PCI Biotech Holding ASA - Third Quarter 2011 Report

Highlights 2011

- **Completed the Phase I/II study of Amphinex® in combination with bleomycin (PC-A11)**
- **Decided next clinical study in Head & Neck cancer patients**
- **Initiated compassionate use on a named patient basis**
- **Received response from CHMP regarding combination pack for PC-A11 in Head & Neck cancer patients**
- **Awarded NOK 10.85 million in BIA grant from The Research Council of Norway**
- **Winner of DnB NOR's Innovation prize**

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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 (PC-A11), Head & Neck cancer

PCI Biotech's lead candidate is the photosensitiser Amphinex® used in combination with the generic cytotoxic agent bleomycin, a product combination named PC-A11. A Phase I/II study of PC-A11 in cancer patients has been completed at University College Hospital (UCH) in London. The study was a dose escalation study, and the primary objective was to assess the maximum tolerated dose of Amphinex®. Secondary objectives included determination of the antitumour activity of the PC-A11 treatment, as well as pharmacokinetics of Amphinex®.

A total of 19 patients were treated in the Phase I/II study, 14 in the dose escalation part and 5 additional patients at a selected therapeutic dose. 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. Please refer to the press release published 23 June 2011 for the main results from the study.

Next clinical study

Amphinex® in combination with bleomycin (PC-A11) development will initially be targeted towards patients with recurrent head & neck cancer 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. 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, Amsterdam, Netherlands and Centre Alexis Vautrin (CAV)-Nancy Université, France, all highly respected cancer institutes. Inclusion of the first patient is expected late Q4 2011 or Q1 2012.

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. The market assessment indicates that the level of skin photosensitivity may be an important factor for a successful commercialisation of Amphinex. No serious skin adverse reactions were reported in the Phase I/II study except at the highest dose, but controlled skin photosensitivity testing induced mild effects also at lower doses. Tumour response was apparently equal across all doses and the lowest dose has therefore been selected for further development. Doses below this level will be studied in an extension study to the Phase I/II trial, to further investigate the therapeutic window in the lower dose range. The extension study will be performed at University College Hospital (UCH) in London, and will include up to 9 patients.

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 planned Phase II study.

The company is planning interactions with the US Food and Drug Administration (FDA) with the view to develop the product also for the US-market. An experienced group of US regulatory consultants has been engaged to support the company through this process.

Regulatory strategy for the combination Amphinex and bleomycin (PC-A11)
In October PCI Biotech received a response from The Committee for Medicinal Products for Human Use (CHMP) in European Medicines Agency (EMA) regarding the possible combination pack PC-A11. It is the CHMP's opinion that Amphinex® should be developed as a single product for use with bleomycin rather than a combination package with bleomycin for the head & neck cancer indication.

Regulatory interactions with National Health Authorities in the UK, Sweden and Netherlands have previously indicated support for a combination pack strategy. Following these interactions, the company decided to seek advice from CHMP to better understand how EMA will evaluate a marketing authorization application for PC-A11 for treatment of head & neck cancer. CHMPs opinion is that Amphinex® should be developed for registration as a single product for use with bleomycin for this indication. PCI Biotech will consider CHMP's opinion in the regulatory development strategy for this and future products. The CHMP opinion will not affect the timelines for the Phase II study in patients with recurrent head & neck cancer not suitable for surgery or radiotherapy and without distant metastases.

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.

Pre-clinical studies with selected new product combinations are ongoing at an internationally recognised Contract Research Organisation (CRO). The first set of results was positive with several cytotoxic agents and studies are now being performed to validate these initial results.

The company aims to start 1-2 clinical Proof of Concept studies during 2012. In addition, the company is currently discussing investigator initiated PCI-studies with some investigators.

PCI for vaccination – initiated pre clinical program as part of BIA grant
The Research Council of Norway has awarded PCI Biotech NOK 10.85 million in a BIA grant to the project "Immunological effects of photochemical internalization – local treatment of cancer with metastasis". The project is planned to run for 3 years, and started during Q3 2011.

The project goal is 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 and results from these initial experiments are expected in 2012.

