THIS DOCUMENT IS IMPORTANT. When considering what action to take on the contents of this document, you are recommended to seek your own financial advice immediately from an independent financial adviser who specialises in advising on the acquisition of shares and other securities being in the case of persons resident in Ireland, an organisation or firm authorised or exempted under the Investment Intermediaries Act 1995 of Ireland or the Stock Exchange Act 1995 of Ireland or in the case of persons resident in the United Kingdom, an organisation or firm authorised pursuant to the Financial Services and Markets Act 2000 of the United Kingdom ("FSMA").

Application has been made for the Enlarged Issued Share Capital of AGI Therapeutics plc to be admitted to trading on the AIM Market of the London Stock Exchange ("AIM") and on the Irish Enterprise Exchange of the Irish Stock Exchange ("IEX") and it is expected that dealings in the Enlarged Issued Share Capital will commence on 27 February, 2006. The Ordinary Shares are not dealt on any other recognised investment exchange and no application has been or is being made for the Ordinary Shares to be admitted to any such exchange.

AIM and IEX are both markets designed primarily for emerging or smaller companies to which a higher investment risk tends to be attached than to larger or more established companies. AIM and IEX securities are not admitted to either the Official List of the UK Listing Authority or the Official List of the Irish Stock Exchange (together the "Official Lists"). A prospective investor should be aware of the risks of investing in such companies and should make the decision to invest only after careful consideration and, if appropriate, consultation with an independent financial adviser. The rules of AIM and IEX are less demanding than those of the Official Lists and it is emphasised that no application is being made for admission of the Ordinary Shares to either of the Official Lists. Furthermore, neither the London Stock Exchange, the Irish Stock Exchange, the UK Listing Authority, nor the Financial Regulator have examined or approved the contents of this document.

Prospective investors should read the whole text of this document and should be aware that an investment in the Company is speculative and involves a higher than normal degree of risk. The attention of prospective investors is drawn in particular to the section entitled "Risk Factors" set out in Part II of this document. All statements regarding the Group's business, financial position and prospects should be viewed in light of these risk factors.

The Directors of AGI Therapeutics plc, whose names appear on page 3 of this document, accept responsibility for the information contained in this document including individual and collective responsibility for compliance with the AIM and IEX Rules. To the best of the knowledge and belief of the Directors (who have taken all reasonable care to ensure that such is the case) the information contained in this document is in accordance with the facts and contains no omission likely to affect the import of such information. In connection with this document and/or the invitation contained in it, no person is authorised to give any information or make any representation other than as contained in this document.

AGI Therapeutics plc

(Incorporated in Ireland with limited liability under the Companies Acts, 1963 to 2005. Registration number 412638)

Placing of 33,730,159 new Ordinary Shares at €1.26 (Stg£0.865) per Ordinary Share and Admission to Trading on AIM and IEX

Nominated Adviser, IEX Adviser and Broker

Davy

EXPECTED SHARE CAPITAL IMMEDIATELY FOLLOWING ADMISSION

Authorised		*Issued and fully paid*	
Amount	*Number*	*Amount*	*Number*
€1,000,000	100,000,000	€1,000,000	67,412,783

Davy, who is regulated in Ireland by the Financial Regulator, is acting exclusively for AGI Therapeutics plc and no-one else in connection with the Placing and Admission. Davy will not regard any other person (whether or not a recipient of this document) as its customer or be responsible to any other person for providing the protections to customers of Davy nor for providing advice in relation to the transactions and arrangements described in this document. Davy is not making any representation or warranty, express or implied, as to the contents of this document.

Davy has been appointed as nominated adviser, IEX adviser and broker to the Company. In accordance with the AIM and IEX Rules, Davy has confirmed to the London Stock Exchange and the Irish Stock Exchange, respectively, that it has satisfied itself that the Directors have received advice and guidance as to the nature of their responsibilities and obligations to ensure compliance by the Company with the AIM Rules and the IEX Rules and that, in its opinion and to the best of its knowledge and belief, all relevant requirements of the AIM and IEX Rules have been complied with. No liability whatsoever is accepted by Davy for the accuracy of any information or opinions contained in this document or for the omission of any material information, for which it is not responsible.

