

Algeta Third Quarter Report 2008

Enrollment into the phase III ALSYMPCA trial well underway

Algeta reached a major milestone in June this year, with the start of its pivotal phase III ALSYMPCA trial in hormone-refractory prostate cancer (HRPC) patients. HRPC is both an under-treated and poorly treated form of cancer. The ALSYMPCA (ALpharadin in SYMptomatic Prostate Cancer) study is a double-blind, controlled trial enrolling symptomatic HRPC patients who will be randomized to receive Alpharadin plus best standard of care or placebo plus best standard of care. Approximately 750 patients are expected to be enrolled at more than 125 medical centers in Europe, Asia, South America and Canada.

Approximately 120,000 men in Europe and the USA die from HRPC each year. Around 85% of men with HRPC have bone metastases, which can cause intractable pain, fractures, hypercalcaemia and spinal cord compression as well as reduced life expectancy. There is therefore an urgent need for an effective, bone-targeted treatment for prostate cancer that prolongs life while also maintaining quality of life. The Coordinating 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 the UK.

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 will monitor and evaluate both the acute and long-term safety profiles of Alpharadin treatment as well as its impact on patient quality of life.

Efficient enrolment of the ALSYMPCA trial is currently Algeta's key focus. Six countries have clinical sites already open for the recruitment of patients: Norway, Sweden, UK, Singapore, Czech Republic and Spain.

A section of Algeta's website (click the ALSYMPCA logo at www.algeta.com) has been developed to inform patients and their physicians about the trial and participating clinical centers.

Further positive supportive data for Alpharadin from phase II trials

Algeta continues to conduct further clinical and preclinical studies with Alpharadin. The results announced in the third quarter continue to confirm and augment the growing base of information regarding Alpharadin's safety and efficacy.

Headline results from the BC1-03 phase II pain palliation study announced in August showed that the primary objective of study was met. The study showed that a single dose of Alpharadin in patients with painful bone metastases had a clear beneficial palliative effect and that there was a clear dose-response effect, with higher doses providing better pain relief. Pain palliation is an important quality of life benefit in metastatic cancer patients.

The BC1-03 study was a double-blind randomized pain control study comparing the palliative effects of four different single dose levels of Alpharadin (5, 25, 50 or 100 kBq/kg body weight) in 100 patients with bony metastatic HRPC. The drug was given

by i.v. injection mainly on an outpatient basis. The palliative efficacy of Alpharadin was measured using an assessment of bone pain as well as the patient's consumption of analgesia.

The study also showed a dose-dependent reduction in bone alkaline phosphatase (ALP). ALP is a key marker of bony metastatic disease and is of prognostic importance.

Importantly, this study further confirms the safety of Alpharadin and highlight its benign side-effect profile. Patients in the higher dose groups had fewer adverse events than patients in lower dose groups. This reproduces the safety profile of the earlier BC1-02 Phase II study where the Alpharadin group (receiving 50 kBq/kg b.w.) experienced fewer adverse effects than the placebo group. Most importantly for a drug in this clinical setting, no significant bone marrow toxicity was observed in patients receiving Alpharadin.

During the third quarter, Algeta completed the BC1-04 study, designed to explore the effects different Alpharadin dose levels. The company is conducting the final analysis of the data.

First cohort of patients treated in US clinical trial

In February 2008, Algeta received FDA approval in the USA of an Investigational New Drug (IND) application for Alpharadin. In August, the company initiated its first US clinical trial (BC1-08) at the Memorial Sloan-Kettering Cancer Center in New York.

BC1-08 is a phase I open label, ascending dose study of Alpharadin (radium-223 chloride) in up to 18 HRPC patients. The trial will evaluate the pharmacokinetics (PK) and biodistribution of Alpharadin in relation to dose and will further expand the information obtained in a similar phase I study (BC1-05), which completed earlier this year. The first cohort of three patients has been treated and data is being analysed before proceeding to the next cohort.

In the study, each patient will be administered a single intravenous injection of Alpharadin and its activity will be measured in the whole body and regions of interest, including the skeleton and the sites of bone metastases. The first group of patients will receive a dose of 50 kBq/kg, the next 100 kBq/kg, and the final group will receive 200 kBq/kg b.w. (0.0014, 0.0027 and 0.0054 mCi/kg). If patients benefit, they will, at the Investigator's discretion, be allowed a second dose of Alpharadin six weeks after the first.

