

# PCI Biotech Holding ASA - Third Quarter 2009 Report

## Highlights

- **First cancer patient in the first phase I/II trial of Amphinex® included in August at University College Hospital (UCH) in London.**
- **Successful completion of the first Amphinex® dose group in the clinical study ongoing at UCH. No serious adverse events have been recorded so far and tumour response was seen even at the first low dose.**
- **PCI technology significantly enhances the effect of a tumour-targeting immunotoxin drug in mice, according to a study published in PLoS ONE.**
- **Initiated studies in pre-clinical disease models for additional cancer indications.**

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## 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.

During the third quarter, 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. PCI's proprietary photosensitizer Amphinex® is in this study combined with the cytotoxic agent bleomycin. When activated by light, Amphinex® promotes effective delivery of large therapeutic molecules such as bleomycin through triggered endosomal release. 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 primary objective of this study is to assess the maximum tolerated dose of Amphinex®, in PCI treatment with bleomycin. Secondary objectives include determination of the antitumour activity of Amphinex® when used in combination with bleomycin, as well as its pharmacokinetics.

The first dose group in the Phase I/II study has been completed, and no serious adverse events have been recorded so far. Tumour response was seen even at the first low dose. The patients at the next dose level have started to sign up for participation in the study and will be treated with Amphinex® as soon as possible.

A collaborative pre-clinical study between the Norwegian Radium Hospital at Oslo University Hospital and MD Anderson Cancer Center in USA, demonstrate a significantly enhanced

effect of a tumour-targeting immunotoxin drug in mice by PCI Biotech's light-activated delivery system. The study was done in mice with human non-pigmented melanoma skin cancer grafts and the results were published in PLoS ONE.

During the quarter, studies in pre-clinical disease models have been initiated on the most interesting and promising cancer indications identified in the disease area evaluation performed during the first half of 2009. The first results from the pre-clinical studies are expected during 1H 2010.

## **Financial Review**

### **Results 3<sup>rd</sup> Quarter 2009**

The company receives grants from Norway and EU. The grants are shown as revenues, and revenues in the quarter were NOK 2.8 million compared with NOK 1.9 million in Q3 2008.

The cost level in 2009 is affected by an increased activity level following the de-merger from Photocure in 2008. The average number of employees has increased from 4 in Q3 2008 to 8 in Q3 2009 and the company has intensified the R&D on its technology, increasing the R&D cost level from NOK 3.0 million in Q3 2008 to NOK 5.1 million in Q3 2009. Total operating costs were NOK 6.7 million in Q3 2009, compared with NOK 4.6 million in Q3 2008.

Operating results were NOK -4.1 million in Q3 2009 compared with NOK -2.7 million in Q3 2008.

Net cash flow from operations was NOK -3.3 million in Q3 2009, compared with NOK -2.9 million in Q3 2008. Net cash flow in the quarter was NOK -2.5 million compared with NOK -2.9 million in Q3 2008.

### **Results YTD 2009**

Revenues were NOK 6.2 million YTD 2009 compared with NOK 5.2 million YTD 2008. Total costs were NOK 20.0 million YTD 2009, compared with NOK 13.0 million YTD 2008.

Operating results were NOK -13.7 million YTD 2009 compared with NOK -7.8 million YTD 2008.

Net cash flow from operations was NOK -13.0 million YTD 2009, compared with NOK -6.3 million YTD 2008. Net cash flow was NOK -10.8 million compared with NOK 48.8 million YTD 2008. Cash flow YTD 2008 was affected by net proceeds from a share issue of NOK 55 million.

### **Balance**

The company held cash and cash equivalents of NOK 39.3 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 38.4 million compared with NOK 49.3 million at the end of 2008. The change in equity reflects the loss in the period.

### **Outlook**

PCI Biotech will continue to focus on the development of drug delivery products based on the company's unique technology platform.

The priority will be on the completion of PCI Biotech's first clinical study at University College Hospital in London, and completion of the pre-clinical studies performed on the identified cancer indications.

## CONDENSED CONSOLIDATED FINANCIAL INFORMATION

### PROFIT AND LOSS

(In NOK '000)

	Note	Q3 2009	Q3 2008	01.01-30.09 2009	01.01-30.09 2008	01.01-31.12 2008
<b>Other Income</b>		2 778	1 873	6 217	5 193	7 367
Research and development expenses		5 110	2 972	14 169	9 919	14 323
General and administrative expenses		1 770	1 581	5 716	3 062	5 182
<b>Operating costs</b>		<b>6 880</b>	<b>4 553</b>	<b>19 885</b>	<b>12 982</b>	<b>19 505</b>
<b>OPERATING RESULT</b>		<b>(4 102)</b>	<b>(2 680)</b>	<b>(13 668)</b>	<b>(7 789)</b>	<b>(12 138)</b>
<b>Financial income and expenses</b>						
Financial income		785	229	2 401	271	992
Financial expenses		(9)	(141)	(143)	(174)	(229)
<b>Net financial result</b>		<b>776</b>	<b>88</b>	<b>2 258</b>	<b>97</b>	<b>763</b>
<b>ORDINARY PROFIT BEFORE TAXES</b>		<b>(3 326)</b>	<b>(2 592)</b>	<b>(11 410)</b>	<b>(7 692)</b>	<b>(11 375)</b>
Tax on ordinary result	10	0	0	0	0	0
<b>Net income for the period</b>	4	<b>(3 326)</b>	<b>(2 592)</b>	<b>(11 410)</b>	<b>(7 692)</b>	<b>(11 375)</b>

