



Fourth Quarter Report 2008

Excellent Progress with Development of Alpharadin

The fourth quarter rounded up a successful year in the development of Alpharadin, Algeta's lead product. The beginning of 2009 has also seen several important events mark the beginning of an exciting year for Algeta.

Alpharadin is a next generation alpha-pharmaceutical (alpha-emitting pharmaceutical) based on radium-223. Alpharadin is in a phase III pivotal clinical trial as a potential new treatment for bone metastases in patients with hormone-refractory prostate cancer (HRPC). Alpharadin has demonstrated in a comprehensive phase II clinical program strong evidence that it can prolong patient survival time and improve quality of life by controlling pain while offering a placebo-like safety profile.

Phase II Program Completed

The comprehensive phase II program for Alpharadin in hormone refractory prostate cancer (HRPC) was completed during the fourth quarter and reported in January 2009. The program comprised three different clinical trials and involved a total of 286 individuals. These trials were designed to provide detailed information on the safety and therapeutic efficacy of different doses of Alpharadin in HRPC patients, both symptomatic and asymptomatic for bone metastases, as well as evaluating its ability to relieve pain caused by bone metastases in symptomatic patients. In all three completed phase II trials, the primary efficacy endpoints were met while providing evidence of the benign, placebo-like safety profile of Alpharadin.

Furthermore, the successful completion of the phase II program also supports Algeta's strategy for targeting Alpharadin in patients with metastatic HRPC who are unsuitable or who have failed docetaxel chemotherapy as well as for first-line use in combination with docetaxel. A combination study with docetaxel is in preparation, which if successful, will enable Algeta to market Alpharadin, either alone or in combination with docetaxel, to the global HRPC market.

Algeta also plans to initiate a phase II trial in patients with bone metastases from breast cancer, an additional potentially large market for this alpha-pharmaceutical. A protocol has been developed in close cooperation with world-leading breast cancer experts. In a previously completed phase I trial with Alpharadin which also included breast cancer patients, there was evidence of efficacy in this patient population with changes in biomarker levels indicative of a therapeutic effect and reduction in bone pain.

Market research conducted by Algeta both in Europe and the US during 2008 has demonstrated that Alpharadin is seen to potentially have the ideal product profile for oncologists, demonstrating an overall survival benefit and enhanced quality of life.

Pivotal Phase III Clinical Trial on Track

After showing significantly increased survival in the phase II program, Algeta embarked on a pivotal HRPC phase III trial in 2008. The first patient was treated in June 2008. The phase III trial named ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) is a double-blind, randomised, placebo-controlled trial.

The primary efficacy endpoint of the trial is overall survival. Secondary endpoints include time to occurrence of specified disease-related events, and time to progression of certain key biomarkers indicative of disease status, including blood levels of serum prostate-specific antigen (PSA) and total alkaline phosphatase (ALP). In addition, the trial monitors and evaluates both the acute and long-term safety profile of Alpharadin treatment as well as its impact on quality of life. The Co-ordinating Investigator for the ALSYMPCA study is Dr. Christopher Parker, a leading clinical oncologist and specialist in prostate cancer based at the Institute of Cancer Research and the Royal Marsden Hospital in Sutton, UK.

Following a successful end-of-phase II meeting with the US Food and Drug Administration (FDA) in January 2009, Algeta will enroll US patients into the ALSYMPCA trial during 2009, making this a truly global phase III trial. Approximately 750 patients are expected to enroll at more than 125 medical centers worldwide.

Details of phase II studies and further activities to support Alpharadin development

A dosimetry trial (BC1-05) was completed in the UK. The trial demonstrated that Alpharadin was rapidly eliminated from blood and taken up in the bone, where it exerts its therapeutic effects on bone metastases. The data also showed that Alpharadin not taken up by the bone is rapidly excreted from the body mainly via faeces. There was no specific uptake in normal organs such as the kidneys or the liver resulting in very low absorbed doses to these organs with corresponding benign side effect profile.

Phase II BC1-03 pain palliation study with Alpharadin was completed and its primary objective was met. The control of pain is an important quality-of-life benefit in cancer patients with bone metastases. The trial also confirmed Alpharadin's benign side-effect profile including, importantly for a drug in this clinical setting, no significant bone marrow toxicity.

BC1-04 results were reported in January 2009. The BC1-04 study demonstrated a dose-response relationship with respect to the proportion of patients showing a PSA response, and validated the six weeks' dosing schedule in order to prepare for combination trials with docetaxel.

A US IND was opened early in 2008, allowing Algeta to initiate the first clinical trial (BC1-08) at the Memorial Sloan-Kettering Cancer Center in New York. The trial is a biodistribution and dosimetry trial to support the overall development package for Alpharadin, and is currently ongoing.