This document comprises an admission document and has been drawn up in accordance with the AIM and IEX Rules and it does not comprise a prospectus for the purposes of the Prospectus (Directive 2003/71/EC) Regulations 2005 in Ireland or the Prospectus Rules published by the Financial Services Authority in the United Kingdom and has not been delivered to the Registrar of Companies in Dublin or the Registrar of Companies in England and Wales. Copies of this document will be available to the public, free of charge, at the offices of Davy, Davy House, 49 Dawson Street, Dublin 2, Ireland and the offices of Field Fisher Waterhouse, 35 Vine Street, London, EC3N 2AA, United Kingdom from the date of this document until at least one month after Admission.

This document does not constitute or include an offer to any person to sell or to subscribe for, or the solicitation of an offer to buy or to subscribe for, Ordinary Shares in any jurisdiction. This document is not for distribution in or into the United States of America, Canada, Australia or Japan or their respective territories or possessions. The Ordinary Shares have not been, and will not be, registered under the United States Securities Act, 1933, as amended (the "Securities Act") or qualified for sale under the laws of any state of the United States of America or under the applicable securities laws of any province or territory of Canada, Australia or Japan and may not be offered or sold in the United States of America except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and, subject to certain exceptions, may not be offered or sold within any of Canada, Australia or Japan or to any national, resident or citizen of any of the United States of America, Canada, Australia or Japan or their respective territories or possessions.

CONTENTS

DIRECTORS, COMPANY SECRETARY AND ADVISERS

DIRECTORS:	Ferdinand Ronan Lambe, *Non-Executive Chairman* John Gerard Devane, *Chief Executive Officer* Mary Lucia Martin, *Chief Operating Officer* Patrick Joseph Ashe, *Senior VP, Business Development* John Gerard O'Sullivan, *Non-Executive Director* Peter William Sandys, *Non-Executive Director* James Francis Kenny, *Non-Executive Director*	
COMPANY SECRETARY:	Paul Francis Donnelly	
REGISTERED OFFICE AND PRINCIPAL PLACE OF BUSINESS:	Adelaide Chambers, Peter Street, Dublin 8, Ireland.	
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REPORTING ACCOUNTANT:	KPMG, 1 Stokes Place, St. Stephen's Green, Dublin 2, Ireland.	
AUDITORS:	RSM Robson Rhodes, RSM House, Herbert Street, Dublin 2, Ireland.	
SOLICITORS TO THE COMPANY:	*As to Irish Law* Beauchamps Solicitors, Dollard House, Wellington Quay, Dublin 2, Ireland.	*As to English Law* Field Fisher Waterhouse, 35 Vine Street, London EC3N 2AA, United Kingdom.
SOLICITORS TO DAVY:	McCann FitzGerald, 2 Harbourmaster Place, Dublin 1, Ireland.	

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BANKERS:

Bank of Ireland, Church Street, Athlone, Co. Westmeath, Ireland.	Anglo Irish Bank Corporation plc, Stephen Court, 18-21 St Stephen's Green, Dublin 2, Ireland.

FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements. These statements relate to the Group's future prospects, developments and business strategies.

Forward-looking statements are identified by their use of terms and phrases such as "believe", "could", "envisage", "estimate", "expect", "intend", "may", "plan" "will" or the negative of those, variations or comparable expressions, including references to assumptions. These statements are primarily contained in Parts I, II and III of this document.

The forward-looking statements in this document are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by those statements. Certain risks to and uncertainties for the Company are specifically described in Part II of this document headed "Risk Factors". If one or more of these risks or uncertainties materialises, or if underlying assumptions prove incorrect, the Company's actual results may vary materially from those expected, estimated or projected. Given these risks and uncertainties, potential investors should not place any reliance on forward-looking statements.

These forward-looking statements speak only as at the date of this document. Neither the Directors nor the Company undertake any obligation to update forward-looking statements or risk factors other than as required by the AIM Rules and the IEX Rules, whether as a result of new information, future events or otherwise.

