



## Report for First Quarter 2010

*This report includes an operational review and the financial results for the three-month period ending 31 March 2010.*

The first quarter of 2010 saw Algeta continue to make good progress on several fronts regarding the clinical development of Alpharadin for the treatment of bone metastases resulting from the spread of certain tumor types.

The development of bone metastases represents a serious development for many cancer patients as they are associated with a dramatic decline in patient health and quality of life, ultimately leading to death. Bone metastases represent a major unmet medical need, occurring frequently in certain late-stage cancers, e.g. prostate, breast and lung.

Alpharadin (radium-223 chloride) is being developed by Algeta and Bayer Schering Pharma AG ("Bayer") and is a first-in-class alpha-pharmaceutical that has a potent and targeted antitumor effect on bone metastases combined with a highly favorable side-effect profile. In Phase II trials studying bone metastases in patients with castration-resistant (hormone-refractory) prostate cancer (CRPC), Alpharadin showed a statistically significant improvement in overall survival compared to placebo. Alpharadin is currently in a global phase III clinical trial (ALSYMPCA) to treat bone metastases resulting from CRPC. Bone metastases are the main cause of disability and death in patients with CRPC and approximately 90% of men with this disease have radiological evidence of bone metastasis.

### **ALSYMPCA phase III trial – size increased and on track**

The ALSYMPCA study (for ALpharadin in SYMptomatic Prostate CAncer) is a double-blind, randomized, controlled phase III clinical trial enrolling patients with CRPC cancer that has spread to the bones. The primary efficacy endpoint of the trial is overall survival. In addition, the trial monitors and evaluates both safety profile of Alpharadin treatment as well as its impact on quality of life.

The trial began in June 2008 and is currently recruiting at more than 100 trial centers worldwide. Additional clinical centers in the USA are initiating during H1 2010. As of April 2010, the number of recruited patients exceeded 600.

In May 2010, Algeta announced that the planned sample size re-estimation of ALSYMPCA was completed successfully on schedule. This limited analysis of blinded data from 500-600 enrolled patients confirmed that the plan to recruit 750 patients into the ALSYMPCA study will meet the goals originally set for the study.

Algeta and Bayer in parallel decided to increase recruitment for ALSYMPCA to 900 patients. This will increase the power of the trial to 90% thereby further improving the statistical likelihood of proving the efficacy of Alpharadin. It will also allow the study to recruit a greater number of US patients, and allow US clinical oncologists to gain experienced with the use of Alpharadin.

Importantly, owing to rapid enrolment into this pivotal study, Algeta and Bayer anticipate the enrolment of ALSYMPCA will still complete in the second half of 2010 with results of the trial anticipated in 2012. This decision will still allow Alpharadin to be filed in 2012 as planned. Furthermore, with Bayer funding the majority of ALSYMPCA clinical development costs, the financial impact of this decision on Algeta will be limited.

## **New Alpharadin trial initiated in second tumor type**

Algeta and Bayer have initiated a new phase II clinical trial in patients with bone metastases resulting from breast cancer that no longer respond to endocrine therapy. Bayer is committed to funding the majority of the costs of this trial as well as future trials to treat bone metastases.

The first patient to be enrolled into this new trial (BC1-09) received their first dose of Alpharadin in January 2010. The trial is designed to investigate if multiple intravenous injections of Alpharadin have a clinically relevant effect on bone markers (i.e. an effect indicative of a positive therapeutic response) in breast cancer patients with bone-dominant metastatic disease.

Algeta aims to recruit 20 women with breast cancer that has spread primarily to the bone into the study, which will be conducted at cancer centers in Oslo (Norway), Brussels (Belgium) and Sheffield (UK). The Principal Investigator for the trial is Professor Robert Coleman, a cancer and bone metastasis specialist at the Weston Park Hospital in Sheffield. Results from the study are expected during H1 2011.

