AGI Therapeutics, plc

Financial results for the 12 months ended 31 December 2008

Dublin, Ireland, 1st April 2009 - AGI Therapeutics plc ("AGI" or the "Company"), a speciality pharmaceutical company focused on gastrointestinal drug products, today reports audited financial results for the 12 months ended 31 December 2008.

Financial highlights

- Revenue of $577,000 (2007: $577,000)
- Cash and short-term deposits at 31 December 2008 of $23.6 million, (2007: $45.5 million)
- R&D spend of $15.9 million (2007:$19.4 million)
- Net loss of $18.2 million (2007: $20.7 million)
- Loss per ordinary share of 27.0 cents (2007: 30.7 cents)

Operational highlights

Rezular™ - AGI's lead product for the treatment of diarrhoea-predominant irritable bowel syndrome (IBS-D), a chronic, relapsing condition that affects millions of people.

- Primary focus on ARDIS, our Phase III programme, comprising of ARDIS-1(efficacy) and ARDIS-3 (safety), both studies to be included in future New Drug Application to US FDA
- Key findings of study to assess pharmacokinetic profile announced in February; possible MoA and further analysis of Phase II data presented at DDW in May
- FDA agreed on the statistical approach for analysis of ARDIS-1 in June and reaffirmed the key parameters of Phase III programme, including current primary endpoint.
- FDA confirmed Rezular™'s eligibility and associated requirements to qualify for 5 year market exclusivity in US
- Completion of patient enrolment for ARDIS-1 announced January 2009; 711 patients randomised in 123 clinical centres in U.S., Europe, South America; top-line data from ARDIS-1 anticipated by end Q2, making Rezular™ the most advanced product in development for IBS-D
- Today, we are pleased to announce that enrolment into ARDIS-3 is now closed and AGI expects that the exposure target of 100 patients for 1 year will be achieved in Q3 2009 and data will be reported in Q1 2010

AGI-004 - A once-daily controlled release transdermal mecamylamine patch being developed for the treatment of chemotherapy-induced diarrhoea (CID) in cancer patients:

- Commencement of patient enrolment in a proof-of-concept Phase II clinical study announced February 2008.
- Preliminary results demonstrating AGI-004 is a promising new therapy for this potentially debilitating side-effect of cancer chemotherapy announced March 2009.

AGI-010 - AGI's modified release formulation of the proton pump inhibitor drug ("PPI") omeprazole which utilizes AGI's CHRONAB technology**:**

- Completion of optimisation phase of development of AGI-010, co-developed with Axcan Pharma Inc., ("Axcan") for treatment of night-time acid breakthrough (NAB) in gastro-esophageal reflux disease (GERD) patients announced March 2008.

Other Projects:

- Continued work on AGI-022 for the treatment of ulcerative colitis and investigated potential to further develop AGI-006 as a novel treatment in a number of clinical indications including gastroparesis, GERD refactory to PPI therapy and chemotherapy-induced nausea and vomiting (CINV). In keeping with our policy of carefully managing financial resources and prioritizing

investment in our most advanced programme, Rezular, we have not committed further expenditure to these projects at this time.

Commenting on the results, Dr. John Devane, CEO of AGI, said:

"In 2008 Rezular dominated our activities. We are very pleased that in the initial weeks of 2009 we completed patient enrollment into ARDIS-1 and we now look forward to reporting top-line data later this year. Through our interaction with the FDA and contact with potential partners, we believe we have the ability to introduce the first new therapy for the treatment of IBS-D in the US in almost 10 years. This is a disease which seriously affects the quality of life of millions of patients and for which there are few effective therapeutic options available."

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Notes to Editors:

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 multiple mechanism 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, 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 novel 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.

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:

Overview

2008 was a year of contrasts for AGI. From an operational standpoint it was a busy and successful year, dominated by our achievements in progressing the Phase III clinical development of our lead product candidate, Rezular™. In addition to managing the ARDIS clinical programme for Rezular, we focused considerable time and effort on our regulatory and intellectual property strategy for this product. We also engaged in preliminary discussions with potential partners for this product, having identified a number of companies who will have sufficient scale and resources to help us complete the development of Rezular and manage its launch into the US market.

