PCI Biotech Holding ASA - First Quarter 2013 Report

Highlights

- **Patient inclusion in the ENHANCE study is open for patients treated with superficial illumination. There is a temporary halt in the inclusion of patients treated with intra-tumour illumination due to stronger local treatment effects than expected and desired. Inclusion of patients treated with intra-tumour illumination is expected to resume in Q2 2013.**
- **Preparation for the Proof of Concept study in bile duct cancer (cholangiocarcinoma) is progressing according to plan. All necessary approvals are granted in the UK and Germany, and inclusion of patients is expected to start in Q2 2013.**
- **Proof-of-principle has been established in an animal model for PCI enhancement of ex vivo vaccination. The preclinical program to investigate PCI used to enhance the effect of in-vivo vaccines is developing according to plan.**
- **The organization is strengthened with the employment of Gaël L'Hévéder as Head of Business Development.**

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Operational Review

Progress in development programs

PCI Biotech Holding ASA (PCI Biotech) is a company developing products for localised cancer treatment. The products are based on PCI Biotech's patented drug-delivery technology, photochemical internalization (PCI), which can enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells.

Amphinex® in combination with bleomycin, head & neck cancer

PCI Biotech's lead candidate is the photosensitiser Amphinex used in combination with the generic cytotoxic agent bleomycin. A Phase I/II study of Amphinex in combination with bleomycin in cancer patients, 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 and strong response to treatment was seen in all patients. Amphinex seems to be well tolerated.

Phase II study in head & neck cancer patients – the ENHANCE study

The ENHANCE study is a single arm, multi-centre, phase II study to evaluate the safety and efficacy of Amphinex in combination with the generic cytotoxic agent bleomycin with superficial and interstitial laser light application in patients with recurrent head & 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.

In December 2012, the company reported that it is necessary to modify the study. 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) recommended the company to optimise the treatment regimen for intra-tumour illumination before further patients are treated with this procedure.

In February 2013, the company decided how to optimize the treatment procedure. Inclusion of patients treated with superficial illumination continues in the ENHANCE study, while the intra-tumour illumination procedure is optimized in a parallel intra-tumour part of the study. This part of the study will be performed at selected hospitals with extensive experience with photodynamic therapy. The Netherlands Cancer Institute in Amsterdam will take over as the coordinating site.

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 12-15 patients at the selected light dose. Patients treated at this level will be included in the ENHANCE study.

These changes have been implemented in amendments to the study protocol, and the amendments are currently being evaluated by the relevant authorities. Inclusion of patients in the optimisation part of the ENHANCE study is expected to start in Q2 2013, subject to approvals from relevant authorities. The PoC part of the study may be completed and reported in 2H 2013 or early 2014, depending on the number of escalations needed.

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, with 8 patients 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 has been decided to broaden the patient population by also including metastatic patients with a need of local disease treatment. This exclusion criterion has proven to limit patient inclusion.

The intention is still to include up to 80 patients in the ENHANCE study, maintaining the possibility to file a Marketing Authorization Application (MAA) in Europe if the favourable results in the Phase I/II study at University College Hospital in London is confirmed in the ENHANCE study.

Clinical study in patients with bile duct cancer (Cholangiocarcinoma)

Preparations for a Proof of Concept study for the use of PCI in patients with bile duct cancer is progressing according to plan. In this indication Amphinex will be used in combination with the generic cytotoxic agent gemcitabine.

Surgery is currently the only curative option for these patients, yet the majority of the tumours are inoperable at presentation. Inoperable patients are treated with stenting to keep the bile duct open and with chemotherapy. Combination of the chemotherapeutics gemcitabine and cisplatin has shown promising results and has become standard treatment in some countries, but there is still a need for better treatments to increase overall survival and quality of life. Bile duct cancer is characterised by a remarkable resistance to common chemotherapy, and new drug classes or alternative methods are needed. The most studied and used drug is gemcitabine, which is one of the identified drugs that is significantly enhanced by PCI in preclinical studies. Light access is easy through the endoscopic methods that are routinely used in the treatment of this disease.

