

**Alizyme plc**  
**Interim Report 2008**



**Alizyme plc**

## **Interim highlights**

**In the year to date, we have further progressed the development of our product portfolio and remain focused on the commercialisation of these products.**

### **Operational**

#### **Cetilistat (obesity and diabetes)**

- Protocols of all three studies in the Phase III programme agreed with FDA under SPA procedure
- FDA indicated a potential labelling for type 2 diabetes, as well as for obesity

#### **COLAL-PRED® (ulcerative colitis)**

- Headline results reported for EU Phase III clinical trial in approximately 800 patients with active moderate to severe ulcerative colitis
- Licence agreement with Norgine BV for Europe and other territories; €2.0 million received up front
- Phase II clinical development commenced in the US by Prometheus Laboratories Inc

#### **ATL-104 (mucositis)**

- Transfer of manufacturing technology to commercial facility ongoing
- Preparations for Phase II study in patients with solid cancer tumours ongoing

#### **Renzapride (irritable bowel syndrome)**

- Development by Alizyme discontinued in April following results of Phase III clinical trial

### **Financial**

- Revenues of £0.05 million recognised in the period (six months ended 30 June 2007: nil)
- Net loss after tax of £8.9 million (six months ended 30 June 2007: £12.3 million)
- Cash, cash equivalents and money market investments of £7.7 million at 30 June 2008 (£19.1 million at 30 June 2007, £5.8 million at 31 December 2007)
- £10.0 million gross raised from shareholders in the placing in March 2008
- Cost saving measures introduced following revised cash flow projections

### **Board changes**

- David Campbell to step down as Finance Director and Company Secretary
- Richard Forrest to step down as Non-Executive Director

## **Interim management report to the members of Alizyme plc**

### **Cautionary Statement**

This Interim Management Report ("IMR") has been prepared solely to provide additional information to shareholders to assess the Group's strategies and the potential for those strategies to succeed. The IMR should not be relied on by any other party or for any other purpose.

The IMR contains certain forward-looking statements. These statements are made by the Directors in good faith based on the information available to them up to the time of their approval of this report and such statements should be treated with caution due to the inherent uncertainties, including both economic and business risk factors, underlying any such forward-looking information.

### **Overview**

During the first half of the year, our main focus has been on the commercialisation of our diverse portfolio, which comprises three late stage products, including one in Phase III development. All of these products have competitive profiles and significant commercial potential.

### **Operational**

#### **Cetilistat**

Alizyme's metabolic product, cetilistat, is being developed for the treatment of obesity and associated co-morbidities (including type 2 diabetes). It is a gastrointestinal lipase inhibitor that blocks fat digestion and absorption, leading to reduced energy intake, and thus weight loss. It is distinct from most other anti-obesity agents as it does not act on the brain to reduce appetite, but acts peripherally. The compound remains in the gastrointestinal tract with no significant absorption into the body. It can, therefore, be expected to have a superior risk-benefit profile to centrally acting drugs. Accordingly, cetilistat is not subject to the safety concerns generally associated with centrally acting drugs.

Roche's Xenical® is an approved obesity product and is also a peripherally acting lipase inhibitor. In clinical trials cetilistat has been demonstrated to be significantly better tolerated than Xenical®, which has side effects that can detrimentally affect patient compliance.

In March 2008, Alizyme announced that FDA had agreed all three protocols for its Phase III development programme for

cetilistat in the treatment of obesity under the Special Protocol Assessment ("SPA") procedure and recommended that Alizyme open a separate IND for the investigation of cetilistat in diabetes.

Takeda Pharmaceutical Company Limited ("Takeda"), our partner in Japan, has been conducting a Phase II study in obese diabetics. The results from this study are due to be reported later this year.

Alizyme continues discussions in relation to licensing this product for territories outside of Japan.

