



## **AGI Therapeutics**

### **Interim financial results for the six months ended 30 June 2008**

***-- ARDIS-1 now 75% enrolled --***

**Dublin, Ireland, 9 September 2008** - AGI Therapeutics plc ("AGI" or the "Company") (AIM, IEX: AGI), a speciality pharmaceutical development company focused on gastrointestinal drug products, today reports interim financial results for the six months ended 30 June 2008.

The Company also announces that enrolment into ARDIS-1, the first of two pivotal Phase III efficacy studies of Rezular™, AGI's lead programme for the treatment of diarrhoea-predominant irritable bowel syndrome (IBS-D) remains on schedule and has now reached 75% of its target enrolment.

#### **Financial highlights:**

- Cash and short term deposits at 30 June 2008 of \$32.8 million (31 December 2007: \$45.5 million)
- R & D spend of \$8.3 million (2007: \$7.0 million)
- Loss per ordinary share of \$0.13 cent (2007: \$0.12 cent)

#### **Operational highlights:**

- The initiation in February of a Phase II clinical study of AGI-004, a transdermal mecamlamine patch being developed for the treatment of chemotherapy-induced diarrhoea (CID).
- The release on 21 February of the key findings of a study to assess the pharmacokinetic profile of Rezular™ and the subsequent presentation of mechanism-of-action and Phase II clinical data on Rezular™ at the Digestive Disease Week conference in San Diego in May
- The key findings, announced on 2 April, of a clinical study to assess the pharmacokinetic profile of arbaclofen (AGI-006), which is being developed for the treatment of upper gastrointestinal (GI) disease such as gastroparesis, a significant gastric disorder amongst diabetics

#### **Highlights post period-end:**

- In July the Company announced that the US Food and Drug Administration (FDA) agreed the statistical plan to be used to analyse the ARDIS-1 study data, allowing AGI to revise the target enrolment in the study to 680 patients. The FDA also re-affirmed the previously agreed key parameters of the Rezular™ Phase III programme, and in particular the acceptability of the current primary endpoint of patient global relief

Commenting on the interim results, Dr. John Devane, Chief Executive of AGI, said:

*"The first six months of 2008 have been dominated by our efforts to ensure that the Phase III programme for Rezular™ remains on track as we work to achieve our goal of reporting of clinical data for the ARDIS-1 study in the first half of 2009. Finalising the road map with the FDA for the development of the Rezular™ new drug application was a hugely important step for us. We believe that Rezular™ can be the first new widely-used and effective treatment to come to market for IBS-D, a disease that affects over 10 million people in the US alone and for which there are currently few safe and effective treatments. This is a large and as yet untapped market with a potential to generate new product sales in excess of \$2 billion annually in the US and we anticipate that Rezular™ will be well-placed to garner a significant portion of that market."*

## **Outlook**

Commenting further on the outlook for the rest of 2008, Dr. Devane added:

*"During the remainder of this year and into 2009 we will remain focused on completing enrolment into the ARDIS-1 and ARDIS-3 studies with the goal of reporting ARDIS-1 results in H1 2009. In that context we are encouraged that enrolment into ARDIS-1 is now at 75% of the target. We will also seek to progress our discussions with potential partners for Rezular™ in anticipation of ARDIS-1 data next year."*

*In addition to our expected report on Rezular™ in 2009, we also look forward to having data early in 2009 from our Phase II study of AGI-004 in patients with chemotherapy-induced diarrhoea, which will allow us to engage with the FDA to further define the development and regulatory pathway for this product."*

-- Ends --

## **Contact Information:**

**AGI Therapeutics plc.**  
David Kelly, Chief Financial Officer

Tel: +353 1 449 3254

**Financial Dynamics – UK**  
Jonathan Birt/Lara Mott

Tel: +44 (0) 20 7269 7182

**Financial Dynamics - Ireland**  
Aisling Garvey

Tel: +353 1 663 3607

**Piper Jaffray Limited**  
Neil Mackison  
Will Carnwath

Tel: +44 (0) 20 3142 8700

**Davy**  
John Frain

Tel: +353 1 614 8761

For further information please see [www.agitherapeutics.com](http://www.agitherapeutics.com).

