PCI Biotech Holding ASA - Second Quarter and First Half-Year 2012 Report

Highlights

- **Started inclusion of patients in the ENHANCE study, the Phase II study in head & neck cancer patients.**
- **Bile duct cancer (Cholangiocarcinoma) selected as next indication for PCI. A Proof of Concept study is expected to start by end of 1H 2013.**
- **Promising results from preclinical program to investigate PCI used with vaccines.**
- **Completed patient inclusion in the Phase I/II extension study of Amphinex®**

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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 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.

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 superficial and interstitial laser light application in patients with recurrent head and neck squamous cell carcinoma unsuitable for surgery and radiotherapy and without distant metastases. The study will include approximately 80 patients, and patient inclusion will be in 2012 and 2013. 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. Five highly respected cancer institutes in four European countries are currently involved in the study, and one additional institute (Aintree University Hospital in Liverpool, UK) is about to be included. To speed up patient inclusion further, a process is ongoing with a number of additional European university hospitals, and it is expected that some of these will participate in the study. The company is also exploring the possibility to open additional sites in India. India has a very high incidence of head & neck cancer, and has a number of hospitals offering high quality treatment options for head & neck cancer patients.

The lowest dose used in the Phase I/II study has been chosen for further development. Doses below this level have been 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 performed at University College Hospital (UCH) in London, and inclusion of patients was completed during Q2 2012.Three patients were treated in the extension study with an Amphinex dose of 0.125mg/kg and it was decided that there was no need for further reduction of the Amphinex dose. Results from the three patients supports the previously selected dose of 0.25mg/kg for the ENHANCE study.

Clinical study in patients with bile duct cancer (Cholangiocarcinoma)
The Board of Directors has decided to start a Proof of Concept study for the use of PCI in patients with bile duct cancer. In this indication Amphinex® will be used in combination with the generic cytotoxic agent gemcitabine. The aim is to start the Proof of Concept study by end of 1H 2013.

About bile duct cancer
The bile duct drains bile from the liver into the small intestine. Bile duct cancer is a relatively rare cancer with an annual incidence of 1-2 cases per 100,000 in the Western world. The incidence rate has been rising worldwide over the past several decades. Survival is less than 25% at 2 years in patients with resectable tumour and less than 1% at 2 years in patients with unresectable tumour. Biliary tract sepsis, liver failure and/or malnutrition and cachexia due to locoregional effects of the disease are the most important causes of death.

Current treatment regime
Currently, surgery is the only curative option for these patients; yet the majority of the tumours are inoperable at presentation. 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 regions, but there is still a need for better treatments to increase overall survival and quality of life.

Could PCI play a role in the treatment of bile duct cancer?
Improved local methods to slow tumour progression and keep the bile duct open are important to extend life span and quality. Bile duct cancer is characterized 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 are 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.

Bile duct cancer is therefore chosen as the next indication for PCI, since there is a clear medical need for a better local treatment, access with light is easy by using already established treatment procedures and one of the most used cytotoxic agents, gemcitabine, is one of the drugs that is significantly enhanced by PCI in preclinical studies.

Clinical study
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 randomization 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.

PCI for vaccination
The company has 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.

Preclinical studies have been performed at University Hospital Zürich, Switzerland and at NTNU in Norway. Results from these studies show that under certain conditions, PCI can increase the effect of

different antigens. Based on these promising results, the Board of Directors has decided to continue the preclinical program to develop and optimise a treatment regime for PCI used with vaccines. These preclinical studies will be performed at University Hospital Zurich in 2H 2012 and 1H 2013, with the aim to establish a protocol for a clinical study that can start in 2013.

Financial Review

Results 2nd 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 0.9 million in Q2 2011. The increased income relates to the BIA project initiated in Q3 2011.

R&D costs in Q2 2012 were NOK 5.9 million compared with NOK 5.5 million in Q2 2011. Costs to external partners and hospitals on pre-clinical and clinical trials were higher in the quarter due to start of the Phase II clinical study and the Phase I/II extension study.

G&A costs in Q2 2012 were NOK 0.3 million compared with NOK 0.5 million in Q2 2011.

Total operating costs were NOK 6.2 million in Q2 2012, compared with NOK 6.0 million in Q2 2011.

Operating results were NOK -4.3 million in Q2 2012 compared with NOK -5.1 million in Q2 2011.

Net cash flow from operations and net cash flow in the quarter was NOK -4.4 million in Q2 2012, compared with NOK -3.8 million in Q2 2011.

Results 1H 2012

Revenues were NOK 3.8 million in 1H 2012 compared with NOK 2.4 million in 1H 2012. Total costs were NOK 14.3 million in 1H 2012, compared with NOK 11.6 million in 1H 2011.

R&D costs in 1H 2012 were NOK 13.5 million, compared with NOK 10.5 million in 1H 2011. G&A costs in 1H 2012 were NOK 0.8 million compared with NOK 1.1 million in 1H 2011.

Operating results were NOK –10.5 million in 1H 2012 compared with NOK -9.2 million in 1H 2011.

Net cash flow from operations and net cash flow was NOK -9.2 million in 1H 2012, compared with NOK -8.3 million in 1H 2011.

Balance

The company held cash and cash equivalents of NOK 85.9 million at the end of the quarter. Total equity was NOK 84.0 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 priorities are to effectively develop Amphinex® in combination with bleomycin and in combination with gemcitabine. The main focus in 2012 is to secure a rapid patient inclusion in the Phase II clinical study in head & neck cancer patients – the ENHANCE study, and prepare for a clinical study in bile duct cancer.

