PCI Biotech Holding ASA - First Quarter 2010 Report

Highlights

- **Secured equity capital of NOK 90 million in a fully guaranteed Rights Issue**
- **Successful completion of the third Amphinex® dose group in the clinical study ongoing at University College Hospital (UCH) in London.**
  - **Strong anti-tumour response observed in all patients.**
  - **No serious adverse reactions deemed drug related have been recorded to date.**
  - **Apparent high treatment specificity for cancer cells.**

* * *

Operational Review

Progress in development programs
PCI Biotech Holding ASA is a cancer-focused drug delivery company. The company is developing a patented drug-delivery technology, photochemical internalization (PCI), to enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells.

PCI Biotech has an ongoing phase I/II study of Amphinex® in cancer patients performed at University College Hospital (UCH) in London. The study is a dose escalation study, and three dose levels are now completed. Eleven patients have been given a single photochemical internalisation (PCI) treatment with the combination product PC-A11, i.e. Amphinex® in combination with the generic cytotoxic agent bleomycin. Complete clinical regression of all evaluable treated tumours is observed within a few weeks of treatment, although one patient died of the underlying disease before complete clinical regression could be achieved. Patients with osteosarcoma (1) and squamous cell carcinoma (7) of the Head & Neck and adenocarinoma (3) of the Breast have been included and the effectiveness of PCI treatment with PC-A11 seems to be similar across all cancers treated so far. The PCI-technology could therefore potentially be used for local treatment of several different cancers. Three serious adverse events have been recorded; however these are not 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.

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. Bladder cancer is an interesting disease area for the use of the PCI technology. Bladder cancer is the 5th most expensive cancer indication, with the highest average per-patient life-time cost, mainly due to a high recurrence rate. The currently used pharmaceutical treatments have limited effect on recurrence and progression, and there is a large unmet medical need. The bladder is easily accessible for the components of the PCI technology: PC-A22 (Amphinex® and epirubicin) and light .

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.

The Scientific Advice meetings held with central and national European Health Authorities during 2009 has provided a clear regulatory route to market for PCI-based combination products.

Rights Issue

On 23 April 2010, the Board of PCI Biotech Holding ASA proposed to strengthen the equity by up to NOK 90 million through a share issue of 2,250,000 shares with pre-emptive subscription rights for existing shareholders (the "Rights Issue"). The Rights Issue is fully guaranteed by a consortium of existing shareholders. The subscription price in the Rights Issue is NOK 40 per new share.

The objective of the Rights Issue is to strengthen the Company's equity to be able to perform planned clinical development studies within selected cancer indications.

The Rights Issue is subject to approval of an Extraordinary General meeting and approval of a Prospectus. For more information, please refer to note 12.

Financial Review

Results 1st Quarter 2010

The company receives grants from Norway and EU. The grants are shown as revenues, and revenues in the quarter were NOK 1.4 million compared with NOK 1.7 million in Q1 2009. The reduction in grants from 2009 is explained by some grants ending 31 December 2009.

R&D costs in Q1 2010 were NOK 4.9 million, in line with Q1 2009, which were affected by a NOK 1.7 million investment in production of Amphinex®. Costs related to preclinical and clinical studies have increased by NOK 1.4 million compared to Q1 2009.

G&A costs have increased mainly due to an increase in number of employees and a NOK 1.1 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 7.1 million in Q1 2010, compared with NOK 7.0 million in Q1 2009.

Operating results were NOK -5.7 million in Q1 2010 compared with NOK -5.2 million in Q1 2009.

Net cash flow from operations was NOK -3.6 million in Q1 2010, compared with NOK -4.3 million in Q1 2009. Net cash flow in the quarter was NOK -3.7 million compared with NOK -4.4 million in Q1 2009.

Balance

The company held cash and cash equivalents of NOK 32.2 million at the end of the quarter. A large proportion of the cash equivalents is placed in Norwegian money market funds with approximately 3 months maturity. Total equity was NOK 29.8 million compared with NOK 35.1 million at the end of 2009. The change in equity reflects the loss in the period.