## **Notes to Editors:**

### **About Rezular™ (AGI-003)**

Rezular™ (AGI-003) is an orally administered triple-action intestinal regulator, a first-in-class mechanism for the treatment of IBS-D. Rezular™ contains arverapamil, a single enantiomer moiety of the racemic drug verapamil. Unlike the currently available commercial forms of racemic verapamil (a mixture of two enantiomers), Rezular™ shows a dominant activity in treating the symptoms of IBS-D without the traditional cardiovascular actions of the racemic drug. The efficacy and safety of Rezular™ in IBS patients has already been established in a Phase II trial, the preliminary results of which were reported by the Company in 2006.

### **About ARDIS**

ARDIS is the Phase III programme for Rezular™ (AGI-003) in the treatment of IBS-D and consists of three pivotal studies.

ARDIS-1 is a randomised, double-blind, placebo-controlled, parallel group, Phase III study in IBS-D patients (both men and women). There are four treatment arms (placebo and three dose levels of Rezular) and patients will be treated for 12 weeks of double-blind therapy. At the end of double-blind therapy in ARDIS-1, patients will be eligible to continue treatment with Rezular™ through enrolment into ARDIS-3.

ARDIS-2 is a confirmatory Phase III efficacy/safety study to be conducted in IBS-D patients upon completion of ARDIS-1.

ARDIS-3 is an open-label safety study designed to capture 1 year extended safety in approximately 100 patients on continuous Rezular™ therapy.

### **About IBS-D**

Irritable bowel syndrome (IBS) is a functional disorder that comprises a cluster of gastrointestinal symptoms which are likely to be life long and which affect between 10% and 20% of the population in developed markets. IBS remains the most common diagnosis made by gastroenterologists and can lead to a substantial reduction in patients' quality of life, accompanied by considerable socio-economic and psychological consequences. Altered intestinal motility is a major component of IBS and patients are diagnosed and sub-typed according to their predominant symptom of bowel disturbance. Diarrhoea-predominant irritable bowel syndrome (IBS-D) is estimated to occur in one-third of all IBS patients. IBS-D represents a significant unmet medical need as there are currently few safe and effective therapeutic options available to these patients.

### **About AGI Therapeutics plc**

AGI is a speciality pharmaceutical company which is focused on the development and commercialisation of differentiated drug products for gastro-intestinal (GI) diseases and disorders. AGI's common shares are listed on the Alternative Investment Market of the London Stock Exchange (AIM) and on the Irish Enterprise Exchange of the Irish Stock Market (IEX) as AGI.

The Company has a portfolio of product candidates derived from its Known Molecular Entity (KME) approach to drug re-profiling and development. The Company's lead product candidate, Rezular™, is an orally administered triple-action intestinal regulator, a first-in-class mechanism for the treatment of diarrhoea predominant Irritable Bowel Syndrome (IBS-D).

KME is a re-profiling methodology used by the Company to identify existing therapeutic drugs which typically have been marketed for a number of years, have established safety profiles and can be developed for new clinical indications or with improved profiles in their

existing clinical indications. In this way, the Company seeks to reduce the risk, time and cost of new product development as compared to the development of new chemical entities.

AGI is developing a range of product candidates to treat a variety of prevalent GI diseases and disorders, including irritable bowel syndrome (IBS), dyspeptic symptoms, gastroparesis, ulcerative colitis, gastro-esophageal reflux disease (GERD) and diarrhoea-related conditions such as chemotherapy-induced diarrhoea (CID). The Company is targeting areas of the GI therapeutic drug products market for its product candidates where there are currently unmet medical needs or where the effectiveness of existing drug therapies can be further improved.

The Company has five active clinical stage product candidates which are either isomers or new drug delivery formulations of existing approved drugs and which have established safety and tolerability profiles in their currently approved clinical indications.

For further information please see [www.agitherapeutics.com](http://www.agitherapeutics.com).