From a corporate perspective, 2008 was certainly a challenging year. Our share price, in common with many in our sector, experienced a precipitous decline in the face of tumultuous events in the global financial markets. We nonetheless feel we have made significant progress during 2008 in building the fundamental value of your company by investing in those later-stage assets which can potentially yield the greatest returns if successful in the clinic. We actively communicated on a regular basis throughout the year with our shareholders to inform you of progress in the business and we are confident that your patience and support of the AGI team and business plan will ultimately be rewarded.

Given the uncertainties in the public markets, which restrict the ability of development-stage companies such as ours to access further funds at a price acceptable to existing shareholders, we moved swiftly in 2008 to concentrate our cash resources on our most advanced programmes. The considerable progress of Rezular™ is discussed more fully below, but, where resources allowed, we continued to add value to certain other products in our pipeline, completing a successful proof of concept Phase II study for AGI-004 in the treatment of chemotherapy-induced diarrhoea in cancer patients, while further optimising our formulation of AGI-010 in collaboration with our partner, Axcan. While we have not been able to undertake further clinical trials across the remainder of the earlier-stage pipeline during 2008, we nonetheless have continued to invest intellectually in these projects, identifying new and attractive clinical opportunities to be pursued as and when additional financial resources become available.

Now, in early 2009, we stand on the verge of the most significant milestone in our company's short history, namely the results from the ARDIS-1 Phase III efficacy study of Rezular, which we expect about mid-year. The outcome of this study will define the efficacy of this product and will be anxiously awaited by the AGI team, potential commercial partners, our shareholders and indeed, patients with this limiting and underserved disease. Developing a new pharmaceutical product with blockbuster market potential such as Rezular is a major challenge for any company, large or small, in any environment. However, we believe that the skill, experience, dedication and enthusiasm of the AGI team, in combination with the continued support of our Board and shareholders, will enable us to meet this challenge. Looking beyond Rezular, we believe we have amassed a clinical-stage pipeline of significant potential, which we look forward to being able to further develop and realise in 2009 and thereafter.

Strategy

Our achievements in 2008 were very much in keeping with our strategy to progress a broad pipeline of compounds through development for a range of GI diseases. We remain focused on developing known molecular entities (KME's) that can be significantly differentiated from current therapies, and which will allow us to provide new and innovative products to serve unmet medical needs in the gastroenterology market. We maintain our aspiration to develop in the longer term into a fully integrated specialty pharmaceutical business with the ability to oversee the sales, marketing and distribution of our own products in the market by targeting medical specialists within our therapeutic areas of expertise. We expect to out-license or partner those products that would benefit from being marketed or co-promoted by larger companies, whilst retaining co-ownership rights to AGI's products where possible.

Operations:

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

Irritable bowel syndrome 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 one of the most common diagnoses 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. IBS-D is estimated to occur in one-third of all IBS patients, and represents a significant unmet medical need, as there are currently few safe and effective therapeutic options available to these patients.

Rezular is an orally administered multiple mechanism 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.

Rezular is the most advanced product in development for the treatment of IBS-D in the US, where there is currently only one available product, Lotronex® (Prometheus/GSK), which is approved as a limited-access treatment for women only with severe IBS-D. Hence there is a significant unmet medical need for new, safe and effective IBS-D treatments and we estimate the market opportunity for new IBS-D therapies to be greater than $2.5 Billion in the US alone.

The Phase III development of Rezular was our primary focus in 2008.

1. We have named the Phase III clinical programme for Rezular "ARDIS". In late 2007, we commenced screening and enrolment of patients into ARDIS-1, a randomised, double-

blind, placebo-controlled, parallel group efficacy /safety study in IBS-D patients (both men and women). There are four treatment arms (placebo and three dose levels of Rezular) and patients are treated for 12 weeks of double-blind therapy. The primary endpoint is patient global relief of IBS symptoms, as agreed with the US Food and Drug Administration (FDA). At the end of double-blind therapy in ARDIS-1, patients become eligible to enrol into ARDIS-3, a Phase III safety study, which is designed to capture safety data in a target of 100 patients treated with Rezular for 1 year of continuous therapy at the highest dose. By the end of 2008, 123 clinical centres were enrolling patients in the United States, Europe and South America for ARDIS-1 and ARDIS-3. ARDIS-1 is the first of two ongoing Phase III studies which will be included in a future New Drug Application (NDA) submission to the FDA for approval of Rezular in the U.S. In January 2009, we announced that we had completed enrolment of a total of 711 patients into ARDIS-1, with 63% of patients being in the United States. The gender breakdown of enrolled patients is 69% female and 31% male, which closely reflects the gender ratio in the general IBS patient population. Top-line results of ARDIS-1 are on track to be reported by the end of the second quarter of 2009. For ARDIS-3 we expect that the exposure target of 100 patients for one year will be achieved in the third quarter of 2009 and that data will be reported in Q1, 2010.