The Proof of Concept study is planned to be an open-label, multi-centre Phase I/II study in up to 45 patients to assess the safety and efficacy of Amphinex induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine in patients with inoperable bile duct cancer. The study will consist of a dose escalation/phase I part to assess the tolerance of local bile duct treatment and a randomized double-arm phase II part. In phase II patients will be randomized to either a control arm (stenting alone followed by gemcitabine/cisplatin chemotherapy) or the PCI arm (stenting followed by Amphinex induced PCI treatment of gemcitabine followed by gemcitabine/cisplatin chemotherapy). The

randomisation ratio for this study is 2.5:1 in favor of the PCI arm. The Phase I primary objective will be to determine a tolerable dose for local bile duct treatment with Amphinex induced PCI of gemcitabine, while the Phase II primary objective will be to assess efficacy in terms of progression free survival. The company has received all necessary approvals from the authorities and ethics committee in the UK and Germany, and is currently clarifying the last details necessary to start patient inclusion. Patient inclusion is expected to start in Q2 2013.

PCI for vaccination

The company has a project supported by Norwegian Research Council with NOK 10.85 million over a three-year period. The project aims to document that PCI Biotech's photochemical internalization technology (PCI) induces immunological effects that can be used in treatment of cancer patient. An important part of the project is 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 and with University Hospital Zürich, Switzerland, where the company currently has personnel deployed to focus and speed up the progress.

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.

Preclinical studies performed by the company's collaborators have shown that under certain conditions, PCI can increase the vaccination effect of antigens. Proof-of-principle has been established in a mouse model for enhancement of ex vivo vaccination. Ex vivo 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 many of the cancer vaccines that are under clinical development.

Further studies at University Hospital Zürich, Switzerland, focus on optimising the treatment regimen for in vivo vaccination, with the aim to establish a protocol for a possible clinical study that can start in 2013, if this is considered beneficial for the company. This project is progressing according to plan. The company will seek partnership for development of the PCI technology within vaccination

Gaël L'Hévéder employed as Head of Business Development

Mr Gael L'Hévéder has joined PCI Biotech as Head of Business Development. Mr L'Hévéder is a 44 years old dual French/US citizen with a Master of Science in organic chemistry. He has more than 15 years industry experience gained both in large pharmaceutical companies (Sanofi-Aventis, Baxter and Roche) and in biotech start-ups. Throughout his career he has worked both in US and Europe. In recent years, Mr L'Hévéder has held the position of Business Development Director, Pharma Partnering at Roche and the position of European Business Intelligence Director at Baxter Healthcare.

Financial Review

Results 1st Quarter 2013

The company received grants from Norway and EU and these are shown as revenues. Revenues in the quarter were NOK 1.4 million compared with NOK 1.9 million in Q1 2012.

R&D costs in Q1 2013 were NOK 8.0 million compared with NOK 7.6 million in Q1 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 Q1 2013 were NOK 0.7 million compared with NOK 0.5 million in Q1 2012.

Total operating costs were NOK 8.6 million in Q1 2013, compared with NOK 8.1 million in Q1 2012.

Operating results were NOK -7.2 million in Q1 2013 compared with NOK -6.2 million in Q1 2012.

Net cash flow from operations and net cash flow in the quarter was NOK -6.7 million in Q1 2013, compared with NOK -4.8 million in Q1 2013.

Balance

The company held cash and cash equivalents of NOK 66.3 million at the end of the quarter. Total equity was NOK 63.3 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 drug delivery platform.

The main focus is an effective development of Amphinex in combination with bleomycin and in combination with gemcitabine. Priorities in 2013 will be to optimize both the treatment procedure and study protocol for the ENHANCE study within head and neck cancer, and to start and secure a rapid patient inclusion in the phase I/II study in bile duct cancer.

Another priority is to complete the preclinical studies of PCI within vaccination, to start a clinical study if considered beneficial, and seek partnership for development of the PCI technology within vaccination.

CONDENSED CONSOLIDATED FINANCIAL INFORMATION

PROFIT AND LOSS

(In NOK ',000)	Note	Q1 2013	Q1 2012	01.01-31.12 2012
Other Income		**1 391**	**1 909**	**6 765**
Research and development	8	7 972	7 572	31 263
General and administrative		663	545	2 856
Operating costs		**8 635**	**8 117**	**34 119**
Operating results		**-7 244**	**-6 208**	**-27 354**
Financial income and costs				
Financial income		419	686	2 322
Financial costs		0	0	-227
Net financial result		**419**	**686**	**2 095**
Ordinary profit before taxes		**-6 825**	**--5 522**	**--25 259**
Tax on ordinary result	9	0	0	0
Net profit/loss	4	**-6 825**	**-5 522**	**-25 259**
Other comprehensive income		0	0	0
Comprehensive income		**-6 825**	**-5 522**	**-25 259**