**Statements contained within this press release may contain forward-looking comments which involve risks and uncertainties that may cause actual results to vary from those contained in the forward-looking statements. In some cases, you can identify such forward-looking statements by terminology such as 'may', 'will', 'could', 'forecasts', 'expects', 'plans', 'anticipates', 'believes', 'estimates', 'predicts', 'potential', or 'continue'. Predictions and forward-looking references in this press release are subject to the satisfactory progress of research which is, by nature, unpredictable. Forward projections reflect management's best estimates based on information available at the time of issue.**

## **Chairman's and Chief Executive's review**

During the first half of 2008 AGI's operational priority was the ongoing execution of ARDIS, our Phase III programme for Rezular™, the Company's lead programme for the treatment of diarrhoea-predominant Irritable Bowel Syndrome, (IBS-D). AGI currently has two Phase III studies ongoing from this programme, ARDIS-1 and ARDIS-3, and it is anticipated that ARDIS-2 study will commence once data from ARDIS-1 is available next year. Both studies are progressing well and we look forward to reporting clinical data from the first Phase III study, ARDIS 1, in the first half of 2009.

In addition to Rezular™ we continue to advance other products in our portfolio. In particular, in February we initiated a Phase IIa clinical study in February of AGI-004, a transdermal mecamlamine patch, in patients suffering from chemotherapy induced diarrhoea (CID). We believe AGI-004 has the potential to address a significant need for a more effective anti-diarrhoeal therapy for patients undergoing chemotherapy.

With financial markets in a state of turmoil in recent months we have been careful to manage our cash resources to ensure that they are concentrated on those programmes with the potential to deliver clinical data in the near to medium term, i.e. Rezular™ and mecamlamine. We believe it is important for the Company to manage its business prudently and set out to maintain a medium-term cash positive outlook until these key development milestones are met and further funding options can be explored if necessary. We have therefore not initiated additional Phase II work on our other programmes in the first half and we expect to move these programmes into the next stage of clinical development when we have greater visibility into our existing studies.

## **Review of key clinical research programmes**

### **Rezular™ (arverapamil, AGI-003) in IBS-D**

Rezular™ is being developed in an oral dosage form for the treatment of IBS-D in both men and women. In late 2007, following the filing and acceptance of an Investigational New Drug (IND) application by the FDA, we commenced our Phase III programme for Rezular™, which we have named ARDIS.

ARDIS-1 is a randomised, double-blind, placebo-controlled, parallel group Phase III study in IBS-D patients (both men and women). There are four treatment arms (placebo and three dose levels of Rezular™) and patients will be treated for 12 weeks of double-blind therapy. At the end of double-blind therapy in ARDIS-1, patients will become eligible to enrol into ARDIS-3. It is planned to randomise 680 patients into ARDIS-1. We currently have over 500 patients enrolled in ARDIS-1 at study sites in the US, Europe and Latin America.

ARDIS-2 is a confirmatory Phase III efficacy/safety study to be conducted in IBS-D patients. This study will commence following the completion of ARDIS 1.

ARDIS-3 is an open-label safety study designed to capture 1 year extended safety in approximately 100 patients on continuous Rezular™ therapy. Currently approximately 80% of patients completing ARDIS-1 are rolling over into ARDIS-3.

Our activities around Rezular™ in the first half of 2008 were focused in four important areas:

1. We have worked closely with our CRO to ensure that the current ARDIS-1 and ARDIS-3 studies are executed as efficiently as possible. This has included preparation of regulatory and investigator documentation, site and investigator

selection, monitoring and replacement of underperforming sites and territories, and ensuring timely availability of clinical supplies to all study sites

2. We met with the FDA's Division of Gastroenterology Products to finalise a number of aspects of the Rezular™ development programme, including the specific statistical approach to the analysis of efficacy data for ARDIS-1, the ongoing Phase III efficacy study which began in late 2007. This has allowed the revision of target enrolment to 680 patients in the ARDIS-1 study. We now expect the last patient to be enrolled in Q4 2008 or Q1 2009, with preliminary data anticipated in H1 2009. The FDA also agreed on the statistical plan to be used to analyse the ARDIS-1 data. Most importantly, the FDA reaffirmed the previously agreed key parameters of all Phase III efficacy studies, and in particular the acceptability of the current primary endpoint of patient global relief
3. Since commencing ARDIS we have initiated discussions with a number of pharmaceutical companies with the sales and marketing capabilities necessary to commercialise a product with the market potential of Rezular™. Our objective is to build commercial partnerships with one or more companies to further develop, register and market Rezular™ in key global markets.
4. During this first half year, we initiated a scientific information campaign to inform the scientific and medical communities of our findings to date with Rezular™ as a potential new treatment for IBS-D. On 21 February, we announced the key findings of a clinical study to assess the pharmacokinetic profile of Rezular™, which study supported the important safety attributes of arverapamil, the R-isomer of verapamil, over racemic verapamil. In May we presented these findings, as well as other data on the mechanism of action of Rezular™ and more detailed data from our previously completed Phase II clinical study, at Digestive Disease Week (DDW) in the US, the leading annual scientific meeting on GI disease