#### **COLAL-PRED®**

COLAL-PRED® is a proprietary gastrointestinal product developed by Alizyme for the treatment of ulcerative colitis, an inflammatory disease of the colon that causes symptoms such as abdominal pain, bleeding, cramping, fatigue and diarrhoea. These conditions are characterised by episodes of acute flare of the inflammation, followed by periods of remission. In severe cases, surgery may be required to remove the diseased tissue. This market is dominated by anti-inflammatory steroids and 5-ASA products, which have safety and/or efficacy issues.

COLAL-PRED® is the combination of Alizyme's proprietary colonic drug delivery system, COLAL®, and prednisolone metasulfobenzoate sodium ("PMSBS"), an approved steroid in Europe. COLAL-PRED® has a coating that is broken down only in the colon, by locally occurring bacteria. This leads to topical delivery of PMSBS to the colon,

rather than systemic delivery. It has been shown in a Phase III clinical trial to provide a significantly improved risk-benefit profile to that of conventional oral prednisolone.

Prometheus Laboratories Inc, Alizyme's partner for COLAL-PRED® in North America, commenced Phase II clinical development for the treatment of ulcerative colitis in the US in May 2008.

TSD Japan Inc, Alizyme's partner for COLAL-PRED® in Japan, has continued preparation for a Phase I study that is expected to commence in the second half of 2008.

In June 2008, Alizyme entered into a licence agreement with Norgine BV, a leading European specialty pharmaceutical company with a focus on gastroenterology. The agreement comprises an exclusive licence to Norgine to develop and market COLAL-PRED® in Europe, South Africa, Australia and New Zealand. Alizyme received an upfront payment of €2.0 million, with additional payments of up to €40.75 million receivable on the achievement of future development and sales milestones. The agreement provides that Norgine is responsible for commercialisation and for payment of double digit royalty rates to Alizyme that increase with higher annual net sales levels.

In January 2008, Alizyme announced the completion of patient recruitment into the pivotal registration Phase III trial of COLAL-PRED® in patients with active

moderate to severe ulcerative colitis. In July 2008, Alizyme reported headline trial results that support the product profile of COLAL-PRED® as a safe treatment for acute ulcerative colitis. The study endpoints were comparisons of efficacy, safety and the combination of safety and efficacy, between COLAL-PRED® and conventional prednisolone. COLAL-PRED® demonstrated superior safety and superior combined safety and efficacy. A co-primary endpoint based on the Disease Activity Index of efficacy of COLAL-PRED® to conventional prednisolone was not met. However, COLAL-PRED® did show equivalent efficacy compared to conventional prednisolone after 8 weeks' dosing in the treatment of acute ulcerative colitis, based on patient reported symptoms. The results also suggest the potential for use in the maintenance of remission of ulcerative colitis.

The Marketing Authorisation Application ("MAA"), previously anticipated in Q4 2008, will be delayed due to one co-primary end point not being met. However, we continue review of the data with our partners and regulatory advisors. In conjunction with our existing partners, we look to progress the development of COLAL-PRED® as a safe and effective treatment for ulcerative colitis.

Following the publication of the Phase III studies, Alizyme has received enquiries in relation to commercialisation of COLAL-PRED® for the territories where it is not currently licensed to commercial partners.

### **ATL-104**

ATL-104 is being developed by Alizyme as an orally administered mouthwash for the treatment of mucositis of the mouth and gastrointestinal tract arising during cancer treatment. This provides ease and convenience of administration and enables local delivery of treatment for oral and gastrointestinal mucositis with no significant absorption into the body.

Globally there are over 4 million new cases of cancer each year. Mucositis occurs in up to 80% of patients being treated for cancer. Mucositis is characterised by severe ulceration, bleeding and pain in the mouth and gastrointestinal tract, caused by damage to the cells that line these tissues by cancer chemotherapy and radiotherapy. These symptoms can be very painful (requiring the administration of opiates), can reduce the ability of the patient to receive nutrition orally, can be a source of infection and can be potentially life threatening.

Having successfully completed a Phase IIa 'proof of concept' clinical trial in patients with lymphoma and myeloma, Alizyme is preparing ATL-104 for a second Phase II study, this time in patients with solid cancer tumours suffering from mucositis. In addition, transfer of manufacturing technology to a commercial facility in preparation for manufacturing scale-up for Phase III clinical trials and commercial supply is ongoing.