The BC1-09 trial will also monitor the safety of Alpharadin treatment in these patients. In an earlier Phase I study, safety data were collected from women with bone metastases from breast cancer as part of the wider Alpharadin clinical program. The results showed that Alpharadin has a benign side-effect profile in these patients and were consistent with safety findings in men with prostate cancer.

According to the American Cancer Society and Cancer Research UK, breast cancer is by far the most common cancer in females, accounting for around 31% of all female cancers. Nearly 200,000 new cases of invasive breast cancer were diagnosed in the US in 2009 and around 40,000 women were expected to die as a result of breast cancer in the US annually. As many as 75% of breast cancer patients with metastatic disease will have metastases in the bone<sup>1</sup>.

## **Alpharadin-docetaxel chemotherapy study to begin mid-2010**

Towards the end of 2009, Algeta and Bayer finalized the protocol for a phase I/IIa study (BC1-10) to investigate whether Alpharadin in combination with docetaxel chemotherapy can be safely used together to treat CRPC patients with bone metastases.

Docetaxel chemotherapy is the current gold standard treatment for metastatic CRPC. ALSYMPCA is recruiting patients with bone metastases who are ineligible for treatment with docetaxel (clinical status, safety concerns) and those patients for whom chemotherapy is ineffective, representing approximately 50% of all CRPC patients. If successful, the combination of Alpharadin with docetaxel could further extend the market opportunity for Alpharadin to patients who have bone metastases and can tolerate chemotherapy.

During 2010, the companies have been undertaking the formal preparations with a leading cancer center in the US at which the trial will take place. The trial is expected to start mid-2010.

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Harvey, H.A. and Cream, L.R. (2007) *Clin. Breast Cancer*. Jul;7 Suppl 1:S7-S13

The phase I/IIa study will aim to enrol up to 60 patients with bone metastases from CRPC for whom treatment with docetaxel is planned. Patients will receive increasing doses of Alpharadin in addition to docetaxel at standard clinical dose. The trial is intended to explore the safety, tolerability and identify the optimal efficacious dose of Alpharadin in combination with docetaxel at the standard clinical dose.

### **New analyses continue to support key clinical benefits of Alpharadin**

Presentations describing two studies and an analysis of overall safety data from the Alpharadin phase I and II clinical program were made at the 2010 Genitourinary Cancers Symposium in San Francisco, CA, USA (5-7 March 2010). The presentations were made by leading cancer specialists involved in the program and support earlier published findings that Alpharadin is specifically targeted to bone metastases and has a highly favorable safety profile.

These data will be presented at the annual American Society of Clinical Oncology (ASCO) meeting in June 2010 and at the European Society of Medical Oncology (ESMO) meeting in October 2010.

### **Production and supply of Alpharadin**

In January 2010, Algeta and the Norway-based Institute for Energy Technology (IFE), agreed to collaborate for the manufacture and supply of Alpharadin for future commercial use and clinical trial. This agreement concluded the first part of Algeta's manufacturing strategy to produce and supply Alpharadin to meet expected needs of Algeta's ongoing ALSYMPCA phase III study and planned clinical trials in other cancer indications.

In addition it is planned that this expanded capacity will supply the expected commercial demand around the world following its approval and worldwide launch in collaboration with Bayer. Under the terms of this agreement Algeta has responsibility for the manufacturing and supply of Alpharadin for commercial use.

### **Outlook**

Algeta has created a solid platform from which to advance its strategy for creating further shareholder value from the development and commercialization of novel targeted cancer therapeutics based on its alpha-pharmaceutical technology. The Company is working towards multiple milestones during 2010 and aims to:

- Recruit 900 CRPC patients with bone metastases into the phase III ALSYMPCA study by the end of 2010
- Advance enrolment of endocrine-refractory breast cancer patients with bone metastases into a phase II clinical trial
- Initiate a phase I/IIa clinical trial to study Alpharadin in combination with docetaxel chemotherapy for CRPC patients with bone metastases
- Secure long-term manufacturing capabilities for future clinical and commercial demand for Alpharadin
- Work closely with Bayer to optimize the future market positioning of Alpharadin and the education of relevant cancer specialists
- Initiate technology programs leading to a pipeline of alpha-pharmaceutical

candidates based on thorium-227 and tumor-targeting molecules

In addition, the Company will continue with its program of investor activities during 2010 with the aim of broadening and strengthening its shareholder base. Important among these activities, Algeta will host its first capital markets days for investors, analysts and press on 25 May in Oslo and on 27 May in London.