### **Mecamylamine (AGI-004) in chemotherapy-induced diarrhoea (CID)**

AGI believes that this controlled release mecamylamine product has the potential to be an effective agent in diarrhoeal states characterised by a high frequency of watery stools. Given the mechanism of action of mecamylamine on nicotinic acetylcholine receptors (nAChR) and the pathophysiology of certain diarrhoeal states which are not satisfied by current therapy, AGI has identified CID as an area of unmet clinical need where mecamylamine CR may have therapeutic benefit.

The current standard of care for CID patients usually involves multiple oral daily doses of an opioid agent such as loperamide. However, many patients who receive loperamide continue to experience significant and debilitating diarrhoea which may require reduction, delay or even withdrawal of chemotherapy. AGI-004 is a controlled release transdermal patch containing the nicotinic antagonist mecamylamine. The patch involves a new anti-diarrhoeal mechanism via selective blockade of enteric nicotinic acetylcholine receptors (nAChR) and offers a significant advantage to current CID therapy via its convenient, once-daily transdermal form.

AGI previously reported data demonstrating a statistically significant improvement in stool consistency in patients with functional diarrhoea. The new Phase II study initiated in February is a randomised, double-blind, placebo-controlled evaluation of AGI-004 in cancer patients experiencing National Cancer Institute (NCI) grade 1 or 2 CID. We expect to complete this study by the end of the year and report preliminary data in Q1 2009.

### **CHRONAB-omeprazole (AGI-010) for nocturnal acid breakthrough (NAB) in GERD**

We are developing a modified release formulation of the proton pump inhibitor drug (PPI), omeprazole, based on our CHRONAB technology which we believe will be effective in treating NAB, a prevalent aspect of current PPI therapy of GERD. GERD is the most prevalent of the major gastrointestinal disorders and is most commonly treated with PPI drugs which achieve global annual sales in excess of €15 billion. NAB is estimated to occur in at least 50 per cent of GERD patients on PPI therapy.

AGI entered into a co-development and license agreement for North American markets with Axcan Pharma Inc. ("Axcan") in September 2006 to jointly develop a modified release omeprazole product based on AGI's CHRONAB formulation approach. We announced on 17 March 2008 the completion of the optimisation phase of development. As part of the optimization phase of development, AGI completed a number of studies in healthy human volunteers. These studies characterized the drug release profile, the pharmacokinetics of omeprazole and the intra-gastric pH following administration of a number of prototype formulations of AGI-010. Based on the outcome of these studies, a formulation has been identified which could have the potential to control intra-gastric pH during the night.

We are currently in discussions with our partner, Axcan, to determine how best to progress this programme to the next stage of development.

#### **Arbaclofen (AGI-006)**

The results of a 64 patient exploratory Phase II trial of arbaclofen in functional dyspepsia reported in early 2007 demonstrated statistically significant improvements across a range of endpoints, including patient global severity, bloating, nausea, condition specific Quality-of-Life (QOL) and use of rescue antacids. AGI determined that the profile of activity of arbaclofen matches well with the desired profile of a therapy for a range of upper GI symptoms. This opens up the potential for arbaclofen to be used in a variety of GI conditions including the dyspeptic symptoms of gastroparesis. Diabetic gastroparesis is the most common manifestation of these symptoms, however effective and well-tolerated therapy options are extremely limited for these patients.

On 2 April 2008 we reported the results of work we carried out on the pharmacokinetic exposure profile of arbaclofen in healthy human subjects, under both fasted and fed conditions. In addition, this study compared the fasted exposure of AGI-006 in terms of both R- and S-isomers of baclofen with the fasted exposure following a single 10mg dose of Lioresal® (a marketed form of racemic baclofen). The results of this work support the Company's belief that the development of AGI-006 can follow a similar clinical/regulatory pathway to Rezular™.

