

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

The first half of 2009 was dominated by activities associated with progressing AGI's lead product, Rezular, for the treatment of diarrhoea-predominant irritable bowel syndrome, (IBS-D). Two Phase III studies, ARDIS 1 and ARDIS 3 were underway during the first half of 2009. ARDIS 1 was a randomised, double-blind, placebo-controlled, parallel-group, Phase III study in IBS-D patients (both men and women). There were four treatment arms (placebo and three dose levels of Rezular) and patients were treated for 12 weeks of double-blind therapy. A total of 711 patients were randomised in 123 clinical centres in the United States, Europe and South America. Of the total patients randomised, 63% were in the United States. ARDIS 3 was an extended safety study, designed to track at least 100 patients exiting ARDIS 1 for a total exposure of one year on active drug.

The Company received the top-line results from ARDIS 1 in mid-May. In summary;

- The study did not show statistically significant differences between drug and placebo in the primary endpoint of patient-reported adequate relief of IBS symptoms
- Statistically significant evidence favouring Rezular treatment was achieved in a number of secondary endpoints, particularly those relating to aspects of diarrhoea e.g. stool form (as assessed by the Bristol Stool Scale), stool frequency and in the majority of sub-categories of quality-of-life (IBS-QOL) scores and in the overall IBS-QOL score
- There were no statistically significant differences between treatments in adequate relief of pain/discomfort or change in severity of pain
- Based on this preliminary data analysis, AGI did not believe that the results of ARDIS-1 would meet the current regulatory requirements for an effective therapy for the broad IBS-D population and therefore ceased development of Rezular in this indication

This was a disappointing result for the Company, shareholders and IBS-D patients for whom no effective therapy to address all their symptoms exists. Having made the decision to discontinue the ARDIS programme, AGI commenced a review of its business strategy, including a fundamental review of its pipeline products and a post-hoc analysis of the data from the ARDIS 1 & 3 studies of Rezular. The Company moved quickly to limit the close out costs of the ARDIS Phase III programme as well as other project commitments in order to maximise the cash available to the business pending completion of the strategy review. The results of that review are made public today and form the basis of AGI's plans to re-build value in the Company.

## **Business Strategy**

The Company intends to leverage its strength in product development by focusing on specialty products in areas where unmet medical needs exist. This means that AGI intends to concentrate its efforts on market segments where the clinical and regulatory route to approval may be less costly and where commercialisation can be successfully undertaken by a smaller and more focused specialty company. Some of these indications will, the Company believes, meet the criteria for Orphan drug status under regulations of the US Food and Drug administration (FDA).

While the therapeutic focus of the Company up until now has been on GI diseases, AGI's approach to development and experience is applicable to numerous therapeutic areas. AGI

now intends to pursue products that fit with the Company's revised business strategy rather than being limited to a single therapeutic area.

Of the current pipeline products, AGI intends to concentrate its future development efforts on alternative applications for Rezular and on AGI-004, AGI's transdermal patch containing mecamlamine where we believe significant additional value can be created for our business and shareholders.

AGI has identified a number of potential new indications for Rezular and intends to prioritise, design and execute value-creating clinical trials in these indications. Where appropriate, study design and endpoints will be reviewed with the FDA. Rezular is discussed in more detail below. AGI-004 has already established clinical proof-of-concept in Chemotherapy Induced Diarrhoea (CID) and AGI is exploring the optimal study design for the next stage of this product's development.

While it is AGI's intention to advance these programmes using its own resources, the Company may consider co-development partnerships or strategic alliances with other pharmaceutical companies.

Non-core products will be monetised and developed through out-licensing or other partnership arrangements. Based on its current financial resources, AGI believes that the most productive way to advance AGI-010 controlled-release omeprazole, AGI-022, a targeted and controlled-release aminosallylate, and AGI-006, an upper-GI pro kinetic agent, will be through partnering. This will allow these products to be financed externally, providing cash and/or future value to AGI. The Company will pursue the establishment of such partnerships over the next year. The Company has already started the process of identifying and meeting with potential partners.

It is the Company's intention to allocate some of its cash resources to the development of new products if suitable candidates are identified. These should meet the criteria of being directed to specialty markets where unmet medical needs exist.