Operating expenses in 2010 are expected to be somewhat above the level of 2009. A substantial majority of development costs, however, will be covered by Bayer and booked as revenue.

## **Financial Review**

### *- Profit and loss*

Revenue for the first quarter 2010 amounted to NOK 64 million versus NOK 24 million last quarter and zero for the first quarter 2009. This total comprised NOK 20 million as recognised part of the deferred USD 61 million signing fee from Bayer and NOK 44 million as cost-sharing revenue from Bayer towards cost incurred for agreed development and manufacturing programs for Alpharadin.

The Group's operating expenses for the first quarter 2010 amounted to NOK 64 million compared with NOK 57 million last quarter and NOK 41 million in the first quarter 2009. R&D costs continue to be driven by patient recruitment and treatment in the ALSYMPCA phase III study. 73% of Algeta's expenses in the first quarter were related to R&D, the majority of which to the ALSYMPCA trial.

The Group's income statement shows a net loss of NOK 9 million for the first quarter 2010 compared with a net loss of NOK 38 million last quarter and NOK 40 million for the first quarter 2009.

### *- Cash flow and balance sheet*

Algeta received the final NOK 55 million of the Bayer signing fee. This amount was pending due to German withholding tax rules at year-end and released to Algeta in January. Net cash flow from operations was zero in the first quarter 2010 versus NOK -50 million last quarter and NOK -34 million first quarter 2009. Net change in cash totalled NOK -10 million in the first quarter 2010 compared to NOK -43 million last quarter and NOK 194 million in the first quarter 2009, a quarter in which Algeta raised NOK 250 million in a private placement.

As of 31 March 2010, the Group had liquid funds in total of NOK 504 million, which are invested in bank deposits and money market funds, compared to NOK 514 million end of year 2009 and NOK 327 million end of March 2009. The Group had no debt.

The total number of outstanding shares as of 31 March 2010 was 39 433 493. The total number of granted share options as of 31 March was 1 728 902 (vested and unvested).

Algeta Group – First quarter report 2010  
Preliminary and unaudited

Condensed consolidated income statement

<i>(Amounts in NOK thousands except per share data)</i>	Note	1st quarter 2010	1st quarter 2009	Full year 2009
Revenue	2	64 106	58	30 671
Total operating revenue		64 106	58	30 671
Research and development expenses	3	46 690	27 533	127 499
Payroll and related costs		12 051	9 403	46 312
Depreciation	5	709	494	2 161
Other expenses		4 480	3 615	17 622
Total operating expenses		63 930	41 045	193 593
Operating profit/(loss)		177	(40 987)	(162 923)
Financial income		1 272	1 558	9 478
Financial expenses		10 924	201	16 654
Net financial income/(loss) <sup>1)</sup>		(9 652)	1 357	(7 176)
Loss before income tax		(9 475)	(39 630)	(170 098)
Income tax		-	-	-
Loss for the year		(9 475)	(39 630)	(170 098)
Profit attributable to:				
Equity holders of the company		(9 475)	(39 630)	(170 098)
Earnings per share				
- basic and diluted NOK		(0,24)	(1,98)	(4,92)

1) Of net financial loss in first quarter 2010 NOK 10,859 thousands was due to currency loss, compared to zero for the same period in 2009 and NOK 15,708 for the year 2009.