## **Interim management report to the members of Alizyme plc continued**

Alizyme is progressing discussions with a number of potential licence partners for this product.

### **Renzapride**

In April 2008, Alizyme announced that following clinical trial results from Study 038, its Phase III study of renzapride in constipation-predominant irritable bowel syndrome ("IBS-C"), no further development would be carried out by Alizyme. As a result, Study 052, the open label extension study to evaluate the long term safety and tolerability of renzapride, was also discontinued. Renzapride therefore no longer forms part of Alizyme's development portfolio.

### **Financial review**

The unaudited condensed financial statements for the six months ended 30 June 2008 are prepared in accordance with the Group's accounting policies based on International Financial Reporting Standards ("IFRS") as adopted by the European Union.

In the six months ended 30 June 2008, Alizyme made a net loss of £8.9 million (six months ended 30 June 2007: £12.3 million).

Revenues of £0.05 million were recognised in the six months ended 30 June 2008, relating to the elements of the US\$2.5 million (£1.2 million) up front payment received from Prometheus Laboratories Inc in November 2007 and of the €2.0 million (£1.6 million) received from Norgine BV in June 2008 that were recognised during the period. There was no revenue for the six months ended 30 June 2007.

Net cash outflow from operating activities for the period was £7.5 million (six months ended 30 June 2007: £9.3 million).

Cash, cash equivalents and money market investments were £7.7 million at 30 June 2008 (£19.1 million at 30 June 2007, £5.8 million at 31 December 2007).

Research and development expenditure was £8.8 million (six months ended 30 June 2007: £12.8 million), reflecting expenditure on the Phase III clinical trials for renzapride and COLAL-PRED® and the long term safety study for renzapride. All costs associated with completing the renzapride studies have been recognised in the period.

Alizyme's outsourcing model means that the limited clinical activity planned for the second half of the year will result in substantially lower research and development expenditure for that period.

Management and administration expenses were £0.7 million (six months ended 30 June 2007: £0.7 million). In addition, share-based payment costs of £0.3 million (six months ended 30 June 2007: £0.3 million) have been charged for the period.

The Directors have revised their forecasts of the cash flow requirements of the Company following significantly increased costs incurred in connection with clinical trial activity. The Directors have made reasonable assumptions about reductions of these clinical trial costs and other cost reduction measures, as well as income on achievement of

milestones by third parties under existing licence agreements. Such reductions and income would enable the Company to continue operations through to the end of 2009 without reliance on revenue streams from new partnerships or further raising of capital. However, as described in note 1 to the condensed financial statements with respect to the Company's ability to continue as a going concern, those assumptions are subject to material uncertainties.

Following completion of Phase III studies for renzapride and COLAL-PRED® earlier this year, the ongoing clinical trial activity has significantly reduced and, as a result, the Directors are in the process of rationalising headcount as well as implementing other cost reduction strategies as appropriate.

### **Board changes**

We announce today that David Campbell has informed the Board that he wishes to step down from his role as Finance Director and Company Secretary and pursue other opportunities and interests. He will formally leave the Company later this year.

We also announce today that Richard Forrest is stepping down as a Non-Executive Director with effect from 31 August 2008.

We wish to thank both David and Richard for the commitment and support that they have provided to the Company and wish them every success in the future.

### Risks and uncertainties

Alizyme faces a number of general risks and uncertainties that are common to biopharmaceutical development companies that are described in the Annual Report for the year ended 31 December 2007, which do not form part of this report. In the forthcoming period to 31 December 2008, the key risks facing the Company are as follows:

It had been anticipated that a MAA for COLAL-PRED® would be submitted in the EU in Q4 2008. There is now uncertainty over the timing of a submission. Submission of an MAA may result in restriction of indication, denial of approval or demands for additional data.

The results from the Phase II study of cetilistat by Takeda are due to be reported this year. There can be no certainty as to the outcome of this study. If successful, we anticipate that Takeda will apply to commence a Phase III study. However, this decision will be made by Takeda, and the ability to commence a study would be subject to regulatory approval, which may result in demands for additional data, amendments to the protocol or delay, and which is not certain.