Financial Review

Results 3rd Quarter 2011

The company receives grants from Norway and EU and these are shown as revenues. Grants in the quarter were NOK 1.1 million compared with NOK 1.4 million in Q3 2010. In September 2011, PCI Biotech was awarded DnB NOR's Innovation price of NOK 1 million and the Peoples award of NOK 0.1 million. The awards are booked as revenues in the quarter. In July 2010 PCI Biotech settled with and received NOK 4.1 million from an undisclosed supplier following a production error. The received settlement was booked as revenues. Total revenues in Q3 2011 were NOK 2.2 million compared with NOK 5.6 million in Q3 2010.

R&D costs in Q3 2011 were NOK 4.7 million, in line with Q3 2010. Costs to external partners and hospitals on pre-clinical and clinical trials were moderate in the quarter.

G&A costs in Q3 2011 were NOK 0.6 million compared with NOK -0.1 million in Q3 2010. Costs in Q3 2010 were affected by a NOK 0.9 million reduction in the provision for social security costs related to the share options.

Total operating costs were NOK 5.2 million in Q3 2011, compared with NOK 4.5 million in Q3 2010.

Operating results were NOK -3.0 million in Q3 2011 compared with NOK 1.0 million in Q3 2010.

Net cash flow from operations was NOK -3.7 million in Q3 2011, compared with NOK -1.8 million in Q3 2010. Net cash flow in the quarter was NOK -3.7 million compared with NOK -1.9 million in Q3 2010.

Results YTD 2011

Revenues were NOK 4.7 million YTD 2011 compared with NOK 8.7 million YTD 2010. Total costs were NOK 16.8 million YTD 2011, compared with NOK 19.9 million YTD 2010.

R&D costs YTD 2011 were NOK 15.1 million, compared with NOK 15.8 million YTD 2010. G&A costs YTD 2011 were NOK 1.7 million compared with NOK 4,0 million YTD 2010. Costs were high in 2010 mainly due to a NOK 1.6 million increase in the provision for social security costs related to the share options.

Operating results were NOK -12.2 million YTD 2011 compared with NOK -11.2 million YTD 2010.

Net cash flow from operations was NOK -12.0 million YTD 2011, compared with NOK -7.7 million YTD 2010. Net cash flow was NOK -12.0 million compared with NOK 75.6 million YTD 2010. Cash flow in 2010 was affected by net proceeds from a rights issue of NOK 83.3 million.

Balance

The company held cash and cash equivalents of NOK 98.8 million at the end of the quarter. Total equity was NOK 96.4 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 Amphinex in combination with bleomycin (PC-A11) and the development of new product combinations with Amphinex® for localised cancer treatment, based on the company's unique drug delivery platform.

The main priority during the next 6 months is to effectively progress Amphinex in combination with bleomycin (PC-A11):

- Start the next clinical study in head & neck cancer patients;
- Continue the interactions with health authorities to determine regulatory strategy in relevant markets

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 2012 based on the results of these studies.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Note	Q3 2011	Q3 2010	01.01-30.09 2011	01.01-30.09 2010	01.01-31.12 2010
Other Income		**2 212**	**5 552**	**4 658**	**8 703**	**10 444**
Research and development expenses		4 651	4 642	15 145	15 841	20 185
General and administrative expenses		580	(120)	1 697	4 014	6 502
Operating costs		**5 231**	**4 522**	**16 842**	**19 855**	**26 687**
OPERATING RESULT		**(3 019)**	**1 030**	**(12 184)**	**(11 152)**	**(16 243)**
Financial income and expenses						
Financial income		780	993	2 454	1 346	2 308
Financial expenses		0	(82)	(3)	(4)	(5)
Net financial result		**780**	**911**	**2 451**	**1 342**	**2 303**
ORDINARY PROFIT BEFORE TAXES		**(2 239)**	**1 941**	**(9 733)**	**(9 810)**	**(13 940)**
Tax on ordinary result	10	0	0	0	0	0
Net profit/loss	4	**(2 239)**	**1 941**	**(9 733)**	**(9 810)**	**(13 940)**
Other comprehensive income		0	0	0	0	0
Comprehensive income		**(2 239)**	**1 941**	**(9 733)**	**(9 810)**	**(13 940)**