We have recently undertaken market research on the potential use of arbaclofen in a number of upper GI conditions. This research will allow us to identify the product's market potential and the appropriate clinical/regulatory development strategy for this product.

#### **4-ASA (AGI-022) in ulcerative colitis**

AGI is developing a modified release oral formulation of 4-aminosalicylate sodium (4-ASA) for the induction and maintenance of remission of mild to moderate ulcerative colitis (UC). UC is a chronic, recurrent, relapsing and remitting inflammatory disease of the colon and/or rectum. AGI believes that its 4-ASA product may offer certain advantages compared with current 5-ASA based therapies which are commonly used to treat UC, including a superior tolerability profile, and a more reliable delivery to the target sites of action in UC leading to a higher efficiency of therapy with potential dosing advantages.

In March 2006, AGI reported on the outcome of a human pharmacokinetics trial in 16 human subjects designed to characterise the *in vivo* drug release profile and pharmacokinetics of three delayed release/controlled release formulations compared with a reference solution of 4-ASA. The study demonstrated delayed and controlled *in vivo* release profiles consistent with targeted colonic delivery.

During 2007, having selected a lead formulation, AGI developed a high unit-dose, once-daily, modified release tablet of this product and has designed a Phase II clinical study to further investigate the efficacy of this product in UC patients. AGI hopes to initiate this study in late 2008 or early in 2009, depending on the progress of other projects, particularly Rezular™.

Dr. Ronan Lambe  
Chairman  
Dublin, 8 September 2008

Dr. John Devane  
Chief Executive Officer

## **Financial review**

### ***Basis of preparation and International Financial Reporting Standards (IFRS)***

The financial information for the six months ended 30 June 2008 has been prepared in accordance with IFRS as adopted by the European Union.

### ***Functional Currency***

Commencing on January 1st 2008, AGI has adopted the US Dollar as the functional currency for the Group. This decision is based on the fact that the Company's primary market for its products under development are in the US, the majority of the Company's costs are denominated in US dollars, and it is likely that most future revenues, whether in the form of license fees, development fees, royalties or product sales, are likely to be earned in dollars. Previously the Company's functional currency was the Euro as most of its costs were Euro-denominated and its funding was raised in Euro.

In the attached financial statements, comparable results and balance sheet have been translated into dollars at a rate of 1 euro to 1.47 dollars, the rate in effect at 1 January 2008.

## ***Operating performance***

### **Revenue**

AGI received an initial milestone payment of \$1.5 million from Axcan Pharma Inc. in 2006 related to a co-development agreement for Chronab omeprazole. This upfront fee is being recognised on a straight line basis over three years, an estimate of the likely term of the underlying development programme. For the six months to June 30 2008 a total of \$0.3 million was recognised as revenue (2007: \$0.3 million).

### **Research and Development expenses**

Total Research and Development expenses for the six months to June 30 2008 were \$8.3 million (2007: \$7.0 million). The significant increase in R&D costs reflects the increased number of clinical programmes associated with the Company's products in development, particularly the ongoing ARDIS Phase III programme for Rezular™.

### **General and Administrative expenses**

General and Administrative expenses in the first six months of 2008 were \$2.0 million (2007: \$1.8 million). This increase is attributable to the general increase in the operational activities of the Company.

### **Interest Income and other**

The Company earned interest on its cash balances, primarily the proceeds of the IPO during 2006. This amounted to \$0.7 million in the first six months of 2008 (2007: \$1.1 million). Interest income has fallen as cash balances have reduced and interest rates for dollars deposits, now the predominant currency held by AGI, are lower than those available on Euro deposits, which were held in the prior period. This category also includes unrealised gains arising from the conversion, for reporting purposes, of those cash balances we still hold in euro into dollars at the period end..

### **Taxation**

While the Company has had a loss to date, not all of this is available for offset against the interest income referred to above. Therefore AGI incurred a tax charge of \$0.1 million for the year (2007: \$0.2 million).