2. During 2008, we met 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 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. During 2008 we had, and continue to have, discussions with a number of pharmaceutical companies with the sales and marketing capabilities necessary to commercialise a product with the market potential of Rezular. Following the reporting of ARDIS-1 data in 2009, we will seek to enter into commercial partnerships with one or more companies to further develop, register and market Rezular in key global markets.

4. In line with the above activities, 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. In February 2008, we announced the key findings of a clinical study to assess the pharmacokinetic profile of Rezular, and which supported the important safety attributes of arverapamil, the R-isomer of verapamil, over racemic verapamil. In May 2008, 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.

5. Rezular is protected by a granted US method-of-use patent that expires in 2022. Further patents are pending in Europe and Japan. In addition, during 2008 AGI reviewed the protection available to Rezular™ under the market exclusivity provisions of the FDA rules. We established in our discussions with FDA that Rezular, as a first use of a single isomer in a new therapeutic indication, could qualify under the FDA Amendment Act (FDAAA) of 2007 for the same 5 year period of market exclusivity normally granted to new chemical entities, (subject to certain data requirements). We also believe that Rezular will qualify for market exclusivity of up to 10 years in Europe and Japan when approved in those territories.

AGI-004 in chemotherapy induced diarrhoea (CID)

AGI-004, a controlled release form of mecamylamine, is a potent, non-competitive specific antagonist at nicotinic acetylcholine receptors (nAChR). More specifically, AGI-004 has been shown to be selectively active on certain nAChR sub-types which are the predominant form found

on enteric neurons, where nAChR is known to regulate a range of gut functions, including modulation of secretory and motility effects. AGI-004 is formulated in a proprietary controlled release transdermal patch which is applied once-daily.

CID is a prevalent and severe side-effect associated with cancer chemotherapy treatment and occurs in up to 50% of patients receiving chemotherapy and can affect up to 80% of patients receiving certain chemotherapy regimens. CID, using measures set by the National Cancer Institute (NCI), may range from troublesome (NCI grade 1) to life-threatening (NCI grade 4). CID can negatively impact a patient's health to the point that they are unable to tolerate their prescribed chemotherapy, commonly leading to delay or reduction in treatment which may diminish the effect of treatment. Loperamide is the current drug of choice for the management of mild to moderate CID, but is limited in terms of its effectiveness and dosing flexibility, and there are currently few effective alternative therapies available.

AGI previously reported data in 2006 demonstrating a statistically significant improvement in stool consistency in patients with functional diarrhoea, which suggested AGI-004 to be a novel anti-diarrhoeal agent. A new proof of concept Phase II study, initiated in February 2008, evaluated AGI-004 in cancer patients experiencing NCI grade 1 or 2 CID as a side-effect of their chemotherapy. We reported the study findings in March 2009.

The Phase II study was a randomised, double-blind, placebo-controlled, balanced, parallel-group trial in 64 cancer patients across 7 sites in Europe. The study evaluated the efficacy of two doses of AGI-004 in controlling diarrhoea resulting from the administration of 5-Fluourouracil, including capecitabine and/or irinotecan or cisplatin, compared with placebo, in patients with NCI grade 1 or 2 CID. Patients were randomly allocated to active treatment or placebo. Treatment was initiated 24 hours prior to chemotherapy and patients continued to self-administer AGI-004 or placebo patches once daily during and after chemotherapy for the duration of the cycle of chemotherapy. Patients were allowed free access to loperamide or other appropriate medications on a rescue basis to treat any active episodes of diarrhoea. Treatment with AGI-004 or placebo was for two consecutive cycles of chemotherapy. The dose of mecamylamine was escalated over the two cycles from the lower dose in the first cycle to the higher dose in the second cycle.

