PCI Biotech Holding ASA - Fourth Quarter 2012 and preliminary full year 2012 Report

Highlights

- **Patient inclusion in the ENHANCE study is on-going for patients treated with superficial illumination. There is a temporary halt in the inclusion of patients treated with intra-tumour illumination due to stronger local treatment effects than expected and desired. A process to evaluate possible changes to the study protocol is ongoing, and will be completed in February 2013.**
- **Preparation for the Proof of Concept study in bile duct cancer (cholangiocarcinoma) is progressing according to plan. All necessary approvals are granted in the UK, and inclusion of patients will start in Q1 or early in Q2 2013.**
- **The preclinical program to investigate PCI used with vaccines is developing according to plan.**

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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 used in combination with the generic cytotoxic agent bleomycin. A Phase I/II study of Amphinex in combination with bleomycin in cancer patients and an extension to this study have been completed at University College Hospital (UCH) in London. A total of 22 patients were treated in these studies and strong response to treatment was seen in all patients. Amphinex seems to be well tolerated.

Phase II study in head & neck cancer patients – the ENHANCE study

The ENHANCE study is a single arm, multi-centre, phase II study to evaluate the safety and efficacy of Amphinex in combination with the generic cytotoxic agent bleomycin with surface and intra-tumour laser light application in patients with recurrent head & neck squamous cell carcinoma unsuitable for surgery and radiotherapy and without distant metastases. The study will include approximately 80 patients and progression free survival at 6 months is the primary endpoint.

Patient inclusion started in May 2012, and the first patient was treated at The National Center for Tumor Diseases (NCT), University Hospital Heidelberg, Germany. In December 2012, the company reported that it is necessary to modify the study. Two different light application procedures are used in the study; surface and intra-tumour illumination. Preliminary findings from some of the patients included in the study indicate that treatment with intra-tumour illumination causes stronger local treatment effects than expected and desired, and stronger treatment effects than what was observed with surface illumination in the Phase I/II study at University College Hospital in London, UK. The Independent Data Monitoring Board (IDMB) recommended the company to optimise the treatment regimen for intra-tumour illumination before further patients are treated with this procedure.

The ENHANCE study is still including patients where the tumour can be treated with superficial illumination while the treatment procedure for intra tumour illumination is being optimised.

The company is currently assessing how to optimise the intra-tumour light application procedure and is simultaneously evaluating changes to the study protocol to complete the study in the most effective manner possible. The assessment will be completed in February 2013. Patient inclusion is expected to continue into 2014.

Clinical study in patients with bile duct cancer (cholangiocarcinoma)

Preparations for a Proof of Concept study for the use of PCI in patients with bile duct cancer is progressing according to plan. Amphinex will in this indication be used in combination with the generic cytotoxic agent gemcitabine.

Surgery is currently the only curative option for these patients, yet the majority of the tumours are inoperable. Inoperable patients are treated with stenting to keep the bile duct open and with chemotherapy. The combination of gemcitabine and cisplatin has shown promising results and has become standard treatment in some countries, but there is still a need for better treatments to increase overall survival and quality of life. Bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and new drug classes or alternative methods are needed. The most studied and used drug is gemcitabine, which is one of the identified drugs that is significantly enhanced by PCI in preclinical studies. Light access is easy through the endoscopic methods that are routinely used in the treatment of this disease.

The Proof of Concept study is planned to be an open-label, multi-centre Phase I/II study in up to 45 patients to assess the safety and efficacy of Amphinex induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine in patients with inoperable bile duct cancer. The study will consist of a dose escalation/phase I part to assess the tolerance of local bile duct treatment and a randomized double-arm phase II part. In phase II patients will be randomized to either a control arm (stenting alone followed by gemcitabine/cisplatin chemotherapy) or the PCI arm (stenting followed by Amphinex induced PCI treatment of gemcitabine followed by gemcitabine/cisplatin chemotherapy). The randomisation ratio for this study is 2.5:1 in favor of the PCI arm. The Phase I primary objective will be to determine a tolerable dose for local bile duct treatment with Amphinex induced PCI of gemcitabine, while the Phase II primary objective will be to assess efficacy in terms of progression free survival. The company has received all necessary approvals from the authorities and ethics committee in the UK, and is currently clarifying all details necessary to start patient inclusion. Patient inclusion will start in Q1 or early in Q2 2013.