The condensed financial statements have been prepared on a going concern basis, relying on assumptions about income from future milestones and reductions in the costs incurred by the Group as explained in note 1 to the condensed financial statements. These events and conditions represent material uncertainties over the profile of Alizyme's future cash flows and hence its ability to continue as a going concern.

### Outlook

Alizyme looks to build on the commercial and clinical progress achieved during the first half of the year as discussions with potential partners in relation to all products in our portfolio continue. Further licence opportunities are being pursued with the objective of building multiple revenue streams and leveraging off the virtual business model. We take this opportunity to thank the team at Alizyme and our collaborators for their significant contribution, commitment and effort throughout the period.

### Responsibility statement

We confirm that to the best of our knowledge:

- (a) the condensed set of financial statements has been prepared in accordance with IAS 34 - 'Interim Financial Reporting';
- (b) the interim management report includes a fair review of the information required by DTR 4.2.7R (indication of important events during the first six months and description of principal risks and uncertainties for the remaining six months of the year); and
- (c) the interim management report includes a fair review of the information required by DTR 4.2.8R (disclosure of related parties' transactions and changes therein).

By order of the Board



**Sir Brian Richards**

Chairman  
29 August 2008



**Tim McCarthy**

Chief Executive Officer  
29 August 2008

## **Independent review report to Alizyme plc**

### **Introduction**

We have been engaged by the Company to review the condensed set of financial statements in the interim statement for the six months ended 30 June 2008, which comprises the condensed consolidated income statement, the condensed consolidated balance sheet, the condensed consolidated statement of changes in equity, the condensed consolidated cash flow statement and related notes 1 to 16. We have read the other information contained in the interim statement and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the Company in accordance with International Standard on Review Engagements 2410 issued by the Auditing Practices Board. Our work has been undertaken so that we might state to the Company those matters we are required to state to them in an independent review report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company for our review work, for this report or for the conclusions we have formed.

### **Directors' responsibilities**

The interim statement is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the interim statement in accordance with the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority.

As disclosed in note 1, the annual financial statements are prepared in accordance with IFRS as adopted by the European Union. The condensed set of financial statements included in the interim statement has been prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting", as adopted by the European Union.

### **Our responsibility**

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the interim statement based on our review.

### **Scope of Review**

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, "Review of Interim Financial information Performed by the Independent Auditor of the Entity" issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the interim statement for the six months ended 30 June 2008 is not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the Disclosure and Transparency Rules of the United Kingdom's Financial Services Authority.

### **Emphasis of matter – going concern**

Without qualifying our conclusion, we draw attention to the disclosures made in note 1 of the condensed financial statements concerning the Group's ability to continue as a going concern. These include the following uncertainties:

- Receipt of milestone income from third parties under existing licence agreements
- Timing and cost to completion of known clinical trial activity undertaken by third parties on behalf of the Group

These events and conditions, along with other matters as set forth in note 1, indicate the existence of material uncertainties which may cast significant doubt about the Group's ability to continue as a going concern. The interim report does not include the adjustments that would result if the Group was unable to continue as a going concern as it is not practicable to determine or quantify them.



### **Deloitte & Touche LLP**

Chartered Accountants  
Cambridge, United Kingdom  
29 August 2008

### **Notes:**

A review does not provide assurance on the maintenance and integrity of the website, including controls used to achieve this, and in particular on whether any changes may have occurred to the financial information since first published. These matters are the responsibility of the Directors but no control procedures can provide absolute assurance in this area.

Legislation in the United Kingdom governing the preparation and dissemination of financial information differs from legislation in other jurisdictions.