The results showed a statistically significant difference in the primary endpoint of reducing the incidence of patient-recorded diarrhoea (response defined as $\leq$ 4 bowel movements per day). This was observed at the higher of two doses of AGI-004 when compared with placebo. The robust response for the higher dose of AGI-004 was further supported by a statistically significant difference in the secondary endpoint of patient recorded severity of diarrhoea, while positive trends were observed in the other secondary measurement of reduction in the use of rescue anti-diarrhoeal medications. Non-significant benefit in the primary endpoint was also observed with the lower dose and, when diarrhoea was rated by the physician using the National Cancer Institute (NCI) grading system, both doses demonstrated positive improvements. Similarly, positive trends were also observed for the higher dose in the co-primary endpoint of reducing the number of bowel movements per day.

While some benefit was seen with the lower dose in treating individual symptoms, the overall results are consistent with a dose response effect. In addition to the full cycle results described above, an analysis of acute (first day of chemotherapy) data, confirmed the robust control of diarrhoea at the higher dose. AGI-004 treatment was well tolerated across both doses and there were no drug-related serious adverse events.

We are pleased with the outcome of this study which we believe supports the continued development of AGI-004. Although designed as a pilot study, we observed a strong pattern of response across multiple measurements of diarrhoea. The development of a novel antidiarrhoeal agent in a convenient transdermal patch which can reduce the occurrence of diarrhoea in patients undergoing chemotherapy offers a significant advance over current standard of care.

AGI-010 in Gastroesophageal Reflux Disease (GERD)

As previously reported, AGI is developing a modified release formulation of the proton pump inhibitor drug (PPI) omeprazole based on its CHRONAB technology which the Company believes 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 US$20 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 with Axcan in September 2006 to jointly develop for North American markets a modified release omeprazole product based on AGI's CHRONAB formulation approach. AGI worked closely with Axcan throughout 2007 to progress omeprazole through Phase II product optimisation.

Following extensive work during 2007 to optimise its earlier prototype formulations, AGI announced in March 2008 that it has identified a formulation of omeprazole for once daily administration which, the Company believes, could specifically address nocturnal acid breakthrough (NAB), a real unmet medical need for GERD patients. With its partner Axcan, AGI will now focus on defining the appropriate development approach for the remainder of the AGI-010 program.

AGI-022 in ulcerative colitis

AGI is developing AGI-022 a once-daily oral formulation of a novel form of aminosalicylate acid (ASA), the primary anti-inflammatory drug class used as first-line therapy for the treatment of ulcerative colitis (UC).

UC is a chronic, recurrent, relapsing and remitting inflammatory disease of the colon and/or rectum and is estimated to affect more than two million people worldwide. A variety of oral forms and formulations of the drug 5-aminosalicylic acid (5-ASA) represent the most widely used first-line therapy to treat UC. ASA therapy is required to be delivered to the colon to achieve a localized therapeutic effect, and systemic uptake of drug is undesirable and is associated with increased side effects.

Our product is a new and improved once-daily formulation of a novel ASA presented in a colon-targeted delayed release/controlled release delivery system. An initial clinical proof-of-concept study of AGI-022 demonstrated optimal delivery and availability of therapeutic amounts of active drug in the colon. AGI believes that AGI-022 may offer certain significant advantages in treating UC compared with current 5-ASA based therapies, such as faster onset of, and enhanced rates of, remission, a reduction in relapse rates, lower variability in response, superior tolerability and reduced dosage and dosing frequency.

AGI-006

The results of a 64 patient exploratory Phase II trial of AGI-006 in functional dyspepsia in early 2007 demonstrated statistically significant improvements across a range of dyspepsia-related endpoints, including patient global severity, bloating, nausea, condition specific Quality-of-Life (QOL) and rescue antacids. AGI determined that the profile of activity of AGI-006 matches well with the desired profile of a therapy for the dyspeptic symptoms associated with a number of gastro-intestinal and related conditions. AGI-006 contains the pure r-isomer of the racemic drug, baclofen, which is currently marketed to treat CNS disorders. We have identified that the r-isomer is the primary active form of baclofen, a GABA-B agonist, and has the potential to have improved tolerability and efficacy characteristics compared to the current racemic form.

Following the proof-of-concept study, we believe that the profile of activity established to date supports the further development of AGI-006 in a number of clinical indications of unmet medical

need, such as gastroparesis, GERD refractory to PPI therapy, and chemotherapy-induced nausea and vomiting (CINV).

