

# PCI Biotech Holding ASA - Second Quarter and First Half-Year Report 2009

## Highlights

- **Amphinex<sup>®</sup> Phase I/II clinical study in cancer patients was approved by UK Authorities in May and Ethics Committee in June**
- **PCI Biotech-led consortium ranked 3rd of more than 300 European projects and awarded € 1.1 million grant from the EU Eurostars Programme for a project on targeted delivery of siRNA**
- **The PCI drug delivery technology is an efficient modality for the treatment of invasive tumours, according to a study in a clinically relevant invasive orthotopic fibrosarcoma implant model published in the journal Photochemistry and Photobiology**
- **The PCI drug delivery technology triggers targeted release of siRNA from nanogel carriers, according to a study published in the journal Advanced Functional Materials**
- **Else Krüger Hagen was elected to the Board of Directors**
- **Bernt-Olav Røttingsnes appointed CFO and responsible for Business Development**

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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.

Preparations to initiate the first clinical study with the PCI technology were completed in the second quarter. University College London Hospital is now ready to enroll the first patient. The study received approval from the UK authorities (MHRA) in May and from the Ethics Committee in June. The clinical study will focus on the safety profile of Amphinex<sup>®</sup> in combination with Bleomycin, a broadly used cytotoxic agent. Secondary endpoints include efficacy in a range of cancers, including head & neck and breast cancer.

A PCI Biotech-led consortium that comprises the three companies PCI Biotech, SpectraCure and siRNAsense was awarded € 1.1 million over 3 years from the Eurostars Programme. The project is entitled "Photochemical Internalisation for delivery of short interfering RNA (siRNA) – towards safe and specific cancer therapy". All Eurostars applications were

assessed by carefully selected independent technical experts and an independent evaluation panel, and thereafter ranked across all industries based on an assessment of the project content, technology and innovation, and market and competitiveness factors. The PCI Biotech-led project was ranked as number three of the 317 submitted applications.

Published pre-clinical studies have further demonstrated and substantiated the effectiveness of the PCI technology for effective treatment of local cancer tumours, as well as effective delivery of macromolecules. For more information, please refer to separate press releases published in 2009.

The company has screened a number of marketed products for enhancement with the PCI technology and found that as many as ~25% of the tested oncology medicines were enhanced by PCI. This gives a broad base for potential further development of the technology. An extensive disease area evaluation has been performed in parallel with the product screening, to identify the most promising potential areas on which to focus the initial clinical development of the PCI technology.

### **Strengthening the organisation**

PCI Biotech has established a core team of highly competent people. All current members of the team have long industry expertise within their respective areas of responsibility. In addition, the company aims to use a selected group of external consultant and academic experts to further develop and realise the potential of the PCI technology.

Else Krüger Hagen, MD, PhD, was elected to the Board of Directors from 30<sup>th</sup> April 2009. She has extensive and broad experience in pharmaceutical development, with specific competence in clinical development and oncology. She has held different clinical leadership positions in the Nycomed / Amersham organisation and has during the last five years worked as Nordic Medical Advisor in oncology in Novartis.

Bernt-Olav Røttingsnes is employed as Chief Financial Officer with responsibility for Business Development. Bernt-Olav has already started in his position in the company. Bernt-Olav holds a Master of Business and Economics from the Norwegian School of Management. He has a broad background within Finance, Business Controlling and Business Development. His previous positions include CFO in Navamedic ASA for 3 years, acting CEO in Navamedic for 6 months, Finance Manager and Marketing Manager in the Norwegian Ski Federation and auditor and Business Controller in PricewaterhouseCoopers.

## **Financial Review**

### **Results 2<sup>nd</sup> Quarter 2009**

The company receives grants from Norway and EU. The grants are shown as revenues, and revenues in the quarter were NOK 1.7 million, in line with Q2 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 3 in Q2 2008 to 7 in Q2 2009 and the company has intensified the R&D on its technology, increasing the R&D cost level from NOK 2.0 million in Q2 2008 to NOK 4.1 million in Q2 2009. Total operating costs were NOK 6.0 million in the quarter, compared with NOK 3.3 million in Q2 2008.

Operating results were NOK -4.3 million in the quarter compared with NOK -1.5 million in Q1 2008.

Net cash flow from operations was NOK -3.9 million in the quarter, compared with NOK -1.3 million in Q2 2008. Net cash flow in the quarter was NOK -3.9 million compared with NOK 53.7 million in Q2 2008. Cash flow in Q2 2008 was affected by the net proceeds from a share issue of NOK 55 million.