## Condensed consolidated income statement

for the six months ended 30 June 2008

Unaudited

	Notes	Six months ended 30 June 2008 £000's	Six months ended 30 June 2007 £000's	Twelve months ended 31 December 2007 Audited £000's
<b>Revenue</b>	6	<b>49</b>	–	13
<b>Operating expenses</b>				
Research and development expenses		<b>(8,770)</b>	(12,761)	(31,136)
Management and administration excluding IFRS 2 charge		<b>(725)</b>	(730)	(1,713)
Share-based payment		<b>(323)</b>	(312)	(676)
Total management and administration expenses		<b>(1,048)</b>	(1,042)	(2,389)
<b>Total operating expenses</b>		<b>(9,818)</b>	(13,803)	(33,525)
<b>Operating loss</b>		<b>(9,769)</b>	(13,803)	(33,512)
Investment income		<b>185</b>	563	845
Loss on foreign exchange transactions		<b>(21)</b>	(32)	(36)
<b>Loss on ordinary activities before taxation</b>		<b>(9,605)</b>	(13,272)	(32,703)
Taxation on loss on ordinary activities		<b>686</b>	931	1,458
<b>Loss for the financial period being the retained loss for the period attributed to the members of Alizyme plc</b>		<b>(8,919)</b>	(12,341)	(31,245)
<b>Loss per share for the period - basic and diluted</b>	7	<b>(4.2)p</b>	(6.2)p	(15.6)p

All amounts relate to continuing activities.

## Condensed consolidated balance sheet

as at 30 June 2008

Unaudited

	Notes	30 June 2008 £000's	30 June 2007 £000's	31 December 2007 Audited £000's
<b>Non-current assets</b>				
Property, plant and equipment	8	<b>134</b>	208	176
<b>Current assets</b>				
Research and development tax credit		<b>686</b>	931	1,458
Prepayments		<b>2,047</b>	2,492	2,673
Accrued income		<b>51</b>	82	82
Other receivables		<b>160</b>	189	398
Money market investments	9	<b>1,650</b>	4,680	3,800
Cash and cash equivalents	9	<b>6,026</b>	14,413	2,002
		<b>10,620</b>	22,787	10,413
<b>Current liabilities</b>				
Trade and other payables	10	<b>(6,867)</b>	(4,209)	(8,888)
Deferred revenue		<b>(187)</b>	–	(80)
		<b>(7,054)</b>	(4,209)	(8,968)
<b>Net current assets</b>				
		<b>3,566</b>	18,578	1,445
<b>Total assets less current liabilities</b>				
		<b>3,700</b>	18,786	1,621
<b>Non-current liabilities</b>				
Deferred revenue		<b>(2,540)</b>	–	(1,115)
Long-term provisions		<b>–</b>	(110)	(8)
		<b>(2,540)</b>	(110)	(1,123)
<b>Net assets</b>				
		<b>1,160</b>	18,676	498
<b>Equity</b>				
Share capital		<b>4,422</b>	4,007	4,021
Share premium account		<b>116,569</b>	107,364	107,712
Capital reserve		<b>1,530</b>	1,530	1,530
Share-based payment reserve		<b>2,865</b>	2,178	2,542
Retained loss		<b>(124,226)</b>	(96,403)	(115,307)
<b>Total equity</b>				
	13	<b>1,160</b>	18,676	498

## Condensed consolidated statement of changes in equity

Unaudited

	Share capital	Share premium account	Capital reserve	Share-based payment reserve	Retained loss	Total
	£000's	£000's	£000's	£000's	£000's	£000's
<b>Balance as at 31 December 2006</b>	3,994	107,106	1,530	1,866	(84,062)	30,434
Loss for the period	–	–	–	–	(12,341)	(12,341)
Share-based payment	–	–	–	312	–	312
Issue of share capital	13	258	–	–	–	271
<b>Balance as at 30 June 2007</b>	4,007	107,364	1,530	2,178	(96,403)	18,676
<b>Balance as at 31 December 2007</b>	4,021	107,712	1,530	2,542	(115,307)	498
Loss for the period	–	–	–	–	(8,919)	(8,919)
Share-based payment	–	–	–	323	–	323
Issue of share capital	401	9,616	–	–	–	10,017
Expenses of share issue	–	(759)	–	–	–	(759)
<b>Balance as at 30 June 2008</b>	4,422	116,569	1,530	2,865	(124,226)	1,160
<b>Balance as at 31 December 2006</b>	3,994	107,106	1,530	1,866	(84,062)	30,434
Loss for the year	–	–	–	–	(31,245)	(31,245)
Share-based payment	–	–	–	676	–	676
Issue of share capital	27	606	–	–	–	633
<b>Balance as at 31 December 2007</b>	4,021	107,712	1,530	2,542	(115,307)	498