Preclinical data for Algeta's therapeutic principle show efficacy against difficult-to-treat cancer cells. The alpha particle radiation from Alpharadin has been demonstrated to kill cancer cells that are chemo- and/or radio-resistant, as well as resting non-dividing cell. This is a very important property that distinguishes alpha radiation for other conventional treatment methods.

The active ingredient radium-223 and the final drug product Alpharadin is manufactured ready-to-use in accordance with Good Manufacturing Practice (GMP) regulations at Institute for Energy Technology, Kjeller, Norway. All patient doses for the clinical trials have during the year continued to be produced and delivered on schedule to every single patient.

Other Development Programs

Algeta is also developing cancer treatments where alpha-emitting radionuclide are linked to cancer-seeking antibodies. This program, TH-1, continues to make progress. Proof-of-principle studies (at the Norwegian Radium Hospital) have shown that a thorium-227-antibody binds specifically to breast cancer tumors in mice, and confirms former positive results treating lymphoma. The technology covering the attachment of an alpha emitter to an antibody has been streamlined and improved in order to be able to be scaled-up in the future. Work is continuing on two feasibility studies with outside partners.

The company believes that of the company's different preclinical development programs, TH-1 currently holds the best return potential and will concentrate its preclinical resources in this area. As a result, the company has decided to put two other early stage preclinical programs (OC-3 and RV-1) on hold.

Senior Management Team Strengthened - Focus on Commercialization

In December 2008, Andrew Kay was appointed as President and Chief Executive Officer. He took up the role on 19 January 2009. Dr. Thomas Ramdahl, formerly President and CEO, continues in Algeta as Executive Vice President and Chief Technology Officer (CTO).

Mr. Kay (53), B. Pharm., joins Algeta from Renovo plc (LSE: RNVO) where he was Executive Director, Commercial. Mr. Kay brings more than 25 years of commercial experience in the pharmaceutical sector, where he has managed the successful licensing and launch of several new oncology drugs. At Renovo, he played a crucial role in successfully securing the company's licensing agreement in 2007 with Shire plc to develop and commercialise Jurist, Renovo's lead drug for the prevention and reduction of scarring following surgery.

At 31 December 2008, Algeta had 34 employees compared to 29 employees at the end of 2007.

Financials

The Group's operating expenses for the fourth quarter 2008 amounted to NOK 53 million compared with NOK 29 million in the fourth quarter 2007. Operating expenses amounted to NOK 186 million in 2008 compared with NOK 89 million in 2007. The increase is due to higher R&D costs as Alpharadin entered a pivotal phase III clinical trial during 2008. At the end of the fourth quarter, ALSYMPCA had eight countries and 47 centers active. On 9 February 2009, 11 countries and 60 centers were active. Patient inclusion is progressing according to plan.

The Group's income statement shows a net loss of NOK 49 million for the fourth quarter 2008 compared with NOK 26 million for the fourth quarter 2007. The net loss for 2008 was NOK 174 million, compared to NOK 77 million in 2007. The parent company Algeta ASA accrued a net loss of NOK 167 million in 2008.

Net cash flow from operations totalled NOK -21 million in the fourth quarter 2008 versus NOK -14 million in the fourth quarter 2007. For the full year 2008, cash flow from operations was NOK -146 million compared to NOK -58 million for 2007. As of 31 December 2008, the Group had liquid funds in total of NOK 133 million, which is invested in bank deposits and money marked funds. The Company has no debt except current liabilities totalling NOK 51 million.

On 18 February 2009, Algeta announced NOK 245 million (USD 35 million) in gross proceeds from a successful private placement of 22.3 million new shares at NOK 11 per share. The transaction will be completed at an EGM on 4 March 2009.

The Algeta Group consists of Algeta ASA and its wholly owned subsidiaries Algeta Innovations AS and Algeta UK Limited. Accounts for the Algeta Group are presented according to the International Financial Reporting Standards adopted by the EU. Algeta ASA, the parent company, presents its accounts according to generally accepted accounting principles in Norway.

Events after 31 December 2008

Events in this report which took place in 2009 primarily comprise:

- Reporting of completed phase II program (January)
- Andrew Kay taking up his duties as CEO (January)
- Successful FDA end-of-phase II meeting (January)
- NOK 245 fundraising in a private placement (February)

Future prospects

Development and approval of a new drug requires significant capital and time. With the ongoing phase III program, it is expected that Algeta's costs level for 2009 and 2010 will be somewhat higher than that of 2008.