Outlook

2009 has started well for AGI. We announced completion of enrolment of ARDIS-1 for Rezular in IBS-D, which is the first Phase III study to be undertaken by our company and represents a major achievement on the part of our management and employees. We also released the preliminary results of our proof-of-concept study of AGI-004 in CID in the first quarter which suggests that we have another promising drug in our portfolio targeted, like Rezular, at an area of high unmet medical need. We are now only months away from receiving the initial results from ARDIS-1, which will be the most significant milestone to date for our company. These results will drive much of our activity in the latter half of 2009, including identifying suitable marketing partners, as we look forward to progressing to our ultimate goal of introducing a much needed new therapy for IBS-D patients.

Dr Ronan Lambe
Chairman
Dublin, 1 April, 2009

Dr John Devane
Chief Executive Officer

Financial review

The financial information for the year ended 31 December 2008 presented below has been prepared according to IFRS, as adopted by the European Union.

Operating performance

Revenue

AGI recorded its first revenues as a result of a License Agreement signed in September 2006 with Axcan Pharma Inc, a Canadian headquartered specialty pharmaceutical company with a focus on GI diseases. An initial milestone payment of $1.5 million is being recognised on a straight line basis over approximately three years, an estimate of the likely term of the underlying development programme. For the year to 31 December 2008 a total of $577,000 was recognised as revenue in respect of this licence agreement (2007: $577,000).

Functional currency

Commencing on January 1st 2008, AGI has adopted the US Dollar as its functional and presentational currency. This decision is based on the fact that the majority of the Company and its subsidiaries costs are denominated in US dollars and its revenues are earned in US 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 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.

Research and development expenses

Total research and development expenses for the year to 31 December 2008 were $15.9 million (2007: $19.4 million). During 2007 and 2008 the company has been running the Phase III pivotal clinical programme of Rezular™ our lead programme for the treatment of diarrhoea-predominant Irritable Bowel Syndrome (IBS-D). This is a significant study with first patients enrolled in late 2007, but with considerable cost being incurred in the set-up of the study sites before enrolment commenced. ARDIS costs will continue into 2009. In addition the company progressed other development programmes in 2008. In 2007 we wrote down the value of intangibles, amounting to

$1,084,000 associated with a discontinued product, which accounts for a significant percentage of the decline in R&D costs overall between 2008 and 2007.

General and administrative expenses

General and administrative expenses in 2008 were $3.5 million (2007: $3.7 million).

Interest income and expense

The company earned interest on its cash balances, primarily the proceeds of the IPO during 2006. This amounted to $1.0 million (2007: $2.2 million). The decline in interest income reflects both the declining interest rates available for deposits as well as the declining cash balances available for deposit.

Interest expense and other costs comprise foreign exchange losses on the translation of Euro transactions to US Dollars and amounted to $362,000 (2007: €155,000).

Taxation

The company has incurred losses to date, and no tax charge arises for 2008. In 2007 not all of that year's losses were available for offset against the tax arising on interest income earned by the group. The tax charge for 2008 amounted to nil (2007: $0.2 million).

Share based compensation expense

During 2008 the Company issued share options to certain employees. While the options were issued at a strike price equal to the market price of our shares on the date of grant, under IFRS 2, 'Share Based Payments', the company is required to account for the fair value of these options as a charge in the income statement. The company has calculated the charge using the Black-Scholes option-pricing model. A charge of $1.5 million (2007: $1.5 million) was recognised in 2008 in respect of this share based compensation expense, disclosed within research and development and general and administration expenses.

Consolidated Income Statement

for the year ended 31 December 2008

	2008 **$'000**	2007 $'000
Revenue	577	577
Operating expenses		
Research and development expenses (share based payment charge of $853,000 (2007: $719,000))	(15,937)	(19,371)
General and administrative expenses (share based payment charge of $685,000 (2007: $759,000))	(3,473)	(3,731)
Operating loss	(18,833)	(22,525)

Interest income	992	2,234
Interest expense and other costs	(362)	(155)
Net finance income	630	2,079
Loss before income tax	(18,203)	(20,446)
Income tax expense	-	(263)
Loss for the year	(18,203)	(20,709)
Attributable to equity holders	(18,203)	(20,709)
Loss per ordinary share		
Basic and diluted loss per share	(27.0)	(30.7)