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 complete the ongoing clinical study at University College Hospital in London, as well as complete pre-clinical studies performed in various cancers, including bladder. Further clinical studies are planned to be initiated by the end of 2011 based on the results of these studies.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK '000)	Note	Q1 2010	Q1 2009	01.01-31.12 2009
Other Income		**1 362**	**1 716**	**8 612**
Research and development expenses		4 856	4 960	19 319
General and administrative expenses		2 222	2 002	6 979
Operating costs		**7 078**	**6 962**	**26 298**
OPERATING RESULT		**(5 716)**	**(5 246)**	**(17 686)**
Financial income and expenses				
Financial income		188	867	2 838
Financial expenses		0	(43)	(167)
Net financial result		**188**	**824**	**2 671**
ORDINARY PROFIT BEFORE TAXES		**(5 528)**	**(4 422)**	**(15 015)**
Tax on ordinary result	10	0	0	0
Net profit/loss	4	**(5 528)**	**(4 422)**	**(15 015)**
Other comprehensive income		0	0	0
Comprehensive income		**(5 528)**	**(4 422)**	**(15 015)**

BALANCE SHEET

(In NOK '000)	Note	31.03.2010	31.03.2009	31.12.2009
Fixed and Intangible Assets				
Intangible assets	8	13	63	27
Operating assets	9	134	178	153
Total fixed and intangible assets		**147**	**241**	**181**
Current Assets				
Short term receivables	7	4 507	3 629	5 017
Cash & cash equivalents		32 171	45 757	35 823
Total current assets		**36 678**	**49 386**	**40 840**
Total assets		**36 825**	**49 627**	**41 021**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		105 108	104 842	105 108
Other reserves		-75 280	-59 821	-70 031
Total equity	11	**29 828**	**45 021**	**35 077**
Trade debtors		518	1 661	2 557
Other short term debt		6 479	2 945	3 387
Total short term debt		**6 997**	**4 606**	**5 944**
Total debt		6 997	4 606	5 944
Total shareholders equity and liabilities		**36 825**	**49 627**	**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		-	-	-	-
Share option scheme	12	-	280	-	280
Comprehensive income in the period		-	-	-5 528	-5 528
Balance at 31 March 2010		**16 249**	**1 486**	**12 094**	**29 828**

CASH FLOW

(In NOK '000)	Q1 2010	Q1 2009	01.01-31.12 2009
Ordinary profit before taxes	-5 528	-4 422	-15 015
Depreciation, Amortization and Write Off	33	32	128
Share options	280	142	791
Changes in pension funds	-	-	-
Other changes	-	-	-
Net financials	-188	-824	-2 258
Changes in working capital	1 563	-63	-110
Cash flow from operations	-3 840	-5 135	-16 464
Net financials	188	824	2 258
Taxes paid	-	-	-
Net cash flow from operations	-3 652	-4 311	-14 206
Cash flow from investments			
Purchase of tangible assets	-	-74	-107
Purchase of intangible assets	-	-	-6
Net cash flow from investments	-	-74	-113
Cash flow from financial activities			
Net proceeds from share issues	-	-	-
Net cash flow from financial activities	-	-	-
Net change in cash during the period	-3 652	-4 385	-14 319
Cash and cash equivalents at the beginning of the period	35 823	50 142	50 142
Cash and cash equivalents at the end of the period	32 171	45 757	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 with their drugs. 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 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. This is the Company's seventh interim report presented in accordance with IAS 34. The same accounting principles have been applied for all reported periods in this report. The board of directors approved the interim condensed financial information on 26 April 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.