BALANCE SHEET

(In NOK '000)	Note	31.03 2013	31.03 2012	31.12 2012
Fixed and Intangible Assets				
Operating assets		22	12	0
Total fixed and intangible assets		**22**	**12**	**0**
Current assets				
Short term receivables	7	5 057	5 339	5 118
Cash & cash equivalents		66 343	90 294	73 083
Total current assets		**71 400**	**95 633**	**78 201**
Total assets		**71 422**	**95 645**	**78 201**
Shareholders equity and liabilities				
Shareholders equity				
Paid in capital		190 808	189 468	191 148
Other reserves		-127 486	-102 137	-96 615
Total equity	***10***	**63 322**	**87 331**	**69 706**
Trade debtors		2 600	2 268	1 984
Other short term debt		5 500	6 046	6 511
Total debt		**8 100**	**8 314**	**8 495**
Total shareholders equity and liabilities		**71 422**	**95 645**	**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 2011		**22 999**	**79 603**	**-10 067**	**92 533**
Share option scheme	9	-	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	9	-	440	-	440
Comprehensive income in the period		-	-	-6 825	-6 825
Balance at 31 March 2013		**22 999**	**82 474**	**-42 151**	**63 322**

CASH FLOW

(In NOK '000)	Note	Q1 2013	Q1 2012	01.01-31.12 2012
Ordinary profit before taxes		-6 825	-5 522	-25 259
Depreciation, Amortization and Write Off		-0	5	17
Share options		440	320	2 431
Net financials		-419	686	-2 095
Changes in working capital		-333	376	779
Cash flow from operations		-7 137	-4 135	-24 127
Net financials		419	-686	2 095
Taxes paid		-	-	-
Net cash flow from operations		-6 718	-4 821	-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		-6 740	-4 821	-22 032
Cash and cash equivalents at the beginning of the period		73 083	95 115	95 115
Cash and cash equivalents at the end of the period		66 343	90 294	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 29 April 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:

	Q1 2013	Q1 2012	FY 2012
Result allocated to shareholders (in NOK '000)	(6 825)	(5 522)	(25 259)
Weighted average of outstanding shares (in '000)	7 666	7 666	7 666
Earnings per share (NOK per share)	-0,89	-0,72	-3,29

Diluted earnings per share:

	Q1 2013	Q1 2012	FY 2012
Result allocated to shareholders (in NOK '000)	(6 825)	(5 522)	(25 259)
Weighted average of outstanding shares (in '000)	8 155	8 467	8 389
Earnings per share (NOK per share)	-0,89	-0,72	-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	Q1 2013	Q1 2012	FY 2012
Radiumhospitalets Forskningsstiftelse	445	280	1 593
Theresa Comiskey Olsen	-	-	3

At the end of the quarter, PCI Biotech had NOK 316,000 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 31 March:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	4			4
Other receivables	5 053	-	-	5 053
Total receivables	**5 057**	**-**	**-**	**5 057**

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 50 million of the cash was placed at accounts with fixed interest. The fixed interest matures in Q2 2013.

8. Research and Development costs

	Q1 2013	Q1 2012	2012
Clinical studies	4 375	2 943	15 938
Pre-clinical studies	1 526	1 667	5 308
CMC and equipment	1 723	1 956	5 840
Patents	287	819	3 041
Other costs		187	1 135
Total	**7 911**	**7 572**	**31 262**

9. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 42.4 million in non-capitalised deferred tax assets.

10. Share options

739,000 share options have been granted to six employees. No options have been allocated in 2013. Costs related to the share options were NOK 0.4 million in Q1 2013.

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 31.03.2013	31.03.2012
2013 - Q3	19.02	255 000	255 000
2014 - Q3	6.47	234 000	234 000
2015 - Q3	37.24	115 000	115 000
2017 - Q3	37.02	135 000	135 000
Total		**739 000**	**739 000**

11. VAT

In March 2013, the Company received notice from the Norwegian Tax Authorities (Skatteetaten) that they are considering to recalculate the 5th term 2012 VAT report, with the implication that the Company should repay NOK 0.9 million in VAT. Skatteetaten argues 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 Company has deducted NOK 4.3 million in VAT in 2012 and NOK 0.9 million in 1st term 2013.

The Company argues that there are good reasons for the Company to continue to deduct VAT and has therefore not made any provisions for the claim. The Company has responded to the letter from Skatteetaten.

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.