Condensed consolidated statement of comprehensive income

<i>(Amounts in NOK thousands)</i>	1st quarter 2010	1st quarter 2009	Full year 2009
Loss for the year	(9 475)	(39 630)	(170 098)
Other comprehensive income	-	-	-
Total comprehensive loss for the year	(9 475)	(39 630)	(170 098)

## Condensed consolidated statement of financial position

<i>(Amounts in NOK thousands)</i>	Note	31 March 2010	31 March 2009	31. Dec. 2009
<b>ASSETS</b>				
Property, plant and equipment	5	9 757	6 797	9 319
Total non-current assets		9 757	6 797	9 319
Receivables <sup>1)</sup>		61 979	7 670	65 832
Cash & cash equivalents		504 387	326 779	514 206
Total current assets		566 366	334 449	580 038
<b>TOTAL ASSETS</b>		<b>576 123</b>	<b>341 246</b>	<b>589 357</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
Share capital	6	19 717	19 406	19 689
Additional paid-in-capital		699 591	685 687	696 948
Accumulated losses		(560 126)	(420 183)	(550 651)
Total equity		159 181	284 910	165 986
<b>Non-current liabilities</b>				
Deferred income - up-front payment <sup>2)</sup>	2	239 102	-	259 596
Total non-current liabilities		239 102	-	259 596
<b>Current liabilities</b>				
Trade and other payables		95 862	56 336	81 798
Deferred income - up-front payment <sup>2)</sup>	2	81 978	-	81 978
Total current liabilities		177 840	56 336	163 776
Total liabilities		416 942	56 336	423 372
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>576 123</b>	<b>341 246</b>	<b>589 357</b>

1) NOK 46,497 thousands of other receivables as at 31 March 2010 is due to Bayer deal, related to cost sharing. NOK 55,924 thousands of other receivables as at 31 December 2009 is due to Bayer deal, related to withholding tax on up-front payments, received January 2010.

2) Non-current and current deferred income of NOK 321,080 thousands in 2010 is deferred up-front payment from the Bayer agreement, representing 47 months income not yet recognized in P&L. See note 2 – Income.

## Condensed consolidated statement of changes in equity

<i>(Amounts in NOK thousands)</i>	Note	Share capital – ordinary shares	Additional paid in capital	Accum. losses	Total
Balance at 1 January 2009		8 256	467 439	(380 553)	95 142
Total comprehensive loss for the year				(39 630)	(39 630)
Share issuance - private placement		11 150	234 150		245 300
Transaction cost - private placement			(16 602)		(16 602)
Share-based compensation			700		700
Balance at 31 March 2009		19 406	685 687	(420 183)	284 910
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Balance at 1 January 2010		19 689	696 948	(550 651)	165 986
Total comprehensive loss for the year				(9 475)	(9 475)
Share issuance, employees	6	28	991		1 019
Share-based compensation	6		1 652		1 652
Balance at 31 March 2010		19 717	699 591	(560 126)	159 181

## Condensed consolidated statement of cash flow

<i>(Amounts in NOK thousands)</i>	Note	1st quarter 2010	1st quarter 2009	Jan-Dec 2009
Profit/(loss) before income tax		(9 475)	(39 630)	(170 098)
Depreciation		709	494	2 161
Share-based compensation		1 652	700	5 824
Net financial (income)/loss		9 652	(1 357)	7 176
<i>Changes in working capital:</i>				
Receivables <sup>1)</sup>		4 138	999	(63 027)
Deferred income - up-front payment <sup>2)</sup>	2	(20 494)	-	341 574
Trade and other payables		13 961	4 794	30 785
<b>Net cash from/(used) in operating activities</b>		<b>142</b>	<b>(34 000)</b>	<b>154 395</b>
Purchases of property, plant and equipment (PPE)	5	(1 147)	(773)	(4 962)
Interest received		163	64	8 761
<b>Net cash received in investing activities</b>		<b>(984)</b>	<b>(710)</b>	<b>3 800</b>
Proceeds from issuance of shares	6	-	228 698	233 026
Proceeds from exercise of options	4	1 019	-	2 092
<b>Net cash generated from financing activities</b>		<b>1 019</b>	<b>228 698</b>	<b>235 118</b>
Net increase/(decrease) in cash and cash equivalents		177	193 988	393 313
Exchange gain/(loss) on cash and cash equivalents		(9 996)	(141)	(12 038)
Cash and cash equivalents at beginning of year		514 206	132 932	132 932
<b>Cash and cash equivalents at end of year</b>		<b>504 387</b>	<b>326 779</b>	<b>514 206</b>

1) NOK 55,924 thousands of the changes in receivables during the year 2009 is due to Bayer deal, related to withholding tax on upfront payments, received January 2010.