## Condensed consolidated cash flow statement

for the six months ended 30 June 2008

Unaudited

	Six months ended 30 June 2008 £000's	Six months ended 30 June 2007 £000's	Twelve months ended 31 December 2007 Audited £000's
<b>Operating activities</b>			
Operating loss	(9,769)	(13,803)	(33,512)
Depreciation charge	43	29	73
Decrease in accounts receivable	926	1,389	999
(Decrease)/increase in accounts payable	(2,021)	1,609	6,288
Increase in deferred revenue	1,532	–	1,195
(Decrease)/increase in provision	(8)	26	(76)
Share-based payment expense	323	312	676
<b>Net cash outflow from operations</b>	<b>(8,974)</b>	<b>(10,438)</b>	<b>(24,357)</b>
Research and development tax credit received	1,458	1,119	1,119
<b>Net cash outflow from operating activities</b>	<b>(7,516)</b>	<b>(9,319)</b>	<b>(23,238)</b>
<b>Investing activities</b>			
Interest received	154	597	879
Net cash withdrawn from money market investments	2,150	620	1,500
Purchase of property, plant and equipment	(1)	(172)	(184)
<b>Net cash inflow from investing activities</b>	<b>2,303</b>	<b>1,045</b>	<b>2,195</b>
<b>Financing activities</b>			
Proceeds on issue of ordinary share capital (net of expenses)	9,258	271	633
<b>Net cash inflow from financing activities</b>	<b>9,258</b>	<b>271</b>	<b>633</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>4,045</b>	<b>(8,003)</b>	<b>(20,410)</b>
Cash and cash equivalents at beginning of period	2,002	22,448	22,448
Effect of foreign exchange rate changes	(21)	(32)	(36)
<b>Cash and cash equivalents at end of period</b>	<b>6,026</b>	<b>14,413</b>	<b>2,002</b>

# Notes to the condensed financial statements

for the six months ended 30 June 2008

## 1 Basis of preparation

These interim financial statements are condensed financial statements that have been prepared in accordance with IAS 34 - 'Interim Financial Reporting' and were approved by the Board on 29 August 2008. They do not constitute statutory financial statements within the meaning of Section 240 of the Companies Act 1985.

The information for the year ended 31 December 2007 does not constitute statutory accounts as defined in Section 240 of the Companies Act 1985. A copy of the statutory accounts for the year ended 31 December 2007 has been delivered to the Registrar of Companies. Those accounts were prepared in accordance with IFRS as adopted by the European Union. The auditors' report on those accounts was not qualified and did not contain statements under Section 237(2) or (3) of the Companies Act 1985.

Results for the six month periods ended 30 June 2008 and 30 June 2007 have not been audited.

### Going concern

In determining the appropriate basis of preparation of the financial statements, the Directors are required to consider whether the Group can continue in operational existence for the foreseeable future.

Alizyme had cash, cash equivalents and money market investments of £7.7 million as at 30 June 2008 and incurred a loss of £8.9 million for the six months ended 30 June 2008. The Group's Directors have prepared a detailed cash flow forecast for the period ending 31 December 2009 ("the Forecast") which include a number of significant assumptions regarding income, expenditure and cashflows.

The Forecast assumes receipt of income on achievement of milestones by third parties under existing licence agreements. Whilst the amounts of the assumed milestones are contracted, the events giving rise to receipt of such milestones, such as further clinical development of the licensed product, are outside the direct control of Alizyme and the timing of receipt of any such milestone is inherently uncertain. Based on their understanding of the status of product development and their discussions with licensees, the Directors are of the view that it is reasonable to assume that certain such milestones will be received.