PCI for vaccination

The company has a project supported by Norwegian Research Council with NOK 10.85 million over a three-year period. The project aims to document that PCI Biotech's photochemical internalization technology (PCI) induces immunological effects that can be used in treatment of cancer patient. An important part of the project is to document and optimise the PCI effect for therapeutic vaccines, i. e. vaccines that aim to treat an already established disease in the patient. This project involves cooperation with NTNU in Trondheim, Norway and with University Hospital Zürich, Switzerland, where the company currently has personnel deployed to focus and speed up the progress.

The two most important components in the immunological response to vaccines are the antibody response and the cellular response. For many vaccines, and especially for therapeutic vaccines, a strong cellular response is of great importance. A possible benefit when applying PCI within vaccination is that PCI can direct the immunological response towards a stronger cellular response. This could be important for the effect of therapeutic vaccines for example within cancer.

Preclinical studies performed by the company's collaborators have shown that under certain conditions, PCI can increase the vaccination effect of antigens. Further studies at University Hospital Zürich, Switzerland focus on optimising the treatment regimen, with the aim to establish a protocol for a possible clinical study that can start in 2013.

Presentations of the PCI technology and clinical results

Results from the Phase I/II study of Amphinex in combination with bleomycin in cancer patients at University College Hospital, London, UK (UCH), were presented at the major oncology conference in Europe, ESMO (European Society for Medical Oncology) 2012 Congress, Vienna, Austria. The presentation was held by Dr Martin Forster (UCH).

In addition, the PCI technology with clinical examples was, amongst others, presented at EACMFS (European Association for Cranio-Maxillo-Facial Surgery) 2012 Congress, Dubrovnik, Croatia. The presentation was held by Dr Colin Hopper (UCH).

Financial Review

Results 4th Quarter 2012

The company received grants from Norway and EU and these are shown as revenues. Revenues in the quarter were NOK 1.4 million compared with NOK 2.8 million in Q4 2011.

R&D costs in Q4 2012 were NOK 8,6 million compared with NOK 6,9 million in Q4 2011. Costs to external partners and hospitals on pre-clinical and clinical trials were higher in the quarter due to inclusion of patients in ENHANCE study and preparations for the Phase I/II study in bile duct cancer.

G&A costs in Q4 2012 were NOK 1.6 million compared with NOK 0.7 million in Q4 2011.

Total operating costs were NOK 10.2 million in Q4 2012, compared with NOK 7.6 million in Q4 2011.

Operating results were NOK -8.8 million in Q4 2012 compared with NOK -4.8 million in Q4 2011.

Net cash flow from operations and net cash flow in the quarter was NOK -4.9 million in Q4 2012, compared with NOK -3.7 million in Q4 2011.

Results in 2012

Revenues were NOK 6.7 million in 2012 compared with NOK 7.4 million in 2011. Total costs were NOK 34.1 million in 2012, compared with NOK 24.4 million in 2011.

R&D costs in 2012 were NOK 31.3 million, compared with NOK 22.5 million in 2011. G&A costs in 2012 were NOK 2.9 million compared with NOK 2.3 million in 2011.

Operating results were NOK -27.4 million in 2012 compared with NOK -17.1 million in 2011.

Net cash flow from operations and net cash flow was NOK -22.0 million in 2012, compared with NOK -15.7 million in 2011.

Balance

The company held cash and cash equivalents of NOK 73.1 million at the end of the quarter. Total equity was NOK 69.7 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 cancer drugs for localised cancer treatment, based on the company's unique drug delivery platform.

The main focus is an effective development of Amphinex in combination with bleomycin and in combination with gemcitabine. Priorities in 2013 will be to optimize both the treatment procedure and study protocol for the ENHANCE study within head and neck cancer, and to start and secure a rapid patient inclusion in the phase I/II study in bile duct cancer.

Another priority is to complete the preclinical studies of PCI within vaccination, to possibly start a clinical study, and seek partnership for development of the PCI technology within vaccination.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK 1,000)	Note	Q4 2012	Q4 2011	01.01- 31.12 2012	01.01-31.12 2011
Other Income		**1 398**	**2 765**	**6 765**	**7 423**
Research and development		8 565	6 913	31 263	22 226
General and administrative		1 634	667	2 856	2 273
Operating costs		**10 199**	**7 580**	**34 119**	**24 499**
Operating results		**-8 801**	**-4 815**	**-27 354**	**-17 076**
Financial income and costs					
Financial income		505	896	2 322	3 350
Financial costs		-67	-20	-227	-23
Net financial result		**438**	**876**	**2 095**	**3 327**
Ordinary profit before taxes		**-8 363**	**-3 939**	**--25 259**	**-13 749**
Tax on ordinary result	9	0	0	0	0
Net profit/loss	4	**-8 363**	**-3 939**	**-25 259**	**-13 749**
Other comprehensive income		0	0	0	0
Comprehensive income		**-8 363**	**-3 939**	**-25 259**	**-13 749**