On behalf of the board

Dr. John Devane
Director

David Kelly
Director

AGI Therapeutics, plc

Consolidated Balance Sheet

at 31 December 2008

	2008	2007
	$'000	$'000
Non-current assets		
Property, plant and equipment	34	71
Intangible assets	1,793	1,715
Total non-current assets	1,827	1,786
Current assets		
Other current assets	163	628
Cash and cash equivalents	23,577	45,504
Total current assets	23,740	46,132
Total assets	25,567	47,918
Shareholder equity		
Share capital	992	992
Share premium	75,194	75,194
Other reserve	4,187	2,649

Retained deficit	(57,428)	(39,225)
Total shareholders' equity	22,945	39,610
Current liabilities		
Trade and other payables	2,622	8,106
Current tax	-	202
Total current liabilities	2,622	8,308
Total liabilities	2,622	8,308
Total equity and liabilities	25,567	47,918

On behalf of the board

Dr. John Devane
Director

David Kelly
Director

AGI Therapeutics, plc

Consolidated Statement of Cash Flows

for the year ended 31 December 2008

	2008 **$'000**	2007 $'000
(Loss) for the year	(18,203)	(20,709)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation of property, plant & equipment	37	27
Amortisation of intangible assets	143	89
Interest income	(992)	(2,234)
Interest expense and other costs	362	155
Impairment of intangible assets	-	1,084
Corporation tax	-	263
Share based payment	1,538	1,478
Operating cash outflow before changes in working capital	(17,115)	(19,847)
Decrease/(increase) in other current assets	289	(140)
(Decrease)/increase in trade and other payables	(5,484)	5,080
Cash absorbed by operations	(22,308)	(14,907)
Interest received	1,227	2,072
(Tax paid)/refunded	(263)	(114)

Net cash outflow from operating activities	(21,344)	(12,949)
Cash flows from investing activities		
Acquisition of intangible assets	(221)	(228)
Purchases of property, plant and equipment	(41)	
Net cash used in investing activities	(221)	(268)
Net (decrease) in cash and cash equivalents	(21,565)	(13,217)
Cash and cash equivalents at the beginning of the year	45,504	58,876
Effect of foreign exchange rate changes	(362)	(155)
Cash and cash equivalents at the end of the year	23,577	45,504

AGI Therapeutics, plc

Notes to the consolidated preliminary financial information

1 Basis of preparation

This consolidated preliminary financial information is presented in US dollars rounded to the nearest thousand, being the functional currency of the company and its subsidiaries. It has been prepared on the historical cost basis of accounting, except for share based payments and financial instruments, which are stated at fair value.

The accounting policies have been applied consistently by all group companies.

This preliminary consolidated financial information does not constitute full statutory financial statements of the Group within the meaning of Regulation 40 of the European Communities (Companies: Group Accounts) Regulations, 1992, but is derived from those Financial Statements. Statutory Financial Statements for the year ended 31 December 2007 have been filed with Companies House. The auditor's report on those financial statements was unqualified. The Statutory Financial Statements for the year ended 31 December 2008 will be delivered to the Companies House following the Company's annual general meeting.

Functional currency

Commencing on January 1st 2008, AGI has adopted the US Dollar as its functional and presentational currency. This decision is based on the fact that the majority of the Company and its subsidiaries costs are denominated in US dollars and its revenues are earned in US 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 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.

Going concern

The company is continuing to develop its lead candidate which is in Phase III clinical trials, and progress the development of its other research programmes. The continuing development of these products will deplete the company's cash reserves in the year and will continue to do so until the company raises cash through financing arrangements or enters into licensing arrangements. The ability of the company to raise additional funds will depend on a number of factors including the results of the company's various research programmes, investor demand and general market conditions. In the absence of raising additional cash resources through either a fundraising or licensing transaction the directors expect that the company would initially take steps to modify its plans and reduce cash outflows. Nevertheless, the company would, in the absence of raising new funds, exhaust its available cash resources towards the end of 2010. The directors are satisfied that the company has sufficient cash resources to support its research programmes for a period of twelve months from the date of approval of these financial statements and therefore the company can continue to trade during this period. Consequently, the directors have adopted the going concern basis in the preparation of the financial statements.

2 Statement of compliance

This preliminary consolidated financial information has been prepared in accordance with the International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB) as adopted by the European Union (herein 'EU IFRS').