PCI Biotech Holding ASA - Second Quarter and First Half-Year 2010 Report

Highlights

- **Completed Rights Issue of NOK 90 million**
- **Completed inclusion of patients at the fourth dose level at UCH**
- **Received inconclusive results from pre-clinical bladder cancer studies**
- **Accelerated process to identify new cancer indications for the PCI technology**
- **Produced Active Pharmaceutical Ingredient (API) for next clinical trials**

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Operational Review

Progress in development programs

PCI Biotech Holding ASA ("PCI Biotech") is an oncology-focused drug delivery 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 has an ongoing Phase I/II study of the combination product PC-A11, i.e. Amphinex® in combination with the generic cytotoxic agent bleomycin, in cancer patients at University College Hospital (UCH) in London. The study is a dose escalation study, and three dose levels are completed. During Q2, UCH had to identify and train some new personnel to support the study. The change of personnel has affected the pace of inclusion of the first patients at the fourth dose level. Inclusion of patients at this dose level is however now complete, but only preliminary results have been received and a dose escalation meeting has not yet been held. The preliminary results from the first patient at the fourth dose level indicate that further dose escalation may not be necessary, as the results suggest that significant skin photosensitivity may be induced at this dose level. Efficacy data from this patient has not yet been received.

At the first three dose levels, a total of 11 patients were treated with PC-A11. Complete clinical regression of all evaluable treated tumours was observed within a few weeks of treatment, although one patient died of the underlying disease before complete clinical regression could be achieved and another patient had tumour recurrence at the three months follow-up visit. Patients with osteosarcoma (1) and squamous cell carcinoma (7) of the Head & Neck and adenocarinoma (3) of the Breast were included and the effectiveness of PCI treatment with PC-A11 seemed to be similar across all cancers treated. In total six serious adverse events were recorded in the three first dose groups; however none of these were deemed drug-related by the investigators.

The investigators at University College Hospital (UCH) in London have observed an apparent high specificity for cancer cells using the PCI treatment with PC-A11. Tumours of very

different depths have been treated and it seems that mainly the cancer cells are killed by the treatment, leaving the healthy tissue underneath the tumour largely unaffected. In addition, one patient with a tumour under the skin has been effectively treated with superficial illumination without ulceration of the skin.

The primary objective of the study is to assess the maximum tolerated dose of the new component Amphinex® in the PC-A11 product. Secondary objectives include determination of the antitumour activity of the PC-A11 treatment, as well as pharmacokinetics of the Amphinex® component.

Preparations for the next clinical study with PC-A11 are progressing according to plan. A formal scientific advice meeting with European Medicines Agency (EMA) is scheduled during 2H and interactions with the US Food and Drug Administration (FDA) are being planned.

PC-A22 Bladder cancer
PCI Biotech has pre-clinical studies ongoing for the use of Photochemical Internalisation (PCI) with PC-A22, i.e. Amphinex® in combination with the generic cytotoxic agent epirubicin, for treatment of Bladder cancer. The pre-clinical studies are being performed at The Norwegian University of Science and Technology (NTNU) in Trondheim, Norway and at Radboud University Nijmegen, Holland. The research at Radboud University is performed at one of the leading urology clinics in Europe under the supervision of Professor Fred Witjes.

Results from the pre-clinical studies have been received during Q2 and Q3. The results are not conclusive, but still indicate a lack of significant treatment effects at the applied conditions. Some further experimental pre-clinical studies with altered dosing conditions are required before the company can decide whether to proceed with the bladder cancer indication.

Other cancer indications
With the very promising results from the ongoing Phase I/II study at UCH and the strengthened cash situation, the company has decided to accelerate the process to identify other cancer indications where the PCI technology could potentially meet a need of improved local cancer control. International advisors have been engaged to assess the data from interviews with key opinion leaders and provide market analyses of the opportunities.

Pre-clinical studies within selected indications will be initiated as soon as possible with the aim to start 1-2 clinical Proof of Concept studies during 2011/2012.

Production of Amphinex®
PCI Biotech has developed a new and improved formulation of Amphinex®. Bridging studies between the old and new formulation are completed, and all future clinical trials will be done with the new formulation of Amphinex®.