Another priority is to progress the development of using PCI to enhance the effect of vaccines.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Note	Q2 2012	Q2 2011	01.01-30.06 2012	01.01-30.06 2011	01.01-31.12 2011
Other Income		**1 896**	**885**	**3 805**	**2 446**	**7 423**
Research and development		5 925	5 482	13 497	10 494	22 226
General and administrative		262	531	793	1 118	2 273
Operating costs		**6 187**	**6 013**	**14 290**	**11 612**	**24 499**
OPERATING RESULT		**-4 291**	**-5 128**	**-10 485**	**-9 166**	**-17 076**
Financial income and costs						
Financial income		528	831	1 213	1 681	3 350
Financial expenses			0	0	-9	-23
Net financial result		**528**	**831**	**1 213**	**1 672**	**3 327**
ORDINARY PROFIT BEFORE TAXES		**-3 763**	**-4 297**	**-9 272**	**-7 494**	**-13 749**
Tax on ordinary result	9	0	0	0	0	0
Net profit/loss	4	**-3 763**	**-4 297**	**-9 272**	**-7 494**	**-13 749**
Other comprehensive income		0	0	0	0	0
Comprehensive income		**-3 763**	**-4 297**	**-9 272**	**-7 494**	**-13 749**

BALANCE SHEET

(In NOK '000)	Note	30.06.2012	30.06.2011	31.12.2011
Fixed and Intangible Assets				
Operating assets	8	0	44	17
Total fixed and intangible assets		**0**	**44**	**17**
Current Assets				
Short term receivables	7	5 892	3 755	5 033
Cash & cash equivalents		85 903	102 508	95 115
Total current assets		**91 795**	**106 263**	**100 148**
Total assets		**91 795**	**106 307**	**100 165**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		189 468	188 958	189 148
Other reserves		-105 437	-90 549	-96 615
Total equity	10	**84 031**	**98 409**	**92 533**
Trade debtors		3 699	1 619	2 168
Other short term debt		4 065	6 279	5 464
Total short term debt		**7 764**	**7 898**	**7 632**
Total debt		7 764	7 898	7 632
Total shareholders equity and liabilities		**91 795**	**106 307**	**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	-	770	-	770
Comprehensive income in the period		-	-	-9 272	-9 272
Balance at 30 June 2012		**22 999**	**80 373**	**-19 339**	**84 031**

CASH FLOW

(In NOK '000)	Q2 2012	Q2 2011	01.01-30.06 2012	01.01-30.06 2011	01.01-31.12 2011
Ordinary profit before taxes	-3 763	-4 297	-9 272	-7 494	-13 749
Depreciation, Amortization and Write Off	12	16	17	34	61
Share options	450	201	770	482	861
Net financials	-528	-831	1 213	1 672	3 327
Changes in working capital	-1 090	314	-727	-1 328	-2 872
Cash flow from operations	-4 919	-4 597	-7 999	-6 634	-12 372
Net financials	528	831	-1 213	-1 672	-3 327
Taxes paid	-	-	-	-	-
Net cash flow from operations	-4 391	-3 766	-9 212	-8 306	-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	-4 391	-3 766	-9 212	-8 306	-15 699
Cash and cash equivalents at the beginning of the period	90 294	106 274	95 115	110 814	110 814
Cash and cash equivalents at the end of the period	85 903	102 508	85 903	102 508	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 20 August 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:

	Q2 2012	Q2 2011	6M 2012	6M 2011	FY 2011
Result allocated to shareholders (in NOK '000)	(3 763)	(4 297)	(9 272)	(7 494)	(13 749)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666	7 666	7 666
Earnings per share (NOK per share)	-0,49	-0,56	-1,21	-0,98	-1,79

Diluted earnings per share:

	Q2 2012	Q2 2011	6M 2012	6M 2011	FY 2011
Result allocated to shareholders (in NOK '000)	(3 763)	(4 297)	(9 272)	(7 494)	(13 749)
Weighted average of outstanding shares (in '000)	8 524	8 389	8 496	8 389	8 389
Earnings per share (NOK per share)	-0,49	-0,56	-1,21	-0,98	-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	Q2 2012	Q2 2011	6M 2012	6M 2011	FY 2011
Radiumhospitalets Forskningsstiftelse	249	725	389	1 037	1 947
Theresa Comiskey Olsen	3	37	3	54	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 30 June:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-			-
Other receivables	5 892	-	-	5 892
Total receivables	**5 892**	**-**	**-**	**5 892**

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 30 million of the cash was placed at accounts with fixed interest. The fixed interest matures in Q3 2012.

8. Tangible assets

Changes in value:

	Second quarter		1.1 - 30.06	
	2012	2011	2012	2011
Carrying value at the beginning of the period	**12**	**60**	**17**	**78**
Additions				
Depreciation in the period	-12	-16	-17	-33
Carrying value at the end of the period	**-**	**44**	**-**	**44**

9. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 35.9 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 0.4 million in Q2 2012 and NOK 0,8 in 1H 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 30.06.2012	30.06.2011
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.

Statement of the Board of Directors and CEO

We confirm that, to the best of our knowledge, the condensed set of financial statements for the first half year of 2012 which has been prepared in accordance with IAS34 Interim Financial Statements gives a true and fair view of the Company s consolidated assets, liabilities, financial position and results of operations, and that the interim management reports includes a fair review of the information required under the Norwegian Securities trading Act section 5-6 fourth paragraph.

The Board of Directors and CEO
PCI Biotech Holding ASA
Oslo, 20 August 2012

Erling Øverland Chairman	Theresa Comiskey Olsen	Else Krüger Hagen
Kjetil Taskén	Flemming Ørnskov	Per Walday CEO