BALANCE SHEET

(In NOK '000)	Note	30.09.2011	30.09.2010	31.12.2010
Fixed and Intangible Assets				
Intangible assets	8	0	0	0
Operating assets	9	29	95	78
Total fixed and intangible assets		**29**	**95**	**78**
Current Assets				
Short term receivables	7	5 038	5 127	3 649
Cash & cash equivalents		98 798	111 385	110 814
Total current assets		**103 836**	**116 512**	**114 463**
Total assets		**103 865**	**116 607**	**114 541**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital	12	188 958	188 477	188 477
Other reserves		-92 598	-79 241	-83 054
Total equity	11	**96 360**	**109 236**	**105 423**
Trade debtors		1 996	1 271	2 047
Other short term debt		5 509	6 100	7 071
Total short term debt		**7 505**	**7 371**	**9 118**
Total debt		7 505	7 371	9 118
Total shareholders equity and liabilities		**103 865**	**116 607**	**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	-	671	-	671
Comprehensive income in the period		-	-	-9 733	-9 733
Balance at 30 September 2011		**22 999**	**79 413**	**-6 051**	**96 360**

CASH FLOW

(In NOK '000)	Note	Q3 2011	Q3 2010	01.01-30.09 2011	01.01-30.09 2010	01.01-31.12 2010
Ordinary profit before taxes		-2 239	1 941	-9 733	-9 810	-13 940
Depreciation, Amortization and Write Off		15	19	49	85	102
Share options		190	135	671	695	1 012
Net financials		-780	-911	2 451	1 342	2 303
Changes in working capital		-1 676	-3 940	-3 003	1 318	4 543
Cash flow from operations		-4 490	-2 756	-9 565	-6 370	-5 980
Net financials		780	911	-2 451	-1 342	-2 303
Taxes paid		-	-	-	-	-
Net cash flow from operations		-3 710	-1 845	-12 016	-7 712	-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		-95		83 274	83 274
Net cash flow from financial activities		-	-95	-	83 274	83 274
Net change in cash during the period		-3 710	-1 940	-12 016	75 562	74 991
Cash and cash equivalents at the beginning of the period		102 508	113 325	110 814	35 823	35 823
Cash and cash equivalents at the end of the period		98 798	111 385	98 798	111 385	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 patented lead candidate Amphinex® in combination with the cytotoxic agent bleomycin (PC-A11). 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 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 31 October 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:

	Q3 2011	Q3 2010	9M 2011	9M 2010	FY 2010
Result allocated to shareholders (in NOK '000)	(2 239)	1 941	(9 733)	(9 810)	(13 940)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666	6 252	6 609
Earnings per share (NOK per share)	-0,29	0,25	-1,27	-1,57	-2,11

Diluted earnings per share:

	Q3 2011	Q3 2010	9M 2011	9M 2010	FY 2010
Result allocated to shareholders (in NOK '000)	(2 239)	1 941	(9 733)	(9 810)	(13 940)
Weighted average of outstanding shares (in '000)	8 389	8 155	8 389	6 017	7 136
Earnings per share (NOK per share)	-0,29	0,25	-1,27	-1,57	-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	Q3 2011	Q3 2010	9M 2011	9M 2010	FY 2010
Radiumhospitalets Forskningsstiftelse	440	140	1 477	1 433	2 427
Theresa Comiskey Olsen	21	18	75	75	92

At the end of the quarter, PCI Biotech held NOK 408,000 in short term debt to Radiumhospitalets Forskningsstiftelse and NOK 27,000 to Theresa Comiskey Olsen.

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 2011.

Maturity profile on receivables as per 30 September:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-		50	50
Other receivables	4 988	-	-	4 988
Total receivables	**4 988**	**-**	**50**	**5 038**

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

9. Tangible assets

Changes in value:

	Third quarter		1.1 - 30.09	
	2011	2010	2011	2010
Carrying value at the beginning of the period	**44**	**114**	**78**	**153**
Additions				
Depreciation in the period	-15	-19	-49	-58
Carrying value at the end of the period	**29**	**95**	**29**	**95**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 31.6 million in non-capitalised deferred tax assets.

11. Share options

No share options have been granted in 2011.

Costs related to the share options granted in 2008, 2009 and 2010 were NOK 0.2 million in the third quarter and NOK 0.7 million YTD 2011.

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 30.09.2011	30.09.2010
2013 - Q3	19.02	255 000	255 000
2014 - Q3	6.47	234 000	234 000
2015 - Q3	37.24	115 000	0
Total		**604 000**	**489 000**

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.

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.

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 the financial statements included in this report.