### BALANCE SHEET

(In NOK '000)

	Note	30.09.2009	30.09.2008	31.12.2008
<b>Fixed and Intangible Assets</b>				
Intangible assets	8	41	90	76
Operating assets	9	173	55	120
<b>Total fixed and intangible assets</b>		<b>214</b>	<b>145</b>	<b>196</b>
<b>Current Assets</b>				
Short term receivables	7	4 675	3 341	4 238
Cash & cash equivalents		39 317	52 919	50 142
<b>Total current assets</b>		<b>43 992</b>	<b>56 260</b>	<b>54 380</b>
<b>Total assets</b>		<b>44 206</b>	<b>56 405</b>	<b>54 576</b>
<b>Shareholders equity and liabilities</b>				
<b>Shareholders equity</b>				
Paid in capital		105 108	105 391	104 700
Other reserves		-66 671	-52 450	-55 399
<b>Total equity</b>	11	<b>38 437</b>	<b>52 941</b>	<b>49 301</b>
Trade debtors		2 177	2 156	2 728
Other short term debt		3 592	1 308	2 547
<b>Total short term debt</b>		<b>5 769</b>	<b>3 464</b>	<b>5 275</b>
<b>Total debt</b>		<b>5 769</b>	<b>3 464</b>	<b>5 275</b>
<b>Total shareholders equity and liabilities</b>		<b>44 206</b>	<b>56 405</b>	<b>54 576</b>

## CHANGES IN SHAREHOLDERS EQUITY

(In NOK '000)	Paid in capital	Other paid in capital/ reserves	Translation differences	Retained earnings	Total
Balance at 31 December 2007	323	20 120	-	-15 203	5 240
Changes in accounting principles	-	-	-	-	-
<b>Balance at 1. January 2008</b>	<b>323</b>	<b>20 120</b>	<b>-</b>	<b>-15 203</b>	<b>5 240</b>
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
Net profit of the period	-	-	-	-11 375	-11 375
<b>Balance at 31 December 2008</b>	<b>16 249</b>	<b>88 451</b>	<b>-</b>	<b>-55 399</b>	<b>49 301</b>
Balance at 31 December 2008	16 249	88 451	-	-55 399	49 301
Changes in accounting principles	-	-	-	-	-
<b>Balance at 1 January 2009</b>	<b>16 249</b>	<b>88 451</b>	<b>-</b>	<b>-55 399</b>	<b>49 301</b>
Issue of shares, net of share issue cost	-	-	-	-	-
Share option scheme	-	546	-	-	546
Translation difference	-	-	-	-	-
Net profit of the period	-	-	-	-11 410	-11 410
<b>Balance at 30 September 2009</b>	<b>16 249</b>	<b>88 997</b>	<b>-</b>	<b>-66 809</b>	<b>38 437</b>

## CASH FLOW

(In NOK '000)	Q3 2009	Q3 2008	01.01-30.09 2009	01.01-30.09 2008	01.01-31.12 2008
Ordinary profit before taxes	-3 326	-2 592	-11 410	-7 692	-11 375
Depreciation, Amortization and Write Off	33	20	94	49	71
Share options	232	275	546	366	415
Changes in pension funds	-	-	-	-	24
Other changes	-	-	-	-49	-49
Net financials	-776	-88	-2 258	-97	-763
Changes in working capital	552	-548	58	1 150	2 433
<b>Cash flow from operations</b>	<b>-3 285</b>	<b>-2 933</b>	<b>-12 970</b>	<b>-6 273</b>	<b>-9 244</b>
Net financials	776	88	2 258	97	763
Taxes paid	-	-	-	-	-
<b>Net cash flow from operations</b>	<b>-2 509</b>	<b>-2 845</b>	<b>-10 712</b>	<b>-6 176</b>	<b>-8 481</b>
<b>Cash flow from investments</b>					
Purchase of tangible assets	-	-18	-107	-50	-
Purchase of intangible assets	-	-	-6	-	-122
<b>Net cash flow from investments</b>	<b>-</b>	<b>-18</b>	<b>-113</b>	<b>-50</b>	<b>-122</b>
<b>Cash flow from financial activities</b>					
Net proceeds from share issues	-	-	-	55 046	55 046
<b>Net cash flow from financial activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>55 046</b>	<b>55 046</b>
<b>Net change in cash during the period</b>	<b>-2 509</b>	<b>-2 863</b>	<b>-10 825</b>	<b>48 820</b>	<b>46 443</b>
Cash and cash equivalents at the beginning of the period	41 826	55 382	50 142	3 699	3 699
<b>Cash and cash equivalents at the end of the period</b>	<b>39 317</b>	<b>52 519</b>	<b>39 317</b>	<b>52 519</b>	<b>50 142</b>

## ***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 Fornebu, 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 2008 (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 26 February 2009. 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 October 2009.

