

PCI Biotech Holding ASA – Report 4th Quarter 2008

Highlights

- Ready to start the first clinical study with Amphinex[®] at the Radium Hospital
- Efficient delivery of siRNA using PCI technology demonstrated in animal model
- Erling Øverland elected as new Chairman of the Board
- Karin Nord, PhD, employed as Pharmaceutical Director

Good progression in research and development

PCI Biotech Holding ASA (PCI Biotech) focus on the development of technology and products for the delivery of existing and future drugs. The company has a patented technology platform within photochemical internalization (PCI), which can be used to increase the effectiveness of cytotoxics and other drugs by combining a light sensitive substance and light to deliver drugs into cells.

PCI Biotech has in the fourth quarter further developed the manufacturing of the active ingredient in Amphinex[®] and significantly reduced the production costs. A new formulation has also been developed, based on well established pharmaceutical ingredients. This new formulation is expected to improve the tolerance of the product.

Preparations for the startup of the first clinical study with the PCI technology were completed in the fourth quarter. The study will focus on the safety profile of Amphinex[®] in combination with the cytotoxic Bleomycin and will be performed amongst others at the trial unit in the Radium Hospital. Secondary endpoints are effects in several types of cancer, such as skin, breast, and head and neck cancer. It has turned out to be more difficult than expected to get access to patients for this study in Norway. The company is therefore in the process of including other clinical centres in Europe.

The PCI technology is particularly suitable for delivery of macromolecules and the company has continued the development of the delivery technology for siRNA. This is a new type of biopharmaceuticals that can potentially be used in a range of important diseases. One of the greatest challenges for utilization of siRNA lies in the transportation of the molecules into cells where they have their target. In the fourth quarter PCI Biotech and collaborators at the University of Utrecht published a study showing that the PCI technology can significantly increase the biological effect of siRNA.

PCI Biotech strengthens its organization

PCI Biotech has strengthened the Board by the appointment of Erling Øverland as new Chairman of the Board at an extraordinary General Meeting 22nd of October 2008. Erling Øverland has extensive international experience in finance, economy, business development and marketing from several corporate leadership positions in Statoil, as well as comprehensive board experience. Erling Øverland was Elected President and Chairman of the Confederation of Norwegian Enterprise from 2004 until 2008.

Karin Nord, PhD, started in PCI Biotech as Pharmaceutical Director 1st of October 2008. She came from the position as Director of GxP projects and quality in GE Healthcare, with responsibility for all global development projects. Karin Nord has a PhD in pharmacy from the University of Oslo and has extensive experience within pharmaceutical development and production.

Results from 4th Quarter 2008

The accounts for the fourth quarter contain consolidated accounts for PCI Biotech Holding ASA for 01.10-31.12.08, and also accountings for the subsidiary PCI Biotech AS for the period 01.01-16.06.08. PCI Biotech AS has previously not been reported for this period. This gives a one-time effect of NOK –4.6 million in the fourth quarter. In the compared numbers below the one-time effect is included in the fourth quarter of 2008. Proforma results for PCI Biotech Holding ASA in isolation are also included.

Revenue was NOK 5.2 million in the fourth quarter 2008 compared to 2.8 in 2007. These are research grants from Norway and the EU.

Total expenses were NOK 14.4 million in the fourth quarter 2008 compared to NOK 3.8 million in 2007.

Operating profit/loss was NOK –8.4 million in the fourth quarter 2008, compared to NOK –0.7 million in 2007.

Results 2008

Other income was NOK 7.4 million in 2008 compared to NOK 5.9 million in 2007. These are research grants from Norway and the EU.

Total expenses were NOK 19.5 million in 2008, divided between NOK 14.3 million in research and development costs and NOK 5.2 million in other operating costs. Equivalent numbers for 2007 were NOK 16.0 million, NOK 14.7 million and NOK 1.3 million, respectively.

Operating profit/loss were NOK –11.4 million for 2008 compared to NOK –10.1 million in 2007.

Cash and cash equivalents was NOK 50.1 million at the end of 2008. The funds are placed in Norwegian money market funds with approximately 3 months maturity. Total equity was at NOK 49.3 million by the end of 2008. There were 5,416,390 shares outstanding on 31 December 2008.

Future prospects

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

Within research and development the focus will be on the performance of PCI Biotech's first clinical study at the Norwegian Radium Hospital and other selected European clinical centres, as well as continuing the pre-clinical activities to expand the application of the company's technology.

The Board of
PCI Biotech Holding ASA
Oslo, 26th of February 2009

Financial statements

The financial statements has been prepared in accordance with IAS34 Interim Financial Statements and gives a true and fair view of the Company s consolidated assets, liabilities, financial position and results of operations. The 4th quarter financial statement is unaudited.

PCI Biotech Holding ASA
Profit & Loss
(all amounts in 000 NOK)

Proforma				2008	2007
Q4 2008	Q4 2008	Q4 2007		1.1-31.12	1.1-31.12
2 174	5 235	2 788	Other Income	7 367	5 867
2 174	5 235	2 788	Total revenue	7 367	5 867
-4 995	-10 995	-3 044	Research and development expenses	-14 323	-14 733
-1 529	-3 369	-781	General and administrative expenses	-5 182	-1 298
-6 524	-14 364	-3 825	Operating costs	-19 505	-16 031
-4 350	-9 130	-1 037	Operating profit/loss(-)	-12 139	-10 164
721	759	335	Financial income	992	354
-55	-74	-14	Financial expences	-229	-329
666	685	321	Net financial profit/loss(-)	763	25
-3 684	-8 444	-716	Profit/loss(-) before tax	-11 375	-10 139
			Tax expenses		
-3 684	-8 444	-716	Net profit/loss(-)	-11 375	-10 139
-0,68	-1,56		Net income/loss(-) per share, basic	-2,82	
-0,68	-1,56		Net income/loss(-) per share, diluted	-2,82	

(1) Basic income/loss per share is calculation based on average weighted number of shares outstanding

(2) Diluted income per share is calculated adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

Balance Sheet (all amounts in 000 NOK)

	31.12.2008	31.12.2007
Non-current assets		
Intangible assets	76	130
Machinery & equipment	119	14
Total non-current assets	196	144
Current assets		
Receivables	4 238	4 020
Cash & cash equivalents	50 142	3 699
Total current assets	54 380	7 719
Total assets	54 576	7 863
Equity and liabilities		
Equity		
Paid-in capital	104 700	20 443
Retained earnings	-55 399	-15 204
Shareholders' equity	49 301	5 239
Liabilities		
Current liabilities	5 275	2 624
Total liabilities	5 275	2 624
Total equity and liabilities	54 576	7 863

Statement of changes in equity (all amounts in 000 NOK)

	2008 1.1-31.12	2007 1.1 - 31.12
Equity at beginning of period	5 239	-4 842
Share issue	60 000	20 220
IPO, expenses	-4 954	
Consolidation effect	-24	
Share-based compensation	415	
Net income/loss(-) for the period	-11 375	-10 139
Equity at end of period	49 301	5 239

Cash Flow Statement (all amounts in NOK 1,000)

	2008 1.1-31.12	2007 1.1 - 31.12
Profit/loss(-) before tax	-11 375	-10 139
Other operational items	1 966	-851
Net cash flow from operations	-9 410	-10 990
Cash flow from investments	810	151
Cash flow from capital transactions	55 042	13 640
Net change in cash during the period	46 443	2 801
Cash & cash equivalents at beginning of period	3 699	898
Cash & cash equivalents at end of period	50 142	3 699