2) NOK 341,574 thousands of the changes in deferred income during the year 2009 is due to deferred up-front payment from the Bayer agreement, representing 50 of 54 months income not yet recognized in P&L. See note 2–Income. The change in deferred income first quarter 2010 represents 3 months income recognized.

## Note 1 - ACCOUNTING PRINCIPLES

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 2009 prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU.

New or amended standards which have an impact on the accounts of the Algeta Group as from 1 January 2010 are described below. The amendments to IFRS 3 and IAS 27 did not affect the consolidated accounts for the first quarter of 2010, as no acquisitions were made and no holdings in subsidiaries bought or sold.

### IFRS 3 – Business Combinations (revised)

Compared with the prevailing IFRS 3, the revised standard introduces certain changes and specifications with respect to the use of the acquisition method (the purchase method). Amendments relate to goodwill in step acquisitions, minority interests and contingent considerations. Acquisition costs in excess of issue and borrowing costs shall be expensed as they occur. The revised standard shall be applied from

the first annual accounting period beginning on or after 1 July 2009. IFRS 3 (R) cannot be applied retrospectively. The Group introduced IFRS 3 (R) as from 1 January 2010. The revised standard will affect the Group's recording of future acquisitions.

### IAS 27 – Consolidated and Separate Financial Statements (revised)

Compared with the prevailing IAS 27, the revised standard gives more guidance regarding the accounting treatment of changes in ownership interests in subsidiaries. The introduction of the revised standard implies that upon loss of control of a subsidiary, any residual holding in the former subsidiary must be measured at fair value and the gain or loss on the disposal recognised in profit or loss. In addition, current rules relating to the distribution of losses between the majority and the minority have been changed, whereby losses are to be charged to the non-controlling interests (minority interests), even if the balance sheet value of the minority interest will thus be negative. The revised standard shall be applied from the first annual accounting period beginning on or after 1 July 2009. The Group introduced IAS 27 (R) as from 1 January 2010. The revised standard will affect the Group's recording of future acquisitions and any sale/purchase of residual holdings in subsidiaries.

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 judgment 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.

### Revenue recognition

Revenue comprises the fair value of the consideration received or receivable for the sale of services in the ordinary course of the Company's activities. Revenue is shown net of value-added tax, returns, rebates and discounts.

The Company's products are still in the research and development phase; correspondingly, the Company does not have revenues from the sale of pharmaceuticals.

The Company's business strategy includes entering into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of the Company's product candidates. The term of the Company's first license agreement with Bayer Schering Pharma AG includes a non-refundable signing fee, funding of R&D, payments based on the achievement of development, manufacturing and sales milestones, and royalties on product sales. Revenue arising from collaborative agreements consisting of multiple elements is allocated to those elements in accordance with contractual terms, which are indicative of the fair values of the individual elements. Significant management judgment is required in determining whether, in substance, elements of such contracts operate independently of other elements and whether they should therefore be accounted for separately. Revenue in respect of each separable element (or, where no elements are separable, in respect of the contract as a whole) is spread over the period over which the Company is expected to complete its service obligations under an arrangement.

Up-front milestones and fees are recognized on a straight-line basis over the performance period. In particular, if the Company is involved in a steering committee as part of a multiple element arrangement, the Company assesses whether its involvement constitutes an obligation or a right to participate. Steering committee services that are considered significant obligations are combined with other research service obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its obligations.