Studies BC1-02, -03 and -04 constitute the phase II evaluation of Alpharadin monotherapy in progressive HRPC. Studies BC1-05 and -08 have generated, or are generating, the detailed dosimetry data required by FDA and other regulatory authorities to assure the safe use of this drug. The analysis of these studies therefore enables Algeta to begin discussions with FDA towards opening phase II/III evaluations in the USA. Algeta has been granted an End-of-Phase II meeting with FDA in the first quarter of 2009 to discuss the design of a program for the further clinical development of Alpharadin.

Other Development Programs

As part of the overall R&D program, Algeta continues to make progress in expanding the use of Alpharadin in different clinical indications. Clinical studies to explore the use of Alpharadin in combination with chemotherapy agents in HRPC and the use of Alpharadin for the treatment of metastatic bone disease associated with breast cancer are under development.

In addition, the TH-1 preclinical program, where alpha-emitting radionuclides are linked with cancer-seeking antibodies, continues to make progress. Proof-of-principle studies (at the Norwegian Radium Hospital) have shown that a ²²⁷Th-antibody binds specifically to breast cancer tumors in mice. 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 together these development programs hold the best return potential and will concentrate its resources in these areas. As a result, and after a cost review, the company has decided to put two early stage preclinical programs (OC-3 and RV-1) on hold.

People

During the third quarter Chief Medical Officer Peter Harris decided to return to the UK to take up a senior management position in the European arm of a major US biotech company. Dr. Harris will continue his employment with Algeta into the first quarter of 2009, leading day to day operations of clinical trial operations as well as ensuring an orderly succession. A search for his replacement is underway.

As of 30 September 2008, Algeta had 34 employees compared to 31 one year ago.

Extraordinary General Meeting

Algeta held an extraordinary general meeting in September to confirm the Board of Directors elected in May, and to note that Kent Gossett of SR One has stepped down as deputy board member. Jens Petter Falck of Incitia Ventures is now the sole deputy board member.

Financial Review

The group's operating expenses for the third quarter 2008 amounted to NOK 39 million versus NOK 21 million in the third quarter 2007 and NOK 56 million in the second quarter 2008. Operating expenses for the first nine months were NOK 133 million, versus NOK 59 million in the corresponding period in 2007. This year's increase was due to the initiation of the ALSYMPCA phase III trial. Costs were particularly high during preparations to start the study in the second quarter.

The Group's net loss for the first nine months was NOK 125 million, versus NOK 52 million for the first nine months of 2007.

Net cash flow from operations totaled NOK -56 million in the third quarter of 2008 versus NOK -21 million in the third quarter of 2007 and NOK -45 million in the second quarter of 2008. The corresponding numbers for the first nine months were NOK -125 million this year and NOK -44 million in 2007.

The group had liquid funds in total of NOK 154 million at the end of the quarter, compared to NOK 210 million at 30 June 2008 and NOK 296 million at 30 September 2007. The funds are invested in bank deposits and money market funds. Although total return on the investments were positive in the quarter, net return on money market funds in September were negative (NOK -0.2 million or -1,5%) as three month NIBOR rose by 111 points during the month.

The total number of outstanding shares as of 30 September 2008 was 16,511,608. The total number of granted share options as of 30 September was 816,000 (vested and unvested).

Outlook

Algeta's costs are primarily driven by the ALSYMPCA study. For the remainder of the phase III trial, costs will primarily be driven by the number of patients receiving treatment in the trial. Treatment activity will increase steadily over the next several quarters and are expected to peak late 2009 or early 2010.

The Algeta group consists of Algeta ASA and its wholly owned subsidiaries Algeta Innovations AS and Algeta UK Ltd. Accounts for the Algeta group are presented according to IFRS. Algeta ASA, the parent company, presents its accounts according to generally accepted accounting principles in Norway.

Oslo, 5 November 2008

The Board of Directors of Algeta ASA

ALGETA ASA – Third Quarter Accounts 2008

CONDENSED CONSOLIDATED INCOME STATEMENT

(All amounts in NOK 1,000 except per share data)

