PCI Biotech Holding ASA - Second Quarter and First half 2013 Report

Highlights

- **Re-designed the ENHANCE-study – a Phase II study in head & neck cancer patients. The study has been amended to include a light dose escalation run-in phase to optimise the intra-tumour treatment regimen and a proof-of-concept part to confirm safety and efficacy. Patient inclusion has been slower than anticipated.**

- **Initiated a Proof of Concept study in bile duct cancer (cholangiocarcinoma). All necessary approvals are granted in the UK and Germany, and three of the five hospitals planned for the first part of the study are now screening for patients.**

- **Increasing the focus on development of PCI as a technology platform for vaccination. Preclinical *ex vivo* and *in vivo* studies demonstrate the potential of PCI as a versatile vaccination platform for both therapeutic and prophylactic vaccination.**

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Operational Review

Progress in development programs

PCI Biotech Holding ASA (PCI Biotech) is an oncology-focused company developing innovative products for cancer treatment. The products are based on PCI Biotech's patented technology, photochemical internalization (PCI). The PCI technology can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells, and can also be used as a vaccination platform that may potentiate the effect of vaccines.

Amphinex® in combination with bleomycin, head & neck cancer

PCI Biotech's lead candidate is the photosensitiser Amphinex. A Phase I/II study of Amphinex in combination with the cytotoxic 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, with the majority being head & neck cancer. A strong response to treatment was seen in all patients and Amphinex seemed 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 & neck squamous cell carcinoma unsuitable for surgery and radiotherapy. The study will include approximately 80 patients with progression free survival at 6 months as the primary endpoint. Patient inclusion started in May 2012.

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. The Independent Data Monitoring Board (IDMB), established for surveillance of the study, recommended the company to optimise the treatment regimen for intra-tumour illumination before further patients are treated with this procedure. Patient inclusion in the ENHANCE study was therefore paused for patients with deeper tumours requiring intra-tumour illumination while the study was redesigned.

The intra-tumour illumination procedure will now be optimized in a separate part of the study, running in parallel to the open inclusion of patients for superficial illumination. The Amphinex dose will not be modified; the optimization will be performed solely by modifying the light dose. Total number of patients in the dose optimisation part of the study will depend on the number of dose escalations needed to find an efficient and safe light dose. Proof of Concept (PoC) of efficacy and safety for intra-tumour treatment and final confirmation of light dose for the ENHANCE study will be achieved by inclusion of 12 patients at the selected light dose. Patients treated at this level will be included in the ENHANCE study. The intra-tumour part of the study will be performed at selected hospitals with extensive experience with photodynamic therapy, with The Netherlands Cancer Institute (NKI) in Amsterdam as the coordinating site. Three European sites are currently open for inclusion and actively screening for patients for the intra-tumour part of the study.

Patient inclusion in the ENHANCE study has been slower than initially expected, due both to too strict inclusion criteria and the too strong effect with intra-tumour illumination. A total of eleven patients have been treated so far. To increase the number of patients eligible for the PCI treatment in head and neck cancer, and to speed up the inclusion, it was decided to broaden the patient population by also including metastatic patients with a need of local disease treatment. Patient inclusion for intra-tumour treatment has however been slower than anticipated over the summer, with one patient included so far. The PoC part of the study may be completed in 1H 2014, depending on the number of light dose escalations needed.

Clinical study in patients with bile duct cancer (Cholangiocarcinoma)

A Proof of Concept study for the use of PCI in patients with bile duct cancer has been initiated. In this indication Amphinex will be used in combination with the generic cytotoxic agent gemcitabine.

The Proof of Concept study is 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 consists 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 is to determine a tolerable dose for local bile duct treatment with Amphinex induced PCI of gemcitabine, while the Phase II primary objective is 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 Germany, and three hospitals in Germany are currently open for inclusion and actively screening for patients.

PCI for vaccination

The company has decided to increase the focus on a project that aims 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, The Radium Hospital, Oslo, Norway and University Hospital Zürich, Switzerland.

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.