The Forecast also includes certain key assumptions with respect to the cash outflows of the Company, particularly with respect to the estimated timing and cost to completion of known clinical trial activity undertaken by third parties on behalf of the Company. Whilst the Directors have made reasonable enquiries as to the factors affecting cash outflows anticipated in meeting the liabilities associated with such activity, these amounts are uncertain and could vary from those forecast.

Following the announcement of results from two large Phase III studies in April 2008 and July 2008, clinical trial activity has significantly reduced and, as a result, the Directors are in the process of rationalising headcount as well as implementing other cost saving strategies as appropriate.

In addition, the Directors are currently in discussions with a number of parties regarding further commercialisation of the Group's intellectual property assets, the successful conclusion of which would give rise to significant cash inflows to the Group, depending upon the specific terms that are agreed. These inflows are not included in the Forecast, which has been prepared solely for the assessment of the going concern basis of preparation of the financial information.

## **1 Basis of preparation (continued)**

### **Going concern (continued)**

Having reviewed the Forecast, and having made reasonable enquiries in making the underlying assumptions, the status of commercial negotiations and possible cost saving strategies, the Directors have a reasonable expectation that the Group will be able to meet its liabilities as they fall due for the foreseeable future. It is on this basis that the Directors consider it appropriate to prepare the Group's interim financial information on the going concern basis. However, for the reasons described above, as at the date of this announcement there exist material uncertainties which may cast doubt about the Group's ability to continue as a going concern and therefore that it may be unable to realise its assets and discharge its liabilities in the normal course of business. The financial information does not include any adjustments which may be necessary if the Group were unable to continue to operate.

Copies of the interim statement for the six months ended 30 June 2008 are being sent to all shareholders. Details can also be found on the Company's website at [www.alizyme.com](http://www.alizyme.com). Further copies of the interim statement and copies of the full financial statements for the year ended 31 December 2007 can be obtained by writing to the Company Secretary at Alizyme plc, Granta Park, Great Abington, Cambridge, CB21 6GX, United Kingdom.

## **2 Segmental reporting**

The Directors consider there to be one business segment for reporting purposes as the Group conducts one business activity and operates from one location, where all net assets are located, in the United Kingdom. The revenue and loss on ordinary activities before taxation derive from the Group's principal activity in the United Kingdom.

## **3 Significant accounting policies**

The significant accounting policies adopted in the preparation of the interim financial statements and methods of computation are consistent with those used in the preparation of the Group's financial statements for the year ended 31 December 2007.

## **4 Accounting estimates**

There were no estimated amounts reported in the current or prior periods.

## **5 Seasonality**

The business of the Group is not subject to seasonal changes.

## **6 Revenue**

In November 2007, Alizyme Therapeutics Limited, a subsidiary of the Company, received an upfront payment of US\$2,500,000 (£1,208,000) under a licence and development agreement with Prometheus Laboratories Inc. Under this agreement, Alizyme Therapeutics Limited has obligations until December 2022. Accordingly, this income is recognised on a straight-line basis over the period from November 2007 to December 2022. £40,000 has been recognised in the period and £13,000 in the year ended 31 December 2007, whilst the balance of £1,155,000 is deferred revenue.

In June 2008, Alizyme Therapeutics Limited received an upfront payment of €2,000,000 (£1,582,000) under a licence and development agreement with Norgine BV. Under this agreement, Alizyme Therapeutics Limited has obligations until February 2023. Accordingly, this income is recognised on a straight-line basis over the period from June 2008 to February 2023, giving rise to revenue of £9,000 in the period, whilst the balance of £1,573,000 is deferred revenue.

There was no revenue for the six months ended 30 June 2007.

## Notes to the condensed financial statements (continued)

for the six months ended 30 June 2008

### 7 Loss per share

As at 30 June 2008 there were outstanding options over 6,507,590 ordinary shares (30 June 2007: 9,995,265 ordinary shares; 31 December 2007: 6,727,395 ordinary shares) in the Company. IAS 33 - "Earnings per Share" requires presentation of diluted earnings per share when a company could be called upon to issue shares that would decrease net profit or increase net loss per share. Only options that are 'in the money' are treated as dilutive and net loss per share would not be increased by the exercise of these options. Therefore no adjustment has been made to dilute loss per share for any outstanding share options.