3 months ending 30.09			9 months ending 30.09		2007
2008	2007		2008	2007	01.01 - 31.12
9 183	6 856	Payroll and related costs	25 454	18 061	27 000
456	353	Ordinary depreciation	1 375	894	1 255
29 618	13 460	Other expenses	106 239	40 353	60 428
39 257	20 669	Total operating expenses	133 068	59 308	88 683
(39 257)	(20 669)	Operating profit/loss(-)	(133 068)	(59 308)	(88 683)
2 099	3 211	Finance income	8 687	7 577	11 512
-	1	Finance costs	(120)	1	(60)
2 099	3 212	Net financial income/(loss)	8 567	7 578	11 452
(37 158)	(17 457)	Loss before taxes	(124 501)	(51 730)	(77 231)
-	-	Income tax expense	-	-	-
(37 158)	(17 457)	Loss for the period	(124 501)	(51 730)	(77 231)
(2.25)	(1.06)	Basic earnings per share	(7.54)	(5.81)	(5.67)
(2.25)	(1.06)	Diluted earnings per share	(7.54)	(5.81)	(5.67)

ALGETA ASA – Third Quarter Accounts 2008

CONDENSED CONSOLIDATED BALANCE SHEET

(All amounts in NOK 1,000)

	2008	2007	2007
	30.09.	30.09.	31.12
ASSETS			
Non-current assets			
Property, plant and equipment	6 989	5 187	6 104
Total non-current assets	6 989	5 187	6 104
Current assets			
Other receivables	19 632	4 633	5 071
Cash & cash equivalents	153 899	296 048	281 255
Total current assets	173 531	300 681	286 326
TOTAL ASSETS	180 520	305 867	292 430
EQUITY AND LIABILITIES			
Equity			
Share capital	8 256	8 253	8 253
Additional paid-in-capital	467 988	463 677	464 620
Accumulated losses	(331 504)	(181 501)	(207 003)
Shareholders' equity	144 740	290 429	265 870
Current liabilities			
Trade and other payables	35 779	15 439	26 560
Total current liabilities	35 779	15 439	26 560
TOTAL EQUITY AND LIABILITIES	180 519	305 867	292 430

ALGETA ASA – Third Quarter Accounts 2008

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

(All amounts in NOK 1,000)

3 months ending 30.09			9 months ending 30.09		
2008	2007		2008	2007	2007
					01.01 - 31.12
180 788	308 844	Equity at beginning of period	265 870	80 307	80 307
-	-	Share issuance preference shares	-	25 000	25 000
-	-	Share issuance, employees	88	818	818
-	-	Share issuance, public offering	-	250 000	250 000
-	-	Share price stabilisation profit	-	1 617	1 616
-	(842)	Offering costs	-	(17 607)	(17 572)
1 109	(117)	Share-based compensation	3 283	2 024	2 932
(37 157)	(17 457)	Net profit/loss(-) for the period	(124 501)	(51 730)	(77 231)
144 740	290 429	Equity at end of period	144 740	290 429	265 870

CONDENSED CONSOLIDATED CASH FLOW STATEMENT

(All amounts in NOK 1,000)

3 months ending 30.09			9 months ending 30.09		
2008	2007		2008	2007	2007
					01.01 - 31.12
(37 158)	(17 457)	Profit/loss(-) before tax	(124 501)	(51 729)	(77 231)
0	0	Interest paid	0	0	0
(18 836)	150	Other operational items	(683)	7 365	19 317
(55 994)	(17 307)	Net cash flow from operations	(125 184)	(44 364)	(57 914)
(422)	(1 807)	Cash flow from investments	(2 260)	(4 018)	(5 297)
0	(842)	Cash flow from capital transactions	88	259 827	259 861
(56 416)	(19 955)	Net change in cash during the period	(127 356)	211 444	196 650
210 314	316 003	Cash & cash equivalents at beginning of period	281 254	84 604	84 604
153 898	296 048	Cash & cash equivalents at end of period	153 898	296 048	281 254

ALGETA ASA – Third Quarter Accounts 2008

Notes to the Interim Financial Statements ending at 30 September 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”).

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 nine-month period ended 30 September 2008:

	Number of options	Weighted average exercise price
Outstanding on 1 January 2008	824 000	29.67
Granted	73 000	23.00
Exercised during the period	(5 000)	18.00
Forfeited during the period	(53 333)	26.08
Expired during the period	(22 667)	20.26
Outstanding at 30 September 2008	816 000	29.64

Note 3 – Property, plant, and equipment

During the nine-month period ended 30 September 2008; the Company invested NOK 2.4 million in property, plant, and equipment, primarily equipment primarily for research purposes.

Note 4 – Share capital

The following table shows the changes in number of outstanding shares in the nine-month period ended 30 September 2008:

	Ordinary Shares
Ordinary shares at 1 January 2008	16 506 608
Share issuance, employees	5 000
At 30 September 2008	16 511 608