### **Results 1 H 2009**

Revenues were NOK 3.4 million in 1H 2009 compared with NOK 3.3 million in 1H 2008. Total costs were NOK 13.0 million in 1H 2009, compared with NOK 8.4 million in 1H 2008.

Operating results were NOK -9.6 million in 1H 2009 compared with NOK -5.1 million in 1H 2008.

Net cash flow from operations was NOK -8.2 million in 1H 2009, compared with NOK -3.3 million in 1H 2008. Net cash flow was NOK -8.3 million compared with NOK 51.7 million in 1H 2008. Cash flow in 1H 2008 was affected by net proceeds from a share issue of NOK 55 million.

### **Balance**

The company held cash and cash equivalents of NOK 41.8 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 41.5 million compared with NOK 49.3 million at the end of 2008. The change in equity reflects the loss in the period.

### **Outlook 2009**

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

Focus will be on the progress of PCI Biotech's first clinical study at University College London Hospital, and initiation of the first in vitro and in vivo studies related to the most interesting and promising disease areas and products..

## CONDENSED CONSOLIDATED FINANCIAL INFORMATION

## PROFIT AND LOSS

Q2 2009	Q2 2008		Notes	2009 1.1-30.6	2008 1.1-30.6	2008 1.1-31.12
1 723	1 765	Other Income		3 439	3 319	7 367
<b>1 723</b>	<b>1 765</b>	<b>Total revenue</b>		<b>3 439</b>	<b>3 319</b>	<b>7 367</b>
-4 099	-2 032	Research and development expenses		-9 059	-6 736	-14 323
-1 944	-1 274	General and administrative expenses		-3 947	-1 664	-5 182
<b>-6 043</b>	<b>-3 307</b>	<b>Operating costs</b>		<b>-13 006</b>	<b>-8 401</b>	<b>-19 505</b>
<b>-4 320</b>	<b>-1 541</b>	<b>Operating profit/loss(-)</b>		<b>-9 566</b>	<b>-5 081</b>	<b>-12 138</b>
749	8	Financial income		1 616	40	992
-91	-15	Financial expences		-134	-27	-229
<b>659</b>	<b>-7</b>	<b>Net financial profit/loss(-)</b>		<b>1 483</b>	<b>13</b>	<b>763</b>
<b>-3 662</b>	<b>-1 548</b>	<b>Profit/loss(-) before tax</b>		<b>-8 084</b>	<b>-5 068</b>	<b>-11 375</b>
0	0	Tax expenses	10	0	0	0
<b>-3 662</b>	<b>-1 548</b>	<b>Net profit/loss(-)</b>		<b>-8 084</b>	<b>-5 068</b>	<b>-11 375</b>
0	0	Other comprehensive income		0	0	0
<b>-3 662</b>	<b>-1 548</b>	<b>Comprehensive income</b>	4	<b>-8 084</b>	<b>-5 068</b>	<b>-11 375</b>

## BALANCE SHEET

	Notes	30.06.2009	30.06.2008	31.12.2008
<b>Non-current assets</b>				
Intangible assets	8	55	103	76
Machinery & equipment	9	192	44	120
<b>Total non-current assets</b>		<b>247</b>	<b>147</b>	<b>196</b>
<b>Current assets</b>				
Receivables	7	3 306	3 746	4 238
Cash & cash equivalents		41 826	55 382	50 142
<b>Total current assets</b>		<b>45 133</b>	<b>59 128</b>	<b>54 380</b>
<b>Total assets</b>		<b>45 380</b>	<b>59 275</b>	<b>54 576</b>
<b>Equity and liabilities</b>				
<b>Equity</b>				
Paid-in capital		105 108	105 025	104 700
Retained earnings		-63 577	-49 767	-55 399
<b>Shareholders' equity</b>		<b>41 531</b>	<b>55 258</b>	<b>49 301</b>
<b>Liabilities</b>				
Payables		1 447	562	2 728
Other current liabilities		2 402	3 455	2 547
<b>Total liabilities</b>		<b>3 849</b>	<b>4 017</b>	<b>5 275</b>
<b>Total equity and liabilities</b>		<b>45 380</b>	<b>59 275</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	-	314	-	-	314
Translation difference	-	-	-	-	-
Net profit of the period	-	-	-	-8 084	-8 084
<b>Balance at 30 June 2009</b>	<b>16 249</b>	<b>88 765</b>	<b>-</b>	<b>-63 483</b>	<b>41 531</b>