PLACING/ADMISSION STATISTICS

Placing Price	€1.26 (Stg£0.865)
Number of Ordinary Shares in issue at the date of this document*	33,682,624
Number of Ordinary Shares in issue following Admission	67,412,783
Gross proceeds of the Placing	€42.5 million (Stg£29.2 million)
Net proceeds of the Placing receivable by the Company	€39.8 million (Stg£27.3 million)
Market capitalisation at the Placing Price upon Admission	€84.9 million (Stg£58.3 million)
Placing Shares as a percentage of the Enlarged Issued Share Capital	50%
Percentage of the Existing Issued Share Capital subject to lock-in and orderly market agreements	100%
Percentage of the Enlarged Issued Share Capital subject to lock-in and orderly market agreements	53.8%
AIM/IEX Symbol	AGI
ISIN code	IE00B0YT0Q82

** Assumes conversion of the A Preferred Shares*

EXPECTED TIMETABLE OF PRINCIPAL EVENTS

Publication of this Admission Document	21 February, 2006
Admission effective and dealings expected to commence on AIM and IEX	27 February, 2006
CREST accounts credited (where applicable)	27 February, 2006
Expected latest date for despatch of definitive share certificates (where applicable)	13 March, 2006

PART I — INFORMATION ON THE GROUP

(1) OVERVIEW OF THE GROUP

AGI is a speciality pharmaceutical company focused on the development and commercialisation of differentiated drug product candidates for gastrointestinal ("GI") diseases and disorders. The Group is focused primarily on the development and commercialisation of clinical stage product candidates for the GI therapeutic drug products market.

Clinical trials are systematic studies in humans aimed at determining the safety and effectiveness of new or unproven drugs or therapies and are typically classified as either Phase I, II or III depending on the extent of safety, efficacy, and pharmacology testing being undertaken. The Group's product candidates are based on existing known drugs, which allows the Group to undertake abridged development programmes. Therefore, the Group does not undertake the full range of Phase I and Phase II clinical trials and instead, in preparation for Phase III clinical trials, may undertake more limited human pharmacokinetics and pharmacodynamics trials to establish profiles of its product candidates in humans.

The Group has a portfolio of product candidates derived from the Known Molecular Entity ("KME") approach to drug re-profiling and development. KME is a re-profiling methodology used by the Group 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. AGI has developed a range of product candidates to treat a variety of prevalent GI diseases and disorders, including irritable bowel syndrome ("IBS"), functional dyspepsia ("FD"), ulcerative colitis ("UC") and gastroesophageal reflux disease ("GERD"). The Group is targeting areas of the GI therapeutic drug products market for its product candidates where the Directors believe there are currently unmet medical needs as there are either few or no existing approved drug therapies available for existing patients or where they believe the effectiveness of existing drug therapies can be further improved.

AGI undertakes and has core expertise in product candidate identification, differentiation and design, intellectual property ("IP") creation, development and protection, formulation and process design, clinical trial and associated protocol design, preparation of regulatory submissions, project management and commercialisation and licensing activities. The Group uses third party providers to conduct certain synthesis, formulation, manufacturing, clinical, patent and regulatory work as required.

The Group has six 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. These six product candidates are all in clinical development with seven clinical programmes currently being undertaken. The Group's product candidates, their active constituents and target clinical indications and the status of the clinical trials currently being undertaken are summarised below:

Product Candidate	*Active Constituent*	*Target Clinical Indications*	*Clinical Trial Status*
AGI-003	R-verapamil isomer	Diarrhoea-predominant Irritable Bowel Syndrome ("d-IBS")	Phase II ongoing
AGI-001	S-pindolol isomer	Functional Dyspepsia	Phase II ongoing
AGI-001	S-pindolol isomer	Irritable Bowel Syndrome	Phase II ongoing
AGI-004	Controlled release mecamylamine	d-IBS	Phase II ongoing
AGI-006	R-baclofen isomer	Functional Dyspepsia	Phase II ongoing
AGI-010	Controlled release omeprazole	GERD (Nocturnal Acid Breakthrough)	Human Pharmacokinetics and Pharmacodynamics ongoing
AGI-022	Controlled release 4-aminosalicylic acid ("4-ASA")	Ulcerative Colitis	Human Pharmacokinetics completed