BALANCE SHEET

(In NOK 1,000)	Note	31.12 2012	31.12 2011
Fixed and Intangible Assets			
Operating assets	*8*	0	17
Total fixed and intangible assets		**0**	**17**
Current assets			
Short term receivables	*7*	5 118	5 033
Cash & cash equivalents		73 083	95 115
Total current assets		**78 201**	**100 148**
Total assets		**78 201**	**100 165**
Shareholders equity and liabilities			
Shareholders equity			
Paid in capital		191 579	189 148
Other reserves		-121 873	-96 615
Total equity	***10***	**69 706**	**92 533**
Trade debtors		1 984	2 168
Other short term debt		6 511	5 464
Total debt		**8 495**	**7 632**
Total shareholders equity and liabilities		**78 201**	**100 165**

CHANGE 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	-	2 431	-	2 431
Comprehensive income in the period		-	-	-25 259	-25 259
Balance at 31 December 2012		**22 999**	**82 034**	**-35 326**	**69 706**

CASH FLOW

(In NOK '000)	Note	Q4 2012	Q4 2011	01.01-31.12 2012	01.01-31.12 2011
Ordinary profit before taxes		-8 363	-3 939	-25 259	-13 749
Depreciation, Amortization and Write Off		-	12	17	61
Share options		1 211	190	2 431	861
Net financials		-438	-876	-2 095	-3 327
Changes in working capital		2 260	54	779	-2 872
Cash flow from operations		-5 330	-4 559	-24 127	-19 026
Net financials		438	876	2 095	3 327
Taxes paid		-	-	-	-
Net cash flow from operations		-4 892	-3 683	-22 032	-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		-4 892	-3 683	-22 032	-15 699
Cash and cash equivalents at the beginning of the period		77 975	98 798	95 115	110 814
Cash and cash equivalents at the end of the period		73 083	95 115	73 083	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 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 eventually 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 29 October 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:

	Q4 2012	Q4 2011	FY 2012	FY 2011
Result allocated to shareholders (in NOK '000)	(8 363)	(3 939)	(25 259)	(13 749)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666	7 666
Earnings per share (NOK per share)	-1,09	-0,51	-3,29	-1,79

Diluted earnings per share:

	Q4 2012	Q4 2011	FY 2012	FY 2011
Result allocated to shareholders (in NOK '000)	(8 363)	(3 939)	(25 259)	(13 749)
Weighted average of outstanding shares (in '000)	8 524	8 389	8 510	8 389
Earnings per share (NOK per share)	-1,09	-0,51	-3,29	-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	Q4 2012	Q4 2011	FY 2012	FY 2011
Radiumhospitalets Forskningsstiftelse	424	470	1 593	1 947
Theresa Comiskey Olsen	-	17	3	92

At the end of the year, PCI Biotech had NOK 315,000 in short term debt to Radiumhospitalets Forskningsstiftelse and no short term debt to 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 December:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	304		4	308
Other receivables	4 810	-	-	4 810
Total receivables	**5 114**	**-**	**4**	**5 118**

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 50.3 million of the cash was placed at accounts with fixed interest. The fixed interest matures in Q1 2013.

8. Tangible assets

Changes in value:

	Fourth quarter		1.1 - 31.12	
	2012	2011	2012	2011
Carrying value at the beginning of the period	**-**	**29**	**17**	**78**
Additions				
Depreciation in the period	-	-12	-17	-61
Carrying value at the end of the period	**-**	**17**	**-**	**17**

9. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 40.5 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 1.2 million in Q4 2012 and NOK 2.4 million in 2012.

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 31.12.2012	31.12.2011
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

On January 22nd the company reported that Dr Flemming Ørnskov resigned from the Board of Director with immediate effect. He has been appointed Chief Executive Designate and Board member of the global pharmaceutical company Shire plc, and is therefore not able to continue as Board member in PCI Biotech.

To the best of PCI Biotech's knowledge, there has been no other event subsequent to the end of the reported interim period that would influence the financial statements included in this report.