### 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 2008.

#### New accounting developments

Management has evaluated the accounting policies according to IFRS and information about new development in IFRS.

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning 1 January 2009.

- IAS 1 (revised), 'Presentation of financial statements'.
- IFRS 8, 'Operating segments'. IFRS 8 replaces IAS 14, 'Segment reporting'.

The following new standards, amendments to standards and interpretations are mandatory for the first time for the financial year beginning 1 January 2009, but are not currently relevant for PCI Biotech:

- IAS 23 (amendment), 'Borrowing costs'.
- IFRS 2 (amendment), 'Share-based payment'.
- IAS 32 (amendment), 'Financial instruments: Presentation'.
- IFRIC 13, 'Customer loyalty programmes'.
- IFRIC 15, 'Agreements for the construction of real estate'.
- IFRIC 16, 'Hedges of a net investment in a foreign operation'.
- IAS 39 (amendment), 'Financial instruments: Recognition and measurement'.

The following new standards, amendments to standards and interpretations have been issued, but are not effective for the financial year beginning 1 January 2009 and have not been early adopted:

- IFRS 3 (revised), 'Business combinations' and consequential amendments to IAS 27, 'Consolidated and separate financial statements', IAS 28, 'Investments in associates' and IAS 31, 'Interests in joint ventures',
- IFRIC 17, 'Distributions of non-cash assets to owners', effective for annual periods beginning on or after 1 July 2009.
- IFRIC 18, 'Transfers of assets from customers', effective for transfers of assets received on or after 1 July 2009.

#### 4. Earnings per share

Earnings per share:

	Q3 2009	Q3 2008	YTD 2009	YTD 2008	FY 2008
Result allocated to shareholders (in NOK '000)	(3 326)	(2 592)	(11 410)	(7 692)	(11 375)
Weighted average of outstanding shares (in '000)	5 416	5 416	5 416	3 559	4 031
Earnings per share (NOK per share)	-0,61	-0,48	-2,11	-2,16	-2,82

Diluted earnings per share:

	Q3 2009	Q3 2008	YTD 2009	YTD 2008	FY 2008
Result allocated to shareholders (in NOK '000)	(3 326)	(2 592)	(11 410)	(7 692)	(11 375)
Weighted average of outstanding shares (in '000)	5 433	2 812	5 427	2 615	4 031
Earnings per share (NOK per share)	-0,61	-0,48	-2,11	-2,16	-2,82

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 cyclical 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	Q3 2009	Q3 2008	YTD 2009	YTD 2008
Radiumhospitalets Forskningsstiftelse	398	397	1 741	1 364
Theresa Comiskey Olsen	1	-	38	-
Photocure ASA	83	171	371	474

At the end of the quarter, PCI Biotech held NOK 497,000 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 Q3 2009.

Maturity profile on receivables as per 30 September:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	4 675	-	-	4 675
<b>Total receivables</b>	<b>4 675</b>	<b>-</b>	<b>-</b>	<b>4 675</b>

### Foreign currency risk

PCI Biotech has transactional currency exposure arising from sales and purchases in currencies other than the functional currency (NOK). PCI Biotech has not implemented any hedging strategy to reduce currency risk.

### 8. Intangible assets

Changes in value:

	Third quarter		YTD	
	2009	2008	2009	2008
Carrying value at the beginning of the period	55	103	76	130
Additions	-	-	6	-
Amortization in the period	-14	-13	-41	-40
<b>Carrying value at the end of the period</b>	<b>41</b>	<b>90</b>	<b>41</b>	<b>90</b>

### 9. Tangible assets

Changes in value:

	Third quarter		YTD	
	2009	2008	2009	2008
Carrying value at the beginning of the period	192	44	119	14
Additions	-	18	107	50
Depreciation in the period	-19	-7	-53	-9
<b>Carrying value at the end of the period</b>	<b>173</b>	<b>55</b>	<b>173</b>	<b>55</b>

### 10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 8.6 million in non-capitalised deferred tax assets.

### 11. Share options

No share options were granted in the third quarter.

In the second quarter, 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 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 0.2 million in the third quarter.



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

Expiry date	Exercise price	Number of shares	
	in NOK per share	30.09.2009	30.09.2008
2013 - Q3	20,00	255 000	210 000
2014 - Q3	6,80	234 000	0

**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 on the financial statements included in this report.