AGI's product candidates are based on known drugs which AGI is attempting to develop for GI clinical indications, either as a differentiated presentation in the already established GI clinical indication (an "improved therapy") or as a new GI use for a therapeutic drug product already approved in a non-GI clinical indication ("a therapeutic switch"). The Group currently has four "therapeutic switch" product candidates in Phase II clinical trials (AGI-001, AGI-003, AGI-004 and AGI-006) and one "improved therapy" product candidate in a human pharmacokinetics and pharmacodynamics clinical trial (AGI-010) and has completed a human pharmacokinetics clinical trial of a further "improved therapy" product candidate (AGI-022).

John Devane PhD, Mary Martin PhD, Patrick Ashe, Jackie Butler PhD and Paul Stark, being the Executive Management Team, have collective substantial experience in the development, registration and commercialisation of therapeutic drug products. Each member of the Executive Management Team has held senior management and operational positions with Élan Corporation plc, has established relationships within the pharmaceutical sector and has a track record of developing, registering, partnering and the bringing to market of re-profiled products in the US (as New Drug Application ("NDA") approvals) and in other countries.

The Directors believe that Admission and the Placing will enhance the Group's prospects. AGI intends to complete its ongoing clinical trials and, dependent on the results of these trials, thereafter intends to (i) select a lead product candidate which it will further develop by undertaking a Phase III clinical programme; (ii) undertake an additional Phase II clinical trial on AGI-006; (iii) seek to enter into licensing and development agreements for its product candidates; (iv) continue with research and development activities on its existing IP; and (v) seek to expand its IP portfolio.

The Company is a newly incorporated company which has been formed for the purposes of acquiring AGI Therapeutics Research Limited (formerly known as AGI Therapeutics Limited), to execute the Placing and to seek admission of the Enlarged Share Capital to trading on AIM and IEX. The Company has never traded or carried on any activities, save that on 20 January 2006 the Company acquired all of the shares in AGI Therapeutics Research Limited by way of the Share Exchange Agreement.

The Executive Directors and the Syndicate Investors have subscribed for a total of 2,976,190 Placing Shares and will not be selling Ordinary Shares in the Placing. In addition, all Shareholders in the Company pre Admission, have each entered into lock-in and orderly market agreements not to sell, transfer or otherwise dispose of any interest in their Ordinary Shares held immediately following Admission for a period of 12 months from the date of Admission and for a further 12 months, they are obliged to sell their Ordinary Shares through Davy for the purpose of preserving an orderly market.

(2) HISTORY AND DEVELOPMENT OF THE GROUP

Each member of the Executive Management Team has held senior management and operational positions with Élan Corporation plc and biographical information on each of them is provided in section 11 of this Part I. In 2001, John Devane founded a pharmaceutical company, Athpharma Limited, to develop KME products and in 2002 Jackie Butler, Paul Stark and Patrick Ashe became employees and shareholders. Athpharma initially acquired rights to two controlled release cardiovascular products, in-licensed intellectual property relating to controlled release statin drugs and completed a fundraising by way of a US$3 million convertible loan. Thereafter, Athpharma invested in the development of its intellectual property and products (including filing six patent applications relating to the improved delivery of cardiovascular and statin drugs), including formulation and process development for its lead cardiovascular and statin products and designed and reached agreement with the FDA on Phase III clinical programmes for its two lead cardiovascular products.

In 2003, Athpharma entered into agreements with Biovail Corporation to sell four of Athpharma's cardiovascular and statin products and their associated intellectual property to Biovail and agreed to a co-development arrangement whereby Athpharma would manage the development of these products in collaboration with Biovail. The consideration for the agreements was an up-front payment of US$44.2 million with additional payments and royalties to be made to Athpharma upon achievement of certain downstream milestones and in-market sales.