## CASH FLOW

(In NOK '000)	Q2 2009	Q2 2008	01.01-30.06 2009	01.01-30.06 2008	01.01-31.12 2008
Ordinary profit before taxes	-3 662	-1 548	-8 084	-5 068	-11 375
Depreciation, Amortization and Write Off	29	15	61	29	71
Share options	172	92	314	92	415
Changes in pension funds	-	-	-	-	24
Other changes	-	-49	-	-49	-49
Net financials	-659	7	-1 483	-13	-763
Changes in working capital	-431	209	-494	1 665	2 433
<b>Cash flow from operations</b>	<b>-4 551</b>	<b>-1 274</b>	<b>-9 686</b>	<b>-3 344</b>	<b>-9 244</b>
Net financials	659	-7	1 483	13	763
Taxes paid	-	-	-	-	-
<b>Net cash flow from operations</b>	<b>-3 892</b>	<b>-1 281</b>	<b>-8 203</b>	<b>-3 331</b>	<b>-8 481</b>
<b>Cash flow from investments</b>					
Purchase of tangible assets	-33	-32	-107	-32	-
Purchase of intangible assets	-6	-	-6	-	-122
<b>Net cash flow from investments</b>	<b>-39</b>	<b>-32</b>	<b>-113</b>	<b>-32</b>	<b>-122</b>
<b>Cash flow from financial activities</b>					
Net proceeds from share issues	-	55 046	-	55 046	55 046
<b>Net cash flow from financial activities</b>	<b>-</b>	<b>55 046</b>	<b>-</b>	<b>55 046</b>	<b>55 046</b>
<b>Net change in cash during the period</b>	<b>-3 931</b>	<b>53 733</b>	<b>-8 316</b>	<b>51 683</b>	<b>46 443</b>
Cash and cash equivalents at the beginning of the period	45 757	1 649	50 142	3 699	3 699
<b>Cash and cash equivalents at the end of the period</b>	<b>41 826</b>	<b>55 382</b>	<b>41 826</b>	<b>55 382</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 Oslo, 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.

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 sixth 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 20 August 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 the group:

- 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:

	Q2 2009	Q2 2008	1H 2009	1H 2008	FY 2008
Result allocated to shareholders (in NOK '000)	(3 662)	(1 548)	(8 084)	(5 068)	(11 375)
Weighted average of outstanding shares (in '000)	5 416	2 812	5 416	2 812	4 031
Earnings per share (NOK per share)	-0,68	-0,55	-1,49	-1,80	-2,82

Diluted earnings per share:

	Q2 2009	Q2 2008	1H 2009	1H 2008	FY 2008
Result allocated to shareholders (in NOK '000)	(3 662)	(1 548)	(8 084)	(5 068)	(11 375)
Weighted average of outstanding shares (in '000)	5 428	2 812	5 427	2 812	4 031
Earnings per share (NOK per share)	-0,68	-0,55	-1,49	-1,80	-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 cyclicity 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 2009	Q2 2008	1H 2009	1H 2008
Radiumhospitalets Forskningsstiftelse	831	682	1 343	967
Theresa Comiskey Olsen	11	-	37	-
Photocure ASA	115	303	288	432

At the end of the quarter, PCI Biotech held NOK 392,000 in short term debt to Radiumhospitalets Forskningsstiftelse and 25,000 to Photocure ASA.

## 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 2009.

Maturity profile on receivables as per 30 June:

	Not due	Less than 3 months	3 to 12 months	Total
Trade receivables	-	-	-	-
Other receivables	3 306	-	-	3 306
Total receivables	3 306	-	-	3 306

### 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		YTD	
	2009	2008	2009	2008
Carrying value at the beginning of the period	63	117	76	130
Additions	6	-	6	-
Amortization in the period	-14	-14	-27	-27
Carrying value at the end of the period	55	103	55	103

## 9. Tangible assets

Changes in value:

	Second quarter		YTD	
	2009	2008	2009	2008
Carrying value at the beginning of the period	174	13	119	14
Additions	33	32	107	32
Depreciation in the period	-15	-1	-34	-2
Carrying value at the end of the period	192	44	192	44

## 10. Deferred tax and deferred tax assets

At the end of the quarter, the company held NOK 7.7 million in non-capitalised deferred tax assets.

## 11. Share options

Share options are granted to selected employees.

On 22 June 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 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 second 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	30.06.2009	30.06.2008
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.

### **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 2009 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, 20 August 2009

Erling Øverland  
Chairman

Theresa Comiskey Olsen

Else Krüger Hagen

Kjetil Taskén

Flemming Ørnskov

Per Walday  
CEO