



ALIZYME

## **PRELIMINARY RESULTS ANNOUNCEMENT**

**For the 12 months ended 31 December 2008**

**Monday 23 March 2009**

**Presentation by**

**Tim McCarthy, Chief Executive Officer**

**Roger Hickling, R&D Director**

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The financial information does not constitute statutory financial statements within the meaning of section 240 of the Companies Act 1985. The unaudited financial results for the year ended 31 December 2008 and the comparative audited financial results for years ended 31 December 2007 and 31 December 2006 are presented in accordance with the Group’s accounting policies based on International Financial Reporting Standards (“IFRS”).

- ◆ Therapeutic product development company
- ◆ Established 1995, listed on LSE 2000 (LSE:AZM)
- ◆ Outsourcing business model
- ◆ Diversified late-stage pipeline - 3 products in Phase II/III
- ◆ Three therapeutic areas:

◆ **Metabolic** → **obesity and type 2 diabetes**

◆ **Gastrointestinal** → **ulcerative colitis**

◆ **Cancer supportive care** → **mucositis**

## Commercial

- ◆ COLAL-PRED® - Licence agreement with Norgine for Europe and other territories; €2.0 million upfront payment received
- ◆ Cetilistat - US\$3.0 million milestone received from Takeda on entering Phase III development in Japan

Cetilistat  
(obesity & type 2 diabetes)

- ◆ Successful results of Phase II study in Japan in obese diabetic patients
- ◆ Phase III development commenced in Japan
- ◆ Protocols of all three studies in the Phase III obesity programme now agreed with FDA under SPA procedure
- ◆ FDA indicated a potential labelling for type 2 diabetes

COLAL-PRED®  
(ulcerative colitis)

- ◆ Headline results reported for EU Phase III clinical trial in approximately 800 patients with active moderate to severe ulcerative colitis
- ◆ Phase II clinical development commenced in the US by Prometheus
- ◆ Phase I clinical development commenced in Japan by TSD

ATL-104  
(mucositis)

- ◆ Preparations for Phase II study in patients being treated for head and neck cancer ongoing

Renzapride  
(irritable bowel syndrome)

- ◆ Development by Alizyme discontinued



	Full Year	2 <sup>nd</sup> Half	1 <sup>st</sup> Half	2007	2006
	2008	2008	2008	2007	2006
	£'000	£'000	£'000	£'000	£'000
<b>Turnover</b>	1,855	1,806	49	13	1,135
<b>Research &amp; development</b>	*(11,225)	*(2,455)	(8,770)	(31,136)	(18,329)
Management & administration	*(1,773)	*(1,048)	(725)	(1,713)	(1,493)
Share-based payment	(602)	(279)	(323)	(676)	(989)
<b>Operating loss</b>	<b>(11,745)</b>	<b>(1,976)</b>	<b>(9,769)</b>	<b>(33,512)</b>	<b>(19,676)</b>
<b>Loss for the period</b>	<b>(10,060)</b>	<b>(1,141)</b>	<b>(8,919)</b>	<b>(31,245)</b>	<b>(17,964)</b>
<b>Cash &amp; liquid resources (£m)</b>	<b>**2.2</b>	<b>**2.2</b>	<b>7.7</b>	<b>5.8</b>	<b>27.7</b>
<b>Employees at period end</b>	<b>13</b>	<b>13</b>	<b>23</b>	<b>23</b>	<b>17</b>

\* Includes one-off costs of £538k associated with termination of employment

\*\* Does not include £1.4 million tax credit received in February 2009

- ◆ New Non-Executive Director – Dr Roger Lloyd (aged 60)
  - ◆ Over 33 years' experience working in ICI, Zeneca and AstraZeneca
  - ◆ Numerous international transactions including corporate acquisitions, product and technology licensing, joint ventures, divestments and corporate merger and demerger
  - ◆ Recently retired as Executive Director, Global Licensing, AstraZeneca
  
- ◆ New Non-Executive Director – Mr Richard de Souza (aged 56)
  - ◆ 22 years' experience working in SmithKline Beecham
  - ◆ President Europe, SmithKline Beecham
  - ◆ President Europe and International, Warner Lambert
  - ◆ Director International, Shire
  - ◆ Currently Chairman and CEO, Archimedes Pharma Ltd
  
- ◆ Rationale for new appointments
  - ◆ Extensive experience at senior level within major pharma companies
  - ◆ Strong global recognition and networks within pharma industry
  - ◆ Invaluable advice and guidance in implementing Alizyme's commercial strategy