Athpharma also advanced the development of product candidates in a separate field, being GI diseases and disorders. In 2001 it in-licensed intellectual property relating to the use of Pindolol (AGI-001) and in 2003 it acquired intellectual property rights relating to the use of Verapamil (AGI-003) for GI purposes, filed patent applications relating to four additional GI product candidates, AGI-004, AGI-006, AGI-010,

and AGI-022 and undertook an initial Phase II clinical trial of AGI-001 for functional dyspepsia. In 2003, John Devane, Patrick Ashe, Jackie Butler, Paul Stark and John Kelly PhD, then a scientific adviser to and shareholder in Athpharma, founded AGI Therapeutics Research Limited for the purpose of developing product candidates directed at the gastrointestinal therapeutic drug products market in a separate company which would have a strategic and commercial focus in the GI market.

In March 2004, the rights and obligations of the intellectual property relating to Athpharma's portfolio of six GI product candidates was acquired by AGI Therapeutics Research Limited and Mary Martin joined the Group as Chief Operating Officer. In conjunction with this, the Group completed a private placement raising €9.5 million from the Syndicate Investors and the Executive Management Team for the purposes of progressing AGI's six product candidates into clinical development. In May 2005, John Devane, Patrick Ashe, Paul Stark, Jackie Butler and John Kelly sold their entire shareholding in Athpharma. Since March 2004, the Group has achieved the following:

(i) Advanced all six product candidates into technical and clinical development;

(ii) Established the formulation and manufacturing methods and sources of supply, and manufactured clinical trials supplies, for all six product candidates;

(iii) Designed and initiated five Phase II clinical trials (with over 450 patients), and a human pharmacokinetics and pharmacodynamics study at sites in Europe, Israel, Canada and the US, including gaining all necessary supporting regulatory approvals. Three of these Phase II clinical trials have now completed patient enrolment, being AGI-001 in both functional dyspepsia and irritable bowel syndrome and AGI-003 in non-constipation dominant irritable bowel syndrome;

(iv) Completed the development and testing in a human pharmacokinetics trial for AGI-022, which has demonstrated that the target controlled release and delivery profile for this product candidate was achieved;

(v) Progressed its intellectual property for its product candidates to non-provisional application status in the US and filed full Patent Cooperation Treaty ("PCT") applications and received the grant of its first US Patent (No. 6,849,661) for its AGI-003 product candidate; and

(vi) Received interest from and initiated discussions with potential partners/licensees for its product candidates, including entering into a number of confidential disclosure agreements to facilitate further and more in-depth discussions.

(3) BACKGROUND TO THE GASTROINTESTINAL THERAPEUTIC DRUG PRODUCTS MARKET

The gastrointestinal therapeutic drug products market that the Group is targeting is broadly divided into three categories by disease, aetiology and symptoms, which are (i) acid-related disorders; (ii) functional GI disorders; and (iii) inflammatory bowel diseases. AGI's product candidates are targeted at these categories, specifically AGI-010 for the acid-related disorder, GERD; AGI-001, AGI-003, AGI-004 and AGI-006 for the functional GI disorders, irritable bowel syndrome and functional dyspepsia; and AGI-022 for the inflammatory bowel disease, ulcerative colitis. The Directors estimate that the global market size, expressed as annual sales of all GI therapeutic drug products, is currently at least US$30 billion.

Acid-related disorders, including ulcers and GERD, are estimated to affect up to 40 per cent of people in the industrialised world. The principal drug therapies that are currently approved for the treatment of ulcers and GERD, are the proton-pump inhibitors ("PPI") and the H_2 antagonist therapeutic drug classes. The acid-related disorders category was estimated to have grown to US$25.5 billion in global annual sales and was the second largest therapeutic drug class by annual sales in 2004 while PPI sales in the US alone were US$12.8 billion in the twelve month period to June 2005. The most commonly used PPI drugs include omeprazole, esomeprazole, lansoprazole and pantoprazole. Given the size of the acid-related disorders market, and in particular of PPI drugs, the Directors believe that there are market opportunities for new PPI formulations with differentiated and improved therapeutic profiles.