The calculation of basic and diluted loss per ordinary share is based on the loss of £8,919,000 for the six months ended 30 June 2008 (six months ended 30 June 2007: £12,341,000; year ended 31 December 2007: £31,245,000) and on 213,393,551 ordinary shares (six months ended 30 June 2007: 200,215,285 ordinary shares; year ended 31 December 2007: 200,366,909 ordinary shares) being the weighted average number of ordinary shares in issue during the period.

### 8 Property, plant and equipment

During the period, the Group acquired fixed assets costing £1,000 (six months ended 30 June 2007: £172,000; year ended 31 December 2007: £184,000).

### 9 Cash, cash equivalents and money market investments

	30 June 2008	30 June 2007	31 December 2007 Audited
	£000's	£000's	£000's
Money market investments	<b>1,650</b>	4,680	3,800
Cash and cash equivalents	<b>6,026</b>	14,413	2,002
	<b>7,676</b>	19,093	5,802

### 10 Trade and other payables

	30 June 2008	30 June 2007	31 December 2007 Audited
	£000's	£000's	£000's
Trade payables	<b>3,133</b>	3,666	4,301
Other taxation and social security	<b>104</b>	78	243
Accruals	<b>3,630</b>	465	4,344
	<b>6,867</b>	4,209	8,888

**11 Long-term provisions**

During the period, the Group has credited the income statement by £8,000 (six months ended 30 June 2007: debit £35,000; year ended 31 December 2007: credit £39,000) in relation to the provision for National Insurance on share option gains. None of the provision (six months ended 30 June 2007: £9,000; year ended 31 December 2007: £37,000) was utilised during the period.

**12 Share capital**

During the period, the Company increased the authorised share capital from 275,000,000 ordinary shares of 2p each to 300,000,000 ordinary shares of 2p each.

In March 2008, the Company completed a placing raising £10.0 million gross of expenses (£9.3 million net), under which 20,033,352 new ordinary shares of 2p each were issued at a price of 50.0p each.

**13 Reconciliation of movements in equity shareholders' funds**

	Six months ended 30 June 2008	Six months ended 30 June 2007	Twelve months ended 31 December 2007 Audited
	£000's	£000's	£000's
Loss for the period	<b>(8,919)</b>	(12,341)	(31,245)
Share-based payment	<b>323</b>	312	676
New ordinary shares issued net of expenses	<b>9,258</b>	271	633
Net increase/(decrease) in shareholders' funds	<b>662</b>	(11,758)	(29,936)
Opening equity shareholders' funds	<b>498</b>	30,434	30,434
<b>Closing equity shareholders' funds</b>	<b>1,160</b>	18,676	498

**14 Contingent liabilities**

As at 31 December 2007, the Group disclosed a contingent liability of £3,000,000 in relation to an amount payable to GlaxoSmithKline after first regulatory approval of renzapride for sale in a major market. Following the decision to cease further development of renzapride by Alizyme, this item is no longer recognised as a contingent liability. There are no other contingent liabilities.

## Notes to the condensed financial statements (continued)

for the six months ended 30 June 2008

### 15 Events after the balance sheet date

There were no significant events after the balance sheet date.

### 16 Related party transactions

The remuneration of the Directors, who are key management personnel of the Group, is set out below in aggregate for each of the categories specified in IAS 24 - "Related Party Disclosures".

	Six months ended 30 June 2008	Six months ended 30 June 2007	Twelve months ended 31 December 2007 Audited
	£000's	£000's	£000's
Short-term employee benefits and fees	<b>412</b>	332	792
Non-Executive Directors' fees	<b>105</b>	105	210
Pension contributions	<b>73</b>	59	118
Share-based payment	<b>145</b>	138	260
	<b>735</b>	634	1,380



**Alizyme plc**

Interim Report 2008

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