### **Rezular™**

Based on the comprehensive analysis of the ARDIS data including a variety of post-hoc analyses, the Company reached the following key conclusions in relation to the efficacy of Rezular in IBS-D:

- The analysis has confirmed the preliminary findings that Rezular at the medium (112.5mg per day) and high dose (225mg per day) showed a clear effect to normalise the loose/watery stool pattern of the IBS-D patients (measured by improvements in stool form using the BSS scale)
- Rezular improved stool frequency and quality of life (QOL) and also showed trends to improve urgency
- Certain post-hoc analyses did suggest an improvement in pain severity under certain circumstances

Overall, the analysis has confirmed the view of AGI that Rezular may offer an effective treatment for chronic diarrhea in a variety of conditions, particularly those associated with altered gut motility.

The immediate focus for AGI is to develop and implement a detailed operational plan that is consistent with the new business strategy approved by the Board. Ultimately we are confident that this new strategy will create increased value in the business.

Dr. Ronan Lambe  
Chairman  
Dublin, 22 September 2009

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 2009 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 Company. 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.

### ***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 AGI-010, Chronab omeprazole. This upfront fee has been 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 2009 a total of \$0.3 million was recognised as revenue (2008: \$0.3 million). As of 30 June 2009 the full amount of \$1.5 million has been recognised. In August 2009 AGI announced that, by mutual consent, AGI and Axcan have terminated this co-development and all associated intellectual property and ownership of the asset has reverted to AGI. There are no further financial obligations on either party associated with this termination.

#### **Research and Development expenses**

Total Research and Development expenses for the six months to June 30 2009 were \$7.8 million (2008: \$8.3 million). R&D costs in both 2008 and 2009 were dominated by the ARDIS Phase III clinical programmes associated with Rezular. As a result of the Company's decision to discontinue ARDIS in May 2009, all significant remaining costs associated with ARDIS were accrued in June 2009 and therefore R&D costs will be substantially lower in the second half of 2009.

#### **General and Administrative expenses**

General and Administrative expenses in the first six months of 2009 were \$1.5 million (2008: \$2.0 million). This decrease is attributable to the elimination of salary bonus payments in 2009, a reduced share-based compensation charge as well as other cost containment measures. As a result of continuing measures to contain costs AGI expects G&A costs to decline further in the second half of 2009.

#### **Interest Income and other income**

The Company earned interest on its cash balances amounting to \$0.1 million in the first six months of 2009 (2008: \$0.7 million). Interest income has fallen as cash balances have reduced and interest rates for cash deposits declined in 2009 compared to 2008. This category also includes an unrealised loss of \$21K in 2009 (2008: \$469K unrealised gain) arising from the translation, of those cash balances AGI still holds in euro into dollars at the period end.

### **Reorganisation expense**

A charge of \$0.4 million has been recognised in the first half of 2009 to account for costs associated with making certain positions redundant and the costs of writing down certain intellectual property. There was no comparable charge in 2008.

### **Taxation**

The Company has had a loss to date and continues to incur losses. Because of these losses no charge for tax arose in the first six months of 2009, although there was a small charge of \$0.1 million for the comparable period of 2008.

### **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 \$0.6 million was expensed during the first half of 2009 (2008: \$0.8 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 \$8.5 million (2008: \$12.5 million), which consisted principally of the loss from operations and changes in working capital balances. At June 30, 2009, AGI had cash and short-term deposits of \$15.1 million, (2008 \$32.8 million). The Company also had short term liabilities consisting of trade payables and accruals in the amount of \$2.7 million at 30 June 2009 a large portion of which related to Rezular. These liabilities are due to be fully discharged in the third quarter of 2009. The Directors have considered the Company's cash position and are satisfied that it is 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 2009

	Notes	Period ended 30 June 2009 \$'000	Period ended 30 June 2008 \$'000
Revenue		288	288
Research and development expenses (share based payment charge of \$322 (2008: \$439))		7,824	8,340
General and administrative expenses (share based payment charge of \$242 (2008: \$400))		1,467	2,016
Reorganisation expense		380	-
Total operating expenses		(9,671)	10,356
<b>Operating loss</b>		(9,383)	(10,068)
Interest income and other income		100	1,121
Loss before tax		(9,283)	(8,947)
<b>Income tax</b>		-	(59)
<b>Loss for the period</b>		(9,283)	(9,006)
<b>Basic loss per ordinary share:</b>			
Basic loss per share (\$ cents)	3	(13.8)	(13.3)