During 1H 2010, the company has invested in production of a large stock of Active Pharmaceutical Ingredients (API) for Amphinex®. Formulation of 2,000 vials of Amphinex® based on the new formulation will be done during 2H 2010. With these investments, PCI Biotech has enough product to complete the planned Phase II/III study and 2-3 additional Proof of Concept studies.

Rights Issue
On 23 April 2010, the Board of Directors of PCI Biotech Holding ASA proposed to strengthen the company's equity by NOK 90 million through a share 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, being ~50% oversubscribed. The rights issue was registered in Foretaksregisteret on 21 June 2010.

Gross proceeds from the rights issue was NOK 90 million. Net proceeds were NOK 83.4 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.

Financial Review

Results 2nd Quarter 2010

The company receives grants from Norway and EU. The grants are shown as revenues, and revenues in the quarter were NOK 1.8 million compared with NOK 1.7 million in Q2 2009. Revenues in Q2 2010 were affected by NOK 0.4 million related to a one-off grant from Innovation Norway.

R&D costs in Q2 2010 were NOK 5.6 million, compared with NOK 4.1 million in Q2 2009. Costs to external partners and hospitals on pre-clinical and clinical trials were moderate in the quarter. During the quarter, NOK 1.4 million was invested in production of API for Amphinex® as part of preparation for next clinical trials.

G&A costs in Q2 2010 were NOK 2.6 million compared with NOK 1.9 million in Q2 2009. Costs have increased mainly due to a NOK 1.4 million increase in the provision for social security costs related to the share options. The increased cost of share options is caused by the increase in the share price during the quarter.

Total operating costs were NOK 8.2 million in Q2 2010, compared with NOK 6.0 million in Q2 2009.

Operating results were NOK -6.4 million in Q2 2010 compared with NOK -4.3 million in Q2 2009.

Net cash flow from operations was NOK -2.2 million in Q2 2010, compared with NOK -3.9 million in Q2 2009. Net proceeds from the rights issue was NOK 83.4 million. Net cash flow in the quarter was NOK 81.2 million compared with NOK -3.9 million in Q2 2009.

Results 1 H 2009

Revenues were NOK 3.2 million in 1H 2010 compared with NOK 3.4 million in 1H 2009. Total costs were NOK 15.2 million in 1H 2010, compared with NOK 13.0 million in 1H 2009.

R&D costs in 1H 2010 were NOK 10.8 million, compared with NOK 9.1 million in 1H 2009. G&A costs in 1H 2010 were NOK 4.4 million compared with NOK 3.9 million in 1H 2009. Costs have increased mainly due to a NOK 2.5 million increase in the provision for social security costs related to the share options. The increased cost of share options is caused by the increase in the share price during the year.

Operating results were NOK -12.1 million in 1H 2010 compared with NOK -9.6 million in 1H 2009.

Net cash flow from operations was NOK -5.9 million in 1H 2010, compared with NOK -8.2 million in 1H 2009. Net cash flow was NOK 77.5 million compared with NOK -8.3 million in 1H 2009. Cash flow in 1H 2010 was affected by net proceeds from the rights issue of NOK 83.4 million.

Balance
The company held cash and cash equivalents of NOK 113.3 million at the end of the quarter. A large proportion of the cash equivalents are placed in Norwegian money market funds with approximately 3 months maturity. Total equity was NOK 107.3 million compared with NOK 35.1 million at the end of 2009. The change in equity reflects the loss in the period and NOK 83.4 million in net proceeds from the rights issue completed in June 2010.

Outlook
PCI Biotech will continue to focus on the development of new combination products with Amphinex® for localised cancer treatment, based on the company's unique drug delivery platform.

The priority is to effectively progress the development of PC-A11:
- Complete the ongoing clinical study at University College Hospital in London in 2010
- Complete formal scientific advice process with the European Medicines Agency (EMA) in 2010 and initiate regulatory discussions with the Food and Drug Administration (FDA) in the US.
- Initiate a phase II/III study in head & neck cancer patients in 2011

PCI Biotech will further focus on identifying new product combinations and indications, and perform pre-clinical studies in various identified cancers. Further clinical studies are planned to be initiated in 2011/12 based on the results of these studies.