Amounts received or receivable under R&D contracts and collaborative research agreements are recognized as revenue in the period in which the related costs are incurred or services are provided. These contributions towards costs incurred are received where the Company is the principal in the transaction, and as such these amounts have been recorded gross as revenue and not netted against costs incurred. As revenue represents contributions towards costs incurred, no amounts have been allocated to cost of sales; instead all costs relating to these development programs are recorded as R&D expenditure.

Non-refundable license fees and payments on the achievement of milestones are recognized as revenue when the Company has a contractual right to receive such payment, the amount can be measured reliably, it is probable that the economic benefits associated will flow to the Company, and when the specific conditions stipulated in the license agreements have been satisfied.

Operating expenses by nature

Research and development expenses relates to external incurred costs. Internal costs to research and development are together with administrative expenses included in payroll and related costs, depreciation and other expenses.

## Note 2 - REVENUE

In September 2009 Algeta Group signed a license and development agreement with Bayer Schering Pharma AG. Algeta Group received a signing fee of EUR 42.5 million and this revenue is spread over the period of 4,5 years which is the time the Group expects to complete its service obligations under this arrangement, i.e. to launch. According to the Bayer agreement the Group are also entitled to cost sharing for R&D services.

<i>(Amounts in NOK thousands)</i>	1st quarter 2010	1st quarter 2009	Jan-Dec 2009
Up-front payment <sup>1)</sup>	20 494	-	27 326
Cost sharing/R&D services	43 511	-	3 050
Other revenue	101	58	294
<b>Total operating revenue</b>	<b>64 106</b>	<b>58</b>	<b>30 671</b>

1) The total up-front payment of EUR 42.5 million is split into 4.5 years starting from September 2009. Deferred income at 31 December 2009 amounts to NOK 342 million and at 31 March 2010 NOK 321 million.

## Note 3 - RESEARCH AND DEVELOPMENT EXPENSES

<i>(Amounts in NOK thousands)</i>	1st quarter 2010	1st quarter 2009	Jan-Dec 2009
Clinical R&D	39 167	22 291	104 659
Cost of goods	4 880	2 851	13 775
Laboratory and Preclinical R&D	768	1 698	3 492
Production and quality	996	605	2 103
Other	1 778	663	6 640
Government grants	(899)	(575)	(3 170)
<b>Total research and development expenses</b>	<b>46 690</b>	<b>27 533</b>	<b>127 499</b>

## Note 4 - SHARE-BASED COMPENSATION

At the Annual General Meeting in May 2009 the board of Algeta was authorized to issue up to 3,000,000 share options to employees, board members, and consultants. The options generally vest over a period from 1 to 4 years and expire 7 years after the grant date. In general, the exercise price for the options is set at the fair value of the shares at grant date.

The following table shows the changes in outstanding options in the three-month period ended 31 March 2010:

	2010	
	Number of options	Weighted average exercise price (in NOK)
Outstanding on 1 January	1 729 159	22,29
Granted during the period <sup>1)</sup>	57 500	57,97
Terminated during the period	(1 396)	33,70
Exercised during the period <sup>2)</sup>	(56 361)	21,66
Expired during the period	-	0,00
Outstanding at 31 March	1 728 902	23,59

1) There were no granted options for shares to key management of the Group during January-March 2010.

2) John E. Berriman, Deputy chairman of the Board, and a primary insider of Algeta ASA, has exercised 40,000 options in the company, corresponding to 40,000 shares at the strike price of NOK 20.

#### Note 5 – PROPERTY, PLANT AND EQUIPMENT

During the first quarter of 2010; the Group invested NOK 1.1 million in property, plant and equipment, primarily equipment for research purposes.

#### Note 6 – SHARE CAPITAL

The following table shows the changes in number of outstanding shares in the three-month period ended 31 March 2010:

<i>(Amounts in NOK thousands)</i>	31 March 2010
	Ordinary shares
Total authorized ordinary shares at 1 January	39 377 132
Share issuance - employees	56 361
Total authorized ordinary shares at 31 March	39 433 493