4. Earnings per share

Earnings per share:

	Q1 2010	Q1 2009	FY 2009
Result allocated to shareholders (in NOK '000)	(5 528)	(4 422)	(15 015)
Weighted average of outstanding shares (in '000)	5 416	5 416	5 416
Earnings per share (NOK per share)	-1,02	-0,82	-2,77

Diluted earnings per share:

	Q1 2010	Q1 2009	FY 2009
Result allocated to shareholders (in NOK '000)	(5 528)	(4 422)	(15 015)
Weighted average of outstanding shares (in '000)	5 905	5 416	5 416
Earnings per share (NOK per share)	-1,02	-0,82	-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	Q1 2010	Q1 2009	FY 2009
Radiumhospitalets Forskningsstiftelse	544	512	2 757
Theresa Comiskey Olsen	24	26	50
Photocure ASA	31	173	423

At the end of the quarter, PCI Biotech held NOK 544,000 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 Q1 2010.

Maturity profile on receivables as per 31 March:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	4 507	-	-	4 507
Total receivables	**4 507**	**-**	**-**	**4 507**

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:

	First quarter	
	2010	2009
Carrying value at the beginning of the period	**27**	**76**
Additions		-
Amortization in the period	-14	-13
Carrying value at the end of the period	**13**	**63**

9. Tangible assets

Changes in value:

	First quarter	
	2010	2009
Carrying value at the beginning of the period	**153**	**119**
Additions		74
Depreciation in the period	-19	-15
Carrying value at the end of the period	**134**	**178**

10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 24.7 million in non-capitalised deferred tax assets.

11. Share options

No share options were granted in the first quarter.

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 first quarter.

Share options outstanding at the end of the period have the following expiry date and exercise prices:

	Exercise price in NOK per	Number of shares	
Expiry date	**share**	**31.03.2010**	**31.03.2009**
2013 - Q3	20,00	255 000	210 000
2014 - Q3	6,80	234 000	0

12. Rights Issue

On 23 April 2010, the Board of Directors PCI Biotech Holding ASA ("PCI Biotech") 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 is guaranteed fully subscribed. The subscription price in the rights issue is NOK 40 per share.

The purpose of the rights issue is to strengthen the equity to enable the company to complete the planned clinical development studies within selected cancer indications.

The rights issue is subject to approval by an extraordinary general meeting. The company will call for the extraordinary general meeting as soon as practicable possible, and it is expected to be held on 18 May 2010.

Transaction highlights:
The proposed share capital increase will be carried out as a rights issue for existing shareholders in PCI Biotech, as per the date of the extraordinary general meeting, who lawfully may participate in the share capital increase. The shares will be traded excluding subscription rights from and including the day after the extraordinary general meeting is held.

It will be issued 0.4154 subscription rights per existing share in PCI Biotech. The number of subscription rights issued to each shareholder will be rounded down to the nearest whole subscription right. Each subscription right entitles subscription of one new share. The subscription rights will be freely transferable and will be sought listed on Oslo Axess during the subscription period. Subscription rights not used during the subscription period will lapse and be without value at the end of the subscription period. Oversubscription is allowed, and it will be permitted to subscribe for shares without the use of subscription rights.

Subject to that the prospectus for the rights offering is approved by The Financial Supervisory Authority of Norway, the subscription period is expected to be from and including 26 May 2010 to and including 9 June 2010. The rights issue is planned to be completed within the end of June 2010.

The subscription price per new share in the rights issue will be NOK 40 per new PCI Biotech share, which is approx. 16.7% below the closing price on 22 April 2010.

The proposed share capital increase is guaranteed fully subscribed by a guarantee consortium, whereby all the guarantors are among the company's largest shareholders. The participants in the guarantee consortium shall subscribe for shares that are not subscribed by others by the end of the subscription period. The guarantee commission is 1.5% of guaranteed amount.

The guarantee consortium has been established by DnB NOR Markets and Fondsfinans, which will act as Managers for the rights issue.

PCI Biotech will prepare a prospectus for the rights issue which shall be approved by The Financial Supervisory Authority of Norway, and will provide further information about the rights issue and the company.

After completion of the rights issue, the company's share capital will be 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

Other than the Rights Issue mentioned in Note 12, and 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 on the financial statements included in this report.