In July 2010 PCI Biotech settled with and received NOK 4.1 million from an undisclosed supplier following a production error. The production error has not had any material negative effect on the company's operations or finances. Results and the cash position in Q3 will be positively affected by NOK 4.1 million.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Q2 2010	Q2 2009	01.01-30.06 2010	01.01-30.06 2009	01.01-31.12 2009
Other Income	**1 789**	**1 723**	**3 151**	**3 439**	**8 612**
Research and development expenses	5 561	4 099	10 816	9 059	19 319
General and administrative expenses	2 620	1 944	4 429	3 947	6 979
Operating costs	**8 181**	**6 043**	**15 245**	**13 006**	**26 298**
OPERATING RESULT	**(6 392)**	**(4 320)**	**(12 094)**	**(9 566)**	**(17 686)**
Financial income and expenses					
Financial income	170	749	343	1 616	2 838
Financial expenses	0	(91)	0	(134)	(167)
Net financial result	**170**	**658**	**343**	**1 482**	**2 671**
ORDINARY PROFIT BEFORE TAXES	**(6 222)**	**(3 662)**	**(11 751)**	**(8 084)**	**(15 015)**
Tax on ordinary result	0	0	0	0	0
Net profit/loss	**(6 222)**	**(3 662)**	**(11 751)**	**(8 084)**	**(15 015)**
Other comprehensive income	0	0	0	0	0
Comprehensive income	**(6 222)**	**(3 662)**	**(11 751)**	**(8 084)**	**(15 015)**

BALANCE SHEET

(In NOK '000)	Note	30.06.2010	30.06.2009	31.12.2009
Fixed and Intangible Assets				
Intangible assets	8	0	55	27
Operating assets	9	115	192	153
Total fixed and intangible assets		**115**	**247**	**181**
Current Assets				
Short term receivables	7	3 859	3 306	5 017
Cash & cash equivalents		113 325	41 826	35 823
Total current assets		**117 184**	**45 133**	**40 840**
Total assets		**117 299**	**45 380**	**41 021**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital	12	188 477	105 108	105 108
Other reserves		-81 222	-63 577	-70 031
Total equity	11	**107 255**	**41 531**	**35 077**
Trade debtors		1 592	1 447	2 557
Other short term debt		8 452	2 402	3 387
Total short term debt		**10 044**	**3 849**	**5 944**
Total debt		10 044	3 849	5 944
Total shareholders equity and liabilities		**117 299**	**45 380**	**41 021**

CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	Note	Paid in capital	Other paid in capital/ reserves	Retained earnings	Total
Balance at 1. January 2008		**323**	**20 120**	**-15 203**	**5 240**
Establishment of Group		884	27 912	-28 821	-25
Capitalization issue		6 042	-6 042	-	-
Share issue		9 000	51 000	-	60 000
Share issue - costs			-4 954	-	-4 954
Share option scheme		-	415	-	415
Comprehensive income in the period		-	-	-11 375	-11 375
Balance at 31 December 2008		**16 249**	**88 451**	**-55 399**	**49 301**
Balance at 31 December 2008		16 249	88 451	-55 399	49 301
Changes in acounting principles			-	-	-
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	76 619	-	83 369
Share option scheme	11	-	560	-	560
Comprehensive income in the period		-	-	-11 751	-11 751
Balance at 30 June 2010		**22 999**	**78 385**	**5 871**	**107 255**

CASH FLOW

(In NOK '000)	Q2 2010	Q2 2009	01.01-30.06 2010	01.01-30.06 2009	01.01-31.12 2009
Ordinary profit before taxes	-6 222	-3 662	-11 751	-8 084	-15 015
Depreciation, Amortization and Write Off	33	29	66	61	128
Share options	280	172	560	314	791
Net financials	-170	-658	343	1 483	-2 258
Changes in working capital	3 694	-431	5 258	-494	-110
Cash flow from operations	-2 385	-4 550	-5 524	-6 720	-16 464
Net financials	170	658	-343	-1 483	2 258
Taxes paid	-	-	-	-	-
Net cash flow from operations	-2 215	-3 892	-5 867	-8 203	-14 206
Cash flow from investments					
Purchase of tangible assets	-	-33	-	-107	-107
Purchase of intangible assets	-	-6	-	-6	-6
Net cash flow from investments	-	-39	-	-113	-113
Cash flow from financial activities					
Net proceeds from share issues	83 369	-	83 369		-
Net cash flow from financial activities	83 369	-	83 369	-	-
Net change in cash during the period	81 154	-3 931	77 502	-8 316	-14 319
Cash and cash equivalents at the beginning of the period	32 171	45 757	35 823	50 142	50 142
Cash and cash equivalents at the end of the period	113 325	41 826	113 325	41 826	35 823

Selected explanatory notes:

Nature of operation

1. Nature of operation

PCI Biotech Holding ASA (PCI Biotech) was established in 2008, and comprises PCI Biotech Holding ASA and the 100 percent owned subsidiary PCI Biotech AS. 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 2009 (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 22 March 2010. 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 23 August 2010.