# Product Portfolio Review

Product	Indication	Phase I	Phase II	Phase III ready	Phase III	Registration & launch	
 <b>Cetilistat</b>	(Takeda, Japan)						
	Obesity						
	Obesity with type 2 diabetes						
 <b>COLAL-PRED®</b>	(Norgine, EU)						
	(Prometheus, US)						
	(TSD, Japan)						
<b>ATL-104</b>	Mucositis						

	Current Stage	Next Stage
Metabolic		
Gastrointestinal		
Cancer supportive care		

## Takeda : Phase III in Japan Phase III ready in ROW



- ◆ Takeda: Successful results of Phase II study in Japan in obese diabetic patients
- ◆ Takeda: Phase III development commenced in Japan
- ◆ ROW: protocols of all three studies in the Phase III obesity programme now agreed with FDA under SPA procedure
- ◆ FDA indicated a potential labelling for type 2 diabetes
- ◆ Improved competitive environment due to withdrawal of CB-1 antagonists in development

**Cetilistat sales potential in excess of US\$1 billion**

**Norgine: EU (Phase III completed)  
Prometheus: Phase II in US    TSD: Phase I in Japan**



- ◆ Norgine license agreement for Europe, South Africa, Australia and New Zealand
  - ◆ Regulatory strategy for submission of EU MAA progressing
- ◆ Prometheus license agreement for North America
  - ◆ Phase II clinical trial in US
- ◆ Co-development agreement with TSD in Japan
  - ◆ Phase I clinical trial in Japan
  
- ◆ Headline results reported for EU Phase III clinical trial

**COLAL-PRED® sales potential in excess of US\$250 million**

## Phase III clinical trial



- ◆ Approximately 800 patients with active moderate to severe ulcerative colitis
- ◆ Demonstrated superior safety
- ◆ Demonstrated superior combined safety and efficacy compared to conventional oral prednisolone
- ◆ Efficacy co-primary endpoint when compared to conventional prednisolone using the Disease Activity Index not met
- ◆ Equivalent efficacy when compared to conventional prednisolone using the Simple Clinical Colitis Activity Index
- ◆ Confirmation for the potential of COLAL-PRED® for long term use in the maintenance of remission of ulcerative colitis
- ◆ Reduction/elimination of systemic side effects
- ◆ Removal of need for weaning (dose tapering)

## Phase II



- ◆ Successful Phase IIa 'proof of concept' clinical trial in patients with lymphoma and myeloma
- ◆ Preparations for Phase II study in patients with head and neck cancer ongoing
- ◆ Manufacturing technology to be transferred to a commercial facility
- ◆ Potential for ATL-104 to be first line treatment for mucositis due to efficacy, safety and ease of administration
- ◆ Further development through partnerships or as internal financial resources permit

**ATL-104 sales potential in excess of US\$500 million**

# Looking Forward

			Income already received	Potential future income	Royalties
Cetilistat	Takeda		\$10.0 million	\$32.0 million	✓
COLAL-PRED®	Prometheus		\$2.5 million	\$15.0 million	✓
COLAL-PRED®	Norgine		€2.0 million	€40.75 million	✓

**Plus additional income from new deals**

- ◆ All Alizyme funded clinical trials completed
  - ◆ Significantly reduced R&D expenditure going forward
  - ◆ Valuable in-house R&D expertise now focussed on supporting our partners
  - ◆ R&D team headcount cut to match reduced clinical activity
  
- ◆ Virtual business model enables overhead costs to match activities
  - ◆ Total staff reduced from 23 to 13 people
  - ◆ Other overhead savings in line with reduced activity
  
- ◆ Annual running costs significantly reduced
  
- ◆ However, investment in Business Development activity maintained

- ◆ Milestone income from existing partnership deals
- ◆ Royalty income from existing partnership deals after products launched
- ◆ Milestone and royalty income from new partnership deals
- ◆ Majority of future R&D expenditure borne by partners
- ◆ Very low operating costs
- ◆ Future profits shielded against taxes by approximately £117 million retained loss

- ◆ Cetilistat
  - ◆ Phase III results in Japan
  
- ◆ COLAL-PRED®
  - ◆ Phase I results in Japan
  - ◆ Phase II results in US
  - ◆ Update on EU regulatory strategy
  
- ◆ ATL-104
  - ◆ Update on development progress
  
- ◆ New licensing deals

- ◆ Significant potential future licensing income
  - ◆ Multiple partnership deals in place
  - ◆ Further partnership deals under negotiation
  
- ◆ Highly experienced team working within low cost out-sourcing business model
  
- ◆ Continued product and commercial news flow
  
- ◆ Strengthened Board
  
- ◆ Alizyme is now well positioned to become a profitable, self-sustaining, biopharmaceutical product development company