Biotechnology from the Norwegian University of Science and Technology (NTNU), Trondheim, Norway. She has experience with clinical development from Novo Nordisk Scandinavia and from The Norwegian Radium Hospital.

Both Lucy and Lena started in their new positions 2nd May.

Financial Review

Results 1st Quarter 2012

The company received grants from Norway and EU and these are shown as revenues. Grants in the quarter were NOK 1.9 million compared with NOK 1.6 million in Q1 2011.

R&D costs in Q1 2012 were NOK 7.6 million compared with NOK 5.0 million in Q1 2011. 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 and start of the Phase I/II extension study.

G&A costs in Q1 2012 were NOK 0.5 million, in line with Q1 2011.

Total operating costs were NOK 8.1 million in Q1 2012, compared with NOK 5.6 million in Q1 2011.

Operating results were NOK -6.2 million in Q1 2012 compared with NOK -4.0 million in Q1 2011.

Net cash flow from operations was NOK -4.8 million in Q1 2012, compared with NOK -4.5 million in Q1 2011. Net cash flow in the quarter was NOK -4.8 million compared with NOK -4.5 million in Q1 2011.

Balance

The company held cash and cash equivalents of NOK 90.2 million at the end of the quarter. Total equity was NOK 87.3 million compared with NOK 92.5 million at the end of 2011. 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	Q1 2012	Q1 2011	01.01-31.12 2011
Other Income		**1 909**	**1 560**	**7 423**
Research and development expenses		7 572	5 012	22 226
General and administrative expenses		545	587	2 273
Operating costs		**8 117**	**5 599**	**24 499**
OPERATING RESULT		**-6 208**	**-4 039**	**-17 076**
Financial income and expenses				
Financial income		686	854	3 350
Financial expenses		0	-13	-23
Net financial result		**686**	**841**	**3 327**
ORDINARY PROFIT BEFORE TAXES		**-5 522**	**-3 198**	**-13 749**
Tax on ordinary result	9	0	0	0
Net profit/loss	4	**-5 522**	**-3 198**	**-13 749**
Other comprehensive income		0	0	0
Comprehensive income		**-5 522**	**-3 198**	**-13 749**

BALANCE SHEET

(In NOK '000)	Note	31.03.2012	31.03.2011	31.12.2011
Fixed and Intangible Assets				
Operating assets	8	12	60	17
Total fixed and intangible assets		**12**	**60**	**17**
Current Assets				
Short term receivables	7	5 339	3 955	5 033
Cash & cash equivalents		90 294	106 274	95 115
Total current assets		**95 633**	**110 229**	**100 148**
Total assets		**95 645**	**110 289**	**100 165**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		189 468	188 757	189 148
Other reserves		-102 137	-86 253	-96 615
Total equity	10	**87 331**	**102 504**	**92 533**
Trade debtors		2 268	560	2 168
Other short term debt		6 046	7 225	5 464
Total short term debt		**8 314**	**7 785**	**7 632**
Total debt		8 314	7 785	7 632
Total shareholders equity and liabilities		**95 645**	**110 289**	**100 165**

CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	Note	Paid in capital	Other paid in capital/ reserves	Retained earnings	Total
Balance at 31 December 2010		**22 999**	**78 742**	**3 682**	**105 423**
Share option scheme	10	-	861	-	861
Comprehensive income in the period		-	-	-13 749	-13 749
Balance at 31 December 2011		**22 999**	**79 603**	**-10 067**	**92 533**
Share option scheme	10	-	320	-	320
Comprehensive income in the period		-	-	-5 522	-5 522
Balance at 31 March 2012		**22 999**	**79 923**	**-15 589**	**87 331**

CASH FLOW

(In NOK '000)	Q1 2012	Q1 2011	01.01-31.12 2011
Ordinary profit before taxes	-5 522	-3 198	-13 749
Depreciation, Amortization and Write Off	5	17	61
Share options	320	280	861
Net financials	686	-841	3 327
Changes in working capital	376	-1 639	-2 872
Cash flow from operations	-4 135	-5 381	-12 372
Net financials	-686	841	-3 327
Taxes paid	-	-	-
Net cash flow from operations	-4 821	-4 540	-15 699
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	-	-	-
Net cash flow from financial activities	-	-	-
Net change in cash during the period	-4 821	-4 540	-15 699
Cash and cash equivalents at the beginning of the period	95 115	110 814	110 814
Cash and cash equivalents at the end of the period	90 294	106 274	95 115

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. 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 2011 (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 12 March 2012. 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 May 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 2011.

The new standards, interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2012 and that could affect the PCI Biotech are discussed in accounting policies, part 3, to the consolidated financial statements for 2011. In the 2011 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 2012	Q1 2011	FY 2011
Result allocated to shareholders (in NOK '000)	(5 522)	(3 198)	(13 749)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666
Earnings per share (NOK per share)	-0,72	-0,42	-1,79

Diluted earnings per share:

	Q1 2012	Q1 2011	FY 2011
Result allocated to shareholders (in NOK '000)	(5 522)	(3 198)	(13 749)
Weighted average of outstanding shares (in '000)	8 467	8 389	8 389
Earnings per share (NOK per share)	-0,72	-0,42	-1,79

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 2012	Q1 2011	FY 2011
Radiumhospitalets Forskningsstiftelse	280	312	1 947
Theresa Comiskey Olsen	-	17	92

At the end of the quarter, PCI Biotech had no short term debt to Radiumhospitalets Forskningsstiftelse or 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 at the end of the quarter.

Maturity profile on receivables as per 31 March:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-			-
Other receivables	5 339	-	-	5 339
Total receivables	**5 339**	**-**	**-**	**5 339**

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 end of the quarter, NOK 60 million of the cash was placed at accounts with fixed interest. The fixed interest matures in Q2 and Q3 2012.

8. Tangible assets

Changes in value:

	First quarter	
	2012	2011
Carrying value at the beginning of the period	**17**	**78**
Additions		
Depreciation in the period	-5	-17
Carrying value at the end of the period	**12**	**60**

9. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 34.9 million in non-capitalised deferred tax assets.

10. Share options

In Q1 2012, a total of 135,000 share options were granted to six employees with an exercise price of NOK 37.02 per share, equal to the average price of the 5 latest days prior to allocation.

The fair value of options granted in Q1 2012 determined using the Black-Sholes valuation model was NOK 3,128,000. The significant inputs into the model were a share price of NOK 37.02 at the grant date, volatility of 100%, dividend yield 0%, an expected option life of three years and an annual risk free rate of 2.16%.

Costs related to the share options were NOK 0.3 million in Q1 2012

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	31.03.2012	31.03.2011
2013 - Q4	19.02	255 000	255 000
2014 - Q4	6.47	234 000	234 000
2015 - Q4	37.24	115 000	115 000
2017 - Q4	37.02	135 000	
Total		**739 000**	**604 000**

11. 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.