Functional GI disorders (including irritable bowel syndrome and functional dyspepsia) are the second most prevalent conditions amongst the target GI disorders after acid related disorders and are estimated to affect approximately from 25 to 40 per cent of the population in developed nations. In the US there are currently no therapeutic drug products approved for the treatment of functional dyspepsia and only

two therapeutic drug products have been approved "with limited use" for the treatment of IBS, namely alosetron for d-IBS and tegaserod for constipation-predominant, or c-IBS. Given the high prevalence rates for functional GI disorders and the current scarcity of effective drug therapies, the Directors view the functional GI disorders category as being largely underserved and representing the category with the highest sales growth potential in the gastrointestinal therapeutic drug products market.

The smallest of the target GI disease categories, by disease prevalence, is inflammatory bowel disease ("IBD"), which includes ulcerative colitis and Crohn's disease. There are an estimated 1 million IBD sufferers in the US, of which approximately 600,000 suffer from ulcerative colitis. The principal drug therapies that are currently approved for the treatment of IBD including ulcerative colitis, are the established aminosalicylate (e.g. 5-aminosalicylic acid, 5-ASA) and corticosteroid drug classes and the newer immunotherapeutic biological agents, such as infliximab. The Directors estimate that global annual sales of therapeutic drug products for IBD are currently at least US$3 billion.

(4) THE GROUP'S BUSINESS MODEL

Overview

AGI is a speciality pharmaceutical company which is focused on the development and commercialisation of proprietary, innovative and differentiated therapeutic drug products to treat a variety of gastrointestinal diseases and disorders. The Group itself undertakes product candidate identification, differentiation and design, IP creation, development and protection, formulation and process design, clinical trial and associated protocol design, preparation of regulatory submissions, project management and commercialisation and licensing activities. AGI uses third party providers to conduct certain synthesis, formulation, manufacturing, clinical, patent and regulatory work as required.

AGI has six product candidates in clinical development which the Directors believe could address unmet medical needs in GI disease categories where there are either few or no existing approved drug therapies or where they believe the effectiveness of existing approved drug therapies can be improved. The Group is attempting to establish new uses and clinical indications or improved therapeutic profiles for its product candidates and is seeking to develop its product candidates to achieve clinical and regulatory results that will increase the value of its product candidates.

The Group seeks to reduce the risk, time and cost of product candidate development as compared to the development of new chemical entities ("NCE") by applying the KME approach to drug re-profiling and development. AGI intends to complete all its ongoing clinical trials and, dependent on the results of these trials, thereafter intends to (i) select a lead product candidate which it will further develop by undertaking a Phase III clinical programme; (ii) undertake an additional Phase II clinical trial on AGI-006; (iii) seek to enter into licensing and development agreements for its product candidates; (iv) continue with research and development activities on its existing IP; and (v) seek to expand its IP portfolio.

AGI will seek to establish alliances with pharmaceutical companies. Dependent on the results of clinical trials currently being or to be undertaken, the Group will seek to enter into licensing and development agreements with pharmaceutical companies so as to enhance the global market reach for its product candidates and achieve optimal revenue and value opportunities for the Group. The Directors expect that such agreements would provide further development funding for AGI's product candidates as well as revenue from licence and milestone fees and royalties.

KME approach to drug re-profiling and development

KME or Known Molecular Entity is a methodology used 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. This approach has enabled AGI to progress its KME product candidates into human clinical development by referencing the existing safety and toxicology information on the identified drugs and bypassing the pre-clinical toxicology and Phase I safety testing which are normally required for NCE drugs. KME may also reduce the requirement for additional safety testing to achieve regulatory approval. The Directors believe that the KME approach will allow the Group to identify and develop products in an accelerated time frame which can be progressed to regulatory filing within 3 to 5 years of initial commencement of development as compared to up to 10 years for NCE drugs.

AGI's product candidates are based on known drugs which AGI is attempting to develop for GI clinical indications, either as a new GI use for a therapeutic drug product already approved in a non-GI clinical

indication (a "therapeutic switch") or as a differentiated presentation in the already established GI clinical indication (an "improved therapy"). The Group currently has four "therapeutic switch" product candidates in Phase II clinical trials (AGI-001, AGI-003, AGI-004 and AGI-006), one "improved therapy" product candidate in a human pharmacokinetics and pharmacodynamics clinical trial (AGI-010), and has completed a human pharmacokinetics clinical trial of a further "improved therapy" product candidate (AGI-022).