Proof-of-principle has been established in a mouse model for enhancement of *ex vivo* vaccination. *Ex vivo* (also called autologous) vaccination is a treatment procedure where immune cells are removed from the patient and treated outside the body. The treated immune cells are then reintroduced to the patient. This principle is employed in the only cancer vaccine that is approved for use in humans, and it is also the basis for several cancer vaccines that are under clinical development. Results from *ex vivo* studies performed in collaboration with researchers at University Hospital Zurich have been accepted for publication in European Journal of Pharmaceutics and Biopharmaceutics in an article with the title 'Photochemical targeting of antigens to the cytosol for stimulation of MHC class-I-restricted T-cell responses'. The researches have tested the ability of PCI to enhance the vaccine induced stimulation of so-called cytotoxic T-cells in an animal model for autologous (*ex vivo*) vaccination. Cytotoxic T-cells are immune cells that are considered to be of primary importance for killing tumour cells after therapeutic cancer vaccination. The results of the study show that the use of the PCI technology substantially increased the amount of antigen-specific cytotoxic T-cells in the animals, an effect that could be very important for improving the efficacy of several different approaches under development for therapeutic cancer vaccination. According to the researchers this study in mice provides proof of principle for the use of PCI-mediated immunization and has revealed the feasibility of using the PCI technology to improve the effect of autologous vaccination. The article is expected to be available late August or early September.

Proof-of-principle has also been established in a mouse model for enhancement of *in vivo* vaccination, where up to 40 times PCI induced enhancement of antigen specific T-cells has been seen. These promising preclinical results have been achieved by simply mixing the antigen and photosensitiser for local injection, and then illuminate locally with an inexpensive light source.

Effective adjuvant technologies are considered key to the success of therapeutic vaccination, and vaccination companies are seeking improved adjuvant technologies for their vaccine technologies. PCI Biotech's novel mode of action may allow the use of PCI as a new adjuvant system for vaccinations where existing adjuvant systems do not work.

PCI represents a simple and innovative adjuvant platform that may be licensed on a non-exclusive basis in an innovative emerging market in need of novel solutions. The company is currently building a robust vaccination IP estate and further strengthening the promising preclinical data to optimise the conditions for PCI vaccination and generate results in relevant tumour models.

Financial Review

Results 2nd Quarter 2013

The company received grants from Norway and EU and these are shown as revenues. Revenues in the quarter were NOK 1.7 million compared with NOK 1.9 million in Q2 2012.

R&D costs in Q2 2013 were NOK 6.6 million compared with NOK 5.9 million in Q2 2012. Costs to external partners and hospitals on pre-clinical and clinical trials were higher due to an increased activity level in all three major projects; head & neck cancer, bile duct cancer and vaccines.

G&A costs in Q2 2013 were NOK 1.0 million compared with NOK 0.3 million in Q2 2012.

Total operating costs were NOK 7.6 million in Q2 2013, compared with NOK 6.2 million in Q2 2012.

Operating results were NOK -5.9 million in Q2 2013 compared with NOK -4.3 million in Q2 2012.

Net cash flow from operations and net cash flow in the quarter was NOK -6.7 million in Q2 2013, compared with NOK -4.4 million in Q2 2012.

Results 1H 2013

Revenues were NOK 3.1 million in 1H 2013 compared with NOK 3.8 million in 1H 2012. Total costs were NOK 16.2 million in 1H 2013, compared with NOK 14.3 million in 1H 2012.

R&D costs in 1H 2013 were NOK 14.5 million, compared with NOK 13.5 million in 1H 2012. G&A costs in 1H 2013 were NOK 1.7 million compared with NOK 0.8 million in 1H 2012.

Operating results were NOK -13.1 million in 1H 2013 compared with NOK -10.5 million in 1H 2012.

Net cash flow from operations and net cash flow was NOK -13.5 million in 1H 2013, compared with NOK -9.2 million in 1H 2012.

Balance

The company held cash and cash equivalents of NOK 59.6 million at the end of the quarter. Total equity was NOK 58.4 million compared with NOK 69.7 million at the end of 2012. 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 PCI technology. An increased focus will also be placed on the development and licensing of PCI as a versatile and innovative adjuvant platform for vaccination.