Oslo, 27 February 2008

The Board of Directors of Algeta ASA

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Preliminary and unaudited

CONSOLIDATED INCOME STATEMENT

(All amounts in NOK thousands except per share data)

3 months ending 31.12			12 months ending 31.12	
2008	2007		2008	2007
63	0	Other income	63	0
(7 355)	(8 939)	Payroll and related costs	(32 809)	(27 000)
(476)	(361)	Ordinary depreciation	(1 851)	(1 255)
(44 678)	(20 075)	Other expenses	(150 916)	(60 428)
(52 509)	(29 375)	Total operating expenses	(185 576)	(88 683)
(52 446)	(29 375)	Operating profit/loss(-)	(185 513)	(88 683)
3 542	3 935	Finance income	12 229	11 512
(146)	(61)	Finance costs	(266)	(60)
3 396	3 874	Net financial income/(loss)	11 963	11 452
(49 050)	(25 501)	Loss before taxes	(173 550)	(77 231)
-	-	Income tax expense	-	-
(49 050)	(25 501)	Loss for the period	(173 550)	(77 231)
(2.97)	(1.54)	Basic earnings per share	(10.51)	(5.67)
(2.97)	(1.54)	Diluted earnings per share	(10.51)	(5.67)

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CONSOLIDATED BALANCE SHEET

(All amounts in NOK thousands)

	2008	2007
	31.12	31.12
ASSETS		
Non-current assets		
Property, plant and equipment	6 518	6 104
Total non-current assets	6 518	6 104
Current assets		
Other receivables	7 174	5 071
Cash & cash equivalents	132 932	281 255
Total current assets	140 106	286 326
TOTAL ASSETS	146 624	292 430
EQUITY AND LIABILITIES		
Equity		
Share capital	8 256	8 253
Additional paid-in-capital	467 439	464 620
Accumulated losses	(380 553)	(207 003)
Total equity	95 142	265 870
Current liabilities		
Trade and other payables	51 483	26 560
Total current liabilities	51 483	26 560
TOTAL EQUITY AND LIABILITIES	146 624	292 430

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CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

(All amounts in NOK thousands)

3 months ending 31.12			12 months ending 31.12	
2008	2007		2008	2007
144 740	290 429	Equity at beginning of period	265 870	80 307
-	-	Share issuance preference shares	-	25 000
-	-	Share issuance, employees	88	818
-	-	Share issuance, public offering	-	250 000
-	(1)	Share price stabilisation profit	-	1 616
-	34	Offering costs	-	(17 572)
(549)	909	Share-based compensation	2 734	2 932
(49 050)	(25 501)	Net profit/loss(-) for the period	(173 550)	(77 231)
95 142	265 870	Equity at end of period	95 142	265 870

CONSOLIDATED CASH FLOW STATEMENT

(All amounts in NOK thousands)

3 months ending 31.12			12 months ending 31.12	
2008	2007		2008	2007
(49 050)	(25 501)	Profit/loss(-) before tax	(173 550)	(77 231)
		Interest paid		
28 089	11 952	Other operational items	27 406	19 317
(20 961)	(13 549)	Net cash flow from operations	(146 144)	(57 914)
(5)	(1 279)	Cash flow from investments	(2 265)	(5 297)
	34	Cash flow from capital transactions	88	259 861
(20 966)	(14 793)	Net change in cash during the period	(148 322)	196 650
153 898	296 048	Cash & cash equivalents at beginning of period	281 255	84 604
132 932	281 255	Cash & cash equivalents at end of period	132 932	281 255

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Notes to the Interim Financial Statements ending at 31 December 2008.

Note 1 - Basis of Presentation

The financial information is prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” (“IAS 34”). This financial information should be read together with the financial statements for the year ended 31 December 2007 prepared in accordance with International Financial Reporting Standards (“IFRS”) as adopted by the EU.

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. Where necessary, the comparatives have been reclassified or extended to take into account any presentational changes made in these Interim Financial Statements.

The preparation of the Interim Financial Statements requires management to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent liabilities at the date of the Interim Financial Statements. If in the future such estimates and assumptions, which are based on management’s best judgement at the date of the Interim Financial Statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the period in which the circumstances change.

Note 2 - Share Options

On 14 May 2008, the General Shareholders’ Meeting authorized the Board of Directors to grant up to 1 592 580 options to employees, Board members, and consultants.

The following table shows the changes in outstanding options in the twelve-month period ended 31 December 2008:

	Number of options	Weighted average exercise price
Outstanding on 1 January 2008	824 000	29.67
Granted	673 000	8.33
Exercised during the period	(5 000)	18.00
Forfeited during the period	(116 111)	29.09
Expired during the period	(22 667)	19.34
Outstanding at 31 December 2008	1 353 222	19.33

Note 3 – Property, plant, and equipment

During the twelve-month period ended 31 December 2008; the Company invested NOK 2.3 million in property, plant, and equipment, primarily equipment for research purposes.

Note 4 – Share capital

The following table shows the changes in number of outstanding shares in the twelve-month period ended 31 December 2008:

	Ordinary Shares
Ordinary shares at 1 January 2008	16 506 608
Share issuance, employees	5 000
At 31 December 2008	16 511 608