### **Share based compensation expense**

The Company issues share options to certain employees on an annual basis. While the options were issued at a strike price equal to the market price of the Company's shares on the date of grant, a calculation is required of the potential expense to the company of issuing those options which is determined using the Black-Scholes option-pricing formula. A total amount of \$0.8 million was expensed during the first half of 2008 (2007: \$0.7 million) for these share based compensation charges, divided between Research and Development and General and Administration expenses.

### **Operating cash flow**

Net cash outflow from operating activities in the period was \$12.5 million (2007: \$3.8 million), which consisted principally of the loss from operations and changes in working capital balances. At June 30, 2008, AGI had cash and short-term deposits of \$32.8 million, (2007 \$55.0 million). The Directors have considered the Company's cash position and are satisfied that they are sufficient to meet the company's financial obligations for at least the coming twelve months.

## UNAUDITED CONDENSED CONSOLIDATED INTERIM INCOME STATEMENTS

For the six months ended 30 June

Notes	Period ended 30 June 2008 \$'000	Period ended 30 June 2007 \$'000
Revenue	288	288
Research and development expenses (share based payment charge of \$439 (2007: \$307))	8,340	7,056
General and administrative expenses (share based payment charge of \$400 (2007: \$392))	2,016	1,769
Total operating expenses	10,356	8,825
Operating loss	(10,068)	(8,537)
Interest income and other	1,121	1,071
Loss before tax	(8,947)	(7,466)
Income tax	(59)	(161)
Loss for the period	(9,006)	(7,627)
<b>Basic loss per ordinary share:</b>		
Basic loss per share (\$ cents)	3	(11.8)

**UNAUDITED CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS**

	<b>30 June 2008 \$'000</b>	<b>31 December 2007 \$'000</b>
<b>Non-Current Assets</b>		
Property, plant and equipment	53	71
Intangible assets	1,865	1,715
<b>Total Non-Current Assets</b>	<b>1,918</b>	<b>1,786</b>
<b>Current Assets</b>		
Other current assets	538	628
Cash and cash equivalents	32,783	45,504
<b>Total Current Assets</b>	<b>33,321</b>	<b>46,132</b>
<b>Total Assets</b>	<b>35,239</b>	<b>47,918</b>
<b>Current Liabilities</b>		
Trade and other payables	3,869	8,381
<b>Total Current Liabilities</b>	<b>3,869</b>	<b>8,381</b>
<b>Total Liabilities</b>	<b>3,869</b>	<b>8,381</b>
<b>Shareholders' Equity</b>		
Share capital	992	992
Share premium	75,194	75,194
Foreign currency translation reserve	87	87
Other reserves	3,488	2,649
Retained loss	(48,391)	(39,385)
<b>Total Shareholders' Equity</b>	<b>31,370</b>	<b>39,537</b>
<b>Total Shareholders' Equity and Liabilities</b>	<b>35,239</b>	<b>47,918</b>

## UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

	<b>30 June 2008 \$'000</b>	<b>30 June 2007 \$'000</b>
Loss for the period	(9,006)	(7,627)
<b>Adjustments to reconcile loss to net cash used in operating activities:</b>		
Depreciation of property, plant and equipment	18	12
Amortisation of intangibles	70	45
Interest income	(652)	(1,071)
Income tax	59	161
Share-based compensation	839	699
Operating cash outflow before changes in working capital	(8,672)	(7,781)
Increase in other current assets	(84)	(237)
(Decrease)/increase in accounts payable	(2,528)	72
(Decrease)/increase in accrued and other liabilities	(2,016)	3,073
Cash used by operations	(13,300)	(4,873)
Interest received	826	1,026
Tax (paid)/refunded	(25)	-
Net cash outflow from operating activities	(12,499)	(3,847)
<b>Investing activities</b>		
Acquisition of intellectual property and other investments	(221)	-
Acquisition of property, plant and equipment	-	(6)
Net cash used by investing activities	(221)	(6)
Net (decrease)/increase in cash and cash equivalents	(12,720)	(3,853)
Cash and cash equivalents at the beginning of period	45,503	58,895
Cash and cash equivalents at the end of the period	32,783	55,042

**UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN  
SHAREHOLDERS' EQUITY**

	Number of Shares	Ordinary share Capital \$'000	Share Premium \$'000	Other Reserves \$'000	Foreign currency translation reserve \$'000	Retained Loss \$'000	Total Amount \$'000
Balance at 31 December 2006	67,412,783	992	75,194	1,171	-	(18,614)	58,743
Loss for the period	-	-	-	-	-	(7,627)	(7,627)
Share-based compensation	-	-	-	699	-	-	699
Balance at 30 June 2007	67,412,783	992	75,194	1,870	-	(26,241)	51,815
Loss for the period	-	-	-	-	-	(13,144)	(13,144)
Share-based compensation	-	-	-	779	-	-	779
Foreign currency reserve arising on change in functional currency	-	-	-	-	87	-	87
Balance at 31 December 2007	67,412,783	992	75,194	2,649	87	(39,385)	39,537
Loss for the period	-	-	-	-	-	(9,006)	(9,006)
Share-based compensation	-	-	-	839	-	-	839
Balance at 30 June 2008	67,412,783	992	75,194	3,488	87	(48,391)	31,370

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

### 1 BASIS OF PREPARATION

These unaudited condensed consolidated interim financial statements (the interim financial statements) have been prepared in accordance with IFRS that are adopted by the European Union (EU) and effective at 30 June 2008. The interim financial statements do not include all of the information required for full annual financial statements.

These interim financial statements are presented in US Dollar rounded to the nearest thousand, being the functional currency of the parent company and the group companies. They are prepared on the historical cost basis, except for financial instruments and share based payments, which are stated at fair value.

The accounting policies applied by AGI in these interim financial statements are the same as those applied by AGI in its consolidated financial statements as at and for the year ended 31 December 2007.

The preparation of interim financial statements requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses. Actual results could differ materially from these estimates. In preparing these interim financial statements, the significant judgements made by management in applying our accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements as at and for the year ended 31 December 2007.

These interim financial statements do not constitute Statutory Financial Statements of the Group within the meaning of Regulation 40 of the European Communities (Companies: Group Accounts) Regulations, 1992. Statutory Financial Statements for the year ended 31 December 2007 have been filed with the Companies Office. The auditor's report on those financial statements was unqualified.

### 2 FUNCTIONAL CURRENCY

On 1 January 2008, the functional currency of the Group changed from Euro to US Dollars as the Group's cost structure became primarily US Dollar based. The Group's principal clinical trials are carried out in the United States and billed in dollars. In addition the Group earns only US Dollar revenue. The US Dollar is the currency of the primary economic environment in which the Group operates. At 1 January 2008 the Group translated its financial statements at 31 December 2007 to US Dollars at the exchange rate prevailing at that date.

Transactions in currencies other than the functional currency of the entities are recorded at the rate of exchange prevailing on the date of the transactions. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated into the respective functional currencies of Group entities at the rate of exchange prevailing at the balance sheet date.

### 3 LOSS PER SHARE

Basic loss per share is computed by dividing the loss for the period available to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted loss per share is computed by dividing the loss for the period, by the weighted average number of ordinary shares outstanding and, when dilutive, adjusted for the effect of all potentially dilutive shares, including stock options, warrants, and convertible debt securities on an as-if-converted basis.

The following table sets forth the computation for basic and diluted loss per share for the six months ended 30 June 2008 and 2007:

	30 June 2008	30 June 2007
	\$000	\$000
<b>Numerator:</b>		
Loss attributable to ordinary shareholders	(9,006)	(7,627)

**Denominator:**

Denominator for basic—weighted average number of shares	67,412,783	67,412,783
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**Basic loss per share:**

Basic loss per share (US\$ cents)	(13.3)	(11.8)
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Potentially dilutive instruments, such as share options have not been treated as dilutive as the Group made a loss in both periods.

**4 RELATED PARTY TRANSACTIONS****(a) Transactions with founding members and shareholders**

In January 2008 the Group acquired intellectual property from J. Dev, a company owned and controlled by John Devane, a director of the Group, for consideration of \$0.2 million.

Frank Kenny, John O'Sullivan and Peter Sandys are Directors of the Company and are board nominees of Delta Partners, ACT Venture Capital and Seroba Bioventures respectively. Fees of \$25,000 annually are paid by the company to each of Delta, ACT and Seroba in respect of their nominees' appointment.

**5 APPROVAL**

The unaudited condensed consolidated interim financial statements were approved by the directors on September 8<sup>th</sup>, 2008