The main priorities with the available funds are to:

- Effectively progress the optimization and proof of concept of intra-tumour head and neck cancer treatment of Amphinex and bleomycin;
- Complete the first part of the proof of concept study of bile duct cancer treatment with Amphinex and gemcitabine;
- Build a robust vaccination IP estate and further strengthen the promising preclinical results;
- Ramp up partnering activities.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK 1,000)	Note	Q2 2013	Q2 2012	01.01- 30.06 2013	01.01-30.06 2012	01.01-31.12 2012
Other Income		**1 688**	**1 896**	**3 078**	**3 805**	**6 765**
Research and development	8	6 551	5 925	14 523	13 497	31 263
General and administrative		1 027	262	1 689	793	2 856
Operating costs		**7 578**	**6 187**	**16 212**	**14 290**	**34 119**
Operating results		**-5 890**	**-4 291**	**-13 134**	**-10 485**	**-27 354**
Financial income and costs						
Financial income		478	528	898	1 213	2 322
Financial costs		0	0	0	0	-227
Net financial result		**478**	**528**	**898**	**1 213**	**2 095**
Ordinary profit before taxes		**-5 412**	**-3 763**	**-12 236**	**-9 272**	**-25 259**
Tax on ordinary result	9	0	0	0	0	0
Net profit/loss	4	**-5 412**	**-3 763**	**-12 236**	**-9 272**	**-25 259**
Other comprehensive income		0	0	0	0	0
Comprehensive income		**-5 412**	**-3 763**	**-12 236**	**-9 272**	**-25 259**

BALANCE SHEET

(In NOK 1,000)	Note	30.06 2013	30.06 2012	31.12 2012
Fixed and intangible assets				
Operating assets		21	0	0
Total fixed and intangible assets		**21**	**0**	**0**
Current assets				
Short term receivables	*7*	4 813	5 892	5 118
Cash & cash equivalents		59 608	85 903	73 083
Total current assets		**64 421**	**97 795**	**78 201**
Total assets		**64 442**	**91 795**	**78 201**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		190 903	189 468	191 148
Other reserves		-132 458	-105 437	-96 615
Total equity	***10***	**58 445**	**84 031**	**69 706**
Trade debtors		1 590	3 699	1 984
Other short term debt		4 407	4 065	6 511
Total debt		**5 997**	**7 764**	**8 495**
Total shareholders equity and liabilities		**64 442**	**91 795**	**78 201**

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**
Share option scheme	10	-	975	-	975
Comprehensive income in the period		-	-	-12 236	-12 236
Balance at 30 June 2013		**22 999**	**83 009**	**-47 562**	**58 445**

CASH FLOW

(In NOK '000)	Note	Q2 2013	Q2 2012	01.01-30.06 2013	01.01-30.06 2012	01.01-31.12 2012
Ordinary profit before taxes		-5 412	-3 763	-12 236	-9 272	-25 259
Depreciation, Amortization and Write Off		1	12	1	17	17
Share options		535	450	975	770	2 431
Net financials		-478	-528	898	-1 213	-2 095
Changes in working capital		-1 859	-1 090	-2 193	-727	779
Cash flow from operations		-7 213	-4 919	-12 555	-10 425	-24 127
Net financials		478	528	-898	1 213	2 095
Taxes paid		-	-	-	-	-
Net cash flow from operations		-6 735	-4 391	-13 453	-9 212	-22 032
Cash flow from investments						
Purchase of tangible assets		-	-	-22	-	-
Purchase of intangible assets		-	-	-	-	-
Net cash flow from investments		-	-	-22	-	-
Cash flow from financial activities						
Net proceeds from share issues		-	-	-	-	-
Net cash flow from financial activities		-	-	-	-	-
Net change in cash during the period		-6 735	-4 391	-13 475	-9 212	-22 032
Cash and cash equivalents at the beginning of the period		66 343	90 294	73 083	95 115	95 115
Cash and cash equivalents at the end of the period		59 608	85 903	59 608	85 903	73 083

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. 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 2012 (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 11 March 2013. 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 19 August 2013.

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 2012.