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 2009.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2010:

IFRS 3 – Business Combinations (revised)
IAS 27 – Consolidated and Separate Financial Statements (revised)

The amendments to IFRS 3 and IAS 27 did not affect the consolidated accounts for the first-half period for 2010, as no acquisitions were made and no holdings in subsidiaries bought or sold.

4. Earnings per share

Earnings per share:

	Q2 2010	Q2 2009	FY 2010	FY 2009	FY 2009
Result allocated to shareholders (in NOK '000)	(6 222)	(3 662)	(11 751)	(8 084)	(15 015)
Weighted average of outstanding shares (in '000)	5 641	5 416	5 528	5 416	5 416
Earnings per share (NOK per share)	-1,10	-0,68	-2,13	-1,49	-2,77

Diluted earnings per share:

	Q2 2010	Q2 2009	FY 2010	FY 2009	FY 2009
Result allocated to shareholders (in NOK '000)	(6 222)	(3 662)	(11 751)	(8 084)	(15 015)
Weighted average of outstanding shares (in '000)	6 130	5 416	6 017	5 416	5 416
Earnings per share (NOK per share)	-1,10	-0,68	-2,13	-1,49	-2,77

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, Photocure ASA 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 2010	Q2 2009	1H 2010	1H 2009	FY 2009
Radiumhospitalets Forskningsstiftelse	749	831	1 293	1 343	2 757
Theresa Comiskey Olsen	33	11	57	37	50
Photocure ASA	-	114	31	288	423

At the end of the quarter, PCI Biotech held NOK 239,000 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 Q2 2010.

Maturity profile on receivables as per 30 June:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	3 859	-	-	3 859
Total receivables	**3 859**	**-**	**-**	**3 859**

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:

	Second quarter		1.1 - 30.06	
	2010	2009	2010	2009
Carrying value at the beginning of the period	**13**	**63**	**27**	**76**
Additions		6		6
Amortization in the period	-13	-14	-27	-27
Carrying value at the end of the period	**-**	**55**	**-**	**55**

9. Tangible assets

Changes in value:

	Second quarter		1.1 - 30.06	
	2010	2009	2010	2009
Carrying value at the beginning of the period	**134**	**174**	**153**	**119**
Additions		33		107
Depreciation in the period	-20	-15	-39	-34
Carrying value at the end of the period	**114**	**192**	**114**	**192**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 26.4 million in non-capitalised deferred tax assets.

11. Share options

No share options were granted in the first six months of 2010.

In the second quarter 2009, a total of 234,000 share options were granted to five employees with an exercise price of NOK 6.80 per share, equal to the average price of the 5 latest days with trading prior to the General Meeting in April 2009.

The fair value of options granted in Q2 2009 determined using the Black-Sholes valuation model was NOK 675,000. The significant inputs into the model were a share price of NOK 6.80 at the grant date, volatility of 82.5%, dividend yield 0%, an expected option life of three years and an annual risk free rate of 3.25%.

Costs related to the share options were NOK 0.3 million in the second quarter and NOK 0.6 million in the first half year of 2010.

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	30.06.2010	30.06.2009
2013 - Q3	19,02	255 000	255 000
2014 - Q3	6,47	234 000	234 000

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 share 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 Foretaksregisteret on 21 June 2010.

Gross proceeds from the rights issue was NOK 90 million. Net proceeds was NOK 83.4 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

In July 2010 PCI Biotech settled with and received NOK 4.1 million from an undisclosed supplier following a production error. The production error has not had any material negative effect on the company's operations or finances. Results and the cash position in Q3 will be positively affected by NOK 4.1 million.

To the best of PCI Biotech's knowledge, there have been no other events subsequent to the end of the reported interim period that would influence on 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 2010 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, 23 August 2010

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