**UNAUDITED CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS**

	<b>30 June 2009 \$'000</b>	<b>31 December 2008 \$'000</b>
<b>Non-Current Assets</b>		
Property, plant and equipment	21	34
Intangible assets	1,618	1,793
<b>Total Non-Current Assets</b>	<b>1,639</b>	<b>1,827</b>
<b>Current Assets</b>		
Other current assets	189	163
Cash and cash equivalents	15,073	23,577
<b>Total Current Assets</b>	<b>15,262</b>	<b>23,740</b>
<b>Total Assets</b>	<b>16,901</b>	<b>25,567</b>
<b>Current Liabilities</b>		
Trade and other payables	2,675	2,622
<b>Total Current Liabilities</b>	<b>2,675</b>	<b>2,622</b>
<b>Total Liabilities</b>	<b>2,675</b>	<b>2,622</b>
<b>Shareholders' Equity</b>		
Share capital	992	992
Share premium	75,194	75,194
Other reserves	4,751	4,187
Retained loss	(66,711)	(57,428)
<b>Total Shareholders' Equity</b>	<b>14,226</b>	<b>22,945</b>
<b>Total Shareholders' Equity and Liabilities</b>	<b>16,901</b>	<b>25,567</b>

**UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS**

	<b>30 June 2009 \$'000</b>	<b>30 June 2008 \$'000</b>
Loss for the period	(9,283)	(9,006))
<b>Adjustments to reconcile loss to net cash used in operating activities:</b>		
Depreciation of property, plant and equipment	13	18
Amortisation and writedown of intangibles	175	70
Interest income	(100)	(652)
Income tax	-	59
Share-based compensation	564	839
Operating cash outflow before changes in working capital	(8,631)	(8,672)
Increase in other current assets	(36)	(84)
Increase/(decrease) in trade and other payables	51	(4,544)
Cash used by operations	(8,616)	(13,300)
Interest received	110	826
Tax refunded/(paid)	2	(25)
Net cash outflow from operating activities	(8,504)	(12,499)
<b>Investing activities</b>		
Acquisition of intellectual property and other investments	-	(221)
Net cash used by investing activities	-	(221)
Net (decrease) in cash and cash equivalents	(8,504)	(12,720)
Cash and cash equivalents at the beginning of period	23,577	45,503
Cash and cash equivalents at the end of the period	15,073	32,783

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

	<b>Number of Shares</b>	<b>Ordinar y share Capital \$'000</b>	<b>Share Premium \$'000</b>	<b>Other Reserves \$'000</b>	<b>Retained deficit \$'000</b>	<b>Total Amount \$'000</b>
Balance at 31 December 2007	67,412,783	992	75,194	2,649	(39,225)	39,610
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	(48,231)	31,443
Loss for the period	-	-	-	-	(9,197)	(9,197)
Share-based compensation	-	-	-	699	-	699
Balance at 31 December 20087	67,412,783	992	75,194	4,187	(57,428)	22,945
Loss for the period	-	-	-	-	(9,283)	(9,283)
Share-based compensation	-	-	-	564	-	564
Balance at 30 June 2009	67,412,783	992	75,194	4,751	(66,711)	14,226

## **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 2009. 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 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 2008.

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 2008.

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 2008 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 Company changed from Euro to US Dollars as the Company's cost structure became primarily US Dollar based. The Company's principal clinical trials are carried out in the United States and billed in dollars. In addition the Company earns only US Dollar revenue. The US Dollar is the currency of the primary economic environment in which the Company operates. At 1 January 2008 the Company 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 2009 and 2008:

	<b>30 June 2009</b>	<b>30 June 2008</b>
	<b>\$000</b>	<b>\$000</b>
<b>Numerator:</b>		
Loss attributable to ordinary shareholders	(9,283)	(9,006)
<b>Denominator:</b>		
Denominator for basic—weighted average number of shares	67,412,783	67,412,783
<b>Basic loss per share:</b>		
Basic loss per share (US\$ cents)	(13.8)	(13.3)

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**

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 17 September, 2009