The new standards, interpretations or amendments to published standards that were effective for the annual period beginning on January 1, 2013 and that could affect the PCI Biotech are discussed in accounting policies, part 3, to the consolidated financial statements for 2012. In the 2012 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 2013	Q2 2012	6M 2013	6M 2012	FY 2012
Result allocated to shareholders (in NOK '000)	(5 412)	(3 763)	(12 236)	(9 272)	(25 259)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666	7 666	7 666
Earnings per share (NOK per share)	-0,71	-0,49	-1,60	-1,21	-3,29

Diluted earnings per share:

	Q2 2013	Q2 2012	6M 2013	6M 2012	FY 2012
Result allocated to shareholders (in NOK '000)	(5 412)	(3 763)	(12 236)	(9 272)	(25 259)
Weighted average of outstanding shares (in '000)	8 135	8 524	8 113	8 524	8 389
Earnings per share (NOK per share)	-0,71	-0,49	-1,60	-1,21	-3,29

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 2013	Q2 2012	6M 2013	6M 2012	FY 2012
Radiumhospitalets Forskningsstiftelse	478	249	923	389	1 593
Theresa Comiskey Olsen	-	3	3	3	3

At the end of the quarter, 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 30 June:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	5			5
Other receivables	4 808	-	-	4 808
Total receivables	**4 813**	**-**	**-**	**4 813**

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 20 million of the cash was placed at accounts with fixed interest. The fixed interest matures in Q4 2013.

8. Research and Development costs

	Q2 2013	Q2 2012	6M 2013	6M 2012	2012
Clinical studies	3 900	3 476	8 336	6 606	15 938
Pre-clinical studies	1 661	544	3 187	2 211	5 308
CMC and equipment	556	963	2 279	2 919	5 840
Patents	434	942	721	1 761	3 041
Other costs					1 135
Total	**6 551**	**5 925**	**14 523**	**13 497**	**31 262**

9. Deferred tax and deferred tax assets
At the end of the quarter, the company held NOK 39.5 million in non-capitalised deferred tax assets.

10. Share options
In Q2 2013, the following changes were made to the option program;

• Options allocated in 2008 expiring in 2013 were extended with 3 years until 2016. At the same time, options allocated in 2008 were reduced with 1/3 from 255,000 to 170,000 options. Strike price is unchanged at NOK 19.02 per share. The fair value of this change using the Black-Scholes valuation model was NOK 725,000. The significant input to the model were a share price of NOK 19,63 at the grant day, volatility of 83% and risk free rate of 1.54 % for the prolonged period and volatility of 55% and risk free rate of 1.44 % for the released options. Dividend yield 0% in both calculations.

• The 85,000 released options were allocated to 2 employees. The employees may exercise 1/3 of the options after 1 year, another 1/3 after 2 years and the last 1/3 after 3 years. The options expire in Q2 2018. Strike price for these share options is NOK 19.63 per share, equal to the average price of all trades the 5 last days with trade prior to allocation. The fair value of this allocation using the Black-Scholes valuation model was NOK 888,000, The significant input to the model were a share price of NOK 19,63 at the grant day, volatility of 83%, dividend yield 0% and risk free rate of 1.54 %.

Costs related to the share options were NOK 0.5 million in Q2 2013 and NOK 1.0 million in 1H 2013.

On 28th June, CFO Bernt Olav Røttingsnes exercised 60,000 options allocated in Q2 2009 with an exercise price of NOK 6.47 per share. The capital increase was completed in July 2013.

Remaining 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 30.06.2013	30.06.2012
2016 - Q3	19.02	170 000	255 000
2014 - Q3	6.47	174 000	234 000
2015 - Q3	37.24	115 000	115 000
2017 - Q3	37.02	135 000	135 000
2018 - Q2	19.63	85 000	
Total		**679 000**	**739 000**

11. VAT

In March 2013, the Company received notice from the Norwegian Tax Authorities (Skatteetaten) that they were considering to recalculate the 5th term 2012 VAT report, with the implication that the Company should repay NOK 0.9 million in VAT. Skatteetaten argued that the Company has not had any VAT related income and therefore has lost the right to deduct the VAT in the VAT reports. The issue was resolved during Q2 without any financial implications for PCI Biotech.

12. 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 2013 which has been prepared in accordance with IAS34 Interim Financial Statements gives a true and fair view of the Company's and Group'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, 19 August 2013

Erling Øverland Chairman	Theresa Comiskey Olsen	Else Krüger Hagen
Kjetil Taskén	Kjell Stenberg	Per Walday CEO