Identification of KME product candidates

AGI uses three primary methodologies to identify new KME product candidates.

The first method involves the review of available literature, including approved drug labelling, published clinical and experimental data and reference to "off-label" uses of known drugs. AGI has identified a number of older KME drugs that have GI-relevant pharmacology, and the Directors believe that these GI signals were sometimes regarded as side effects of the drug. Some of these drugs were used "off-label" in certain GI conditions. Identifying such GI-relevant signals and understanding the GI-relevant pharmacology and mechanism of action is an important component in AGI's selection of product candidates.

The second method involves the systematic in-vitro screening of existing known drugs against established or putative GI pharmacological targets. AGI accesses target libraries through third parties with capabilities in high-throughput in vitro screening and a subset of known drugs has been screened to date.

The third method involves the review of information on existing approved GI therapeutic drug products, including approved labelling on current use, dosing and administration, side effects and contra-indications to determine any shortcomings in current use profiles which might be improved upon.

Differentiation strategies

Following identification and selection of candidates, the Group develops strategies to emphasise and differentiate the new or improved GI use. Once AGI has selected a known drug for further development as a GI product candidate, it employs a variety of enabling and differentiation strategies to achieve the desired therapeutic profile. In the case of three of its current product candidates (AGI-001, AGI-003 and AGI-006), this involves the development of single stereo-isomers of the parent or racemic drug, while its other three product candidates (AGI-004, AGI-010 and AGI-022) employ drug delivery and controlled release approaches.

Many older drugs contain a racemic or equal mixture of two stereo-isomers. These stereo-isomers are chemically identical but can often have markedly different pharmacological activities and effects in the body. At times, the desired therapeutic effects reside solely in one isomer form with side effects in the other form. In the case of AGI-001, AGI-003 and AGI-006, the parent racemic forms (respectively pindolol, verapamil and baclofen) exhibit a primary non-GI pharmacology, while a substantial GI-relevant alternative pharmacology is also observed. For each of these three drugs, AGI has identified the particular isomer form that is dominantly associated with the GI-relevant pharmacology. These single isomer forms are the active constituents of AGI-001, AGI-003 and AGI-006. By developing these single isomer forms, AGI believes it can establish new and effective GI therapeutic uses with the potential to obtain novel use patent claims.

AGI also uses drug delivery techniques to differentiate its product candidates to achieve a new or improved clinical use. Such drug delivery systems are designed to achieve specific patterns of release and drug exposure profiles in the body and also represent important patent claim opportunities.

Clinical Research Organisations and Contract Manufacturing

The Group contracts clinical research organisations ("CRO's") to conduct its clinical trial programmes. All CRO's are selected against a strict set of criteria including proven GI-relevant experience, quality and cost. All clinical trials have, are and will be conducted in compliance with the Declaration of Helsinki, the ICH GCP Guidelines, the European Communities Clinical Trials on Medicinal Products for Human Use Regulations (2004) and the FDA guidelines and good laboratory practice standards, as applicable.

The Group itself does not own or operate any R&D and manufacturing facilities and therefore is and will be dependent upon third parties for the manufacture of its products to good manufacturing practice

("GMP") standards. The Group has GMP sources for all active pharmaceutical ingredients used in its product candidates and has contracted GMP-compliant sub-contractors in Europe and the US to develop, manufacture, test and package its product candidates for use in its current clinical trials. Similarly the Group will employ GMP-compliant contractor(s) to manufacture and package its clinical supplies for the planned Phase III programme, Phase II trial and any other future clinical trials programmes.

Intellectual Property and Patents and Market Exclusivity

The Directors believe that establishing and maintaining market exclusivity for its product candidates is very important to the long-term success of the Group's business. The Group utilises a number of methods to establish and maintain market exclusivity, including taking advantage of statutory market exclusivity provisions, seeking patent protection for its product candidates and otherwise protecting its intellectual property.

AGI seeks to protect the rights in its product candidates and associated new or improved uses, formulations and processes that are invented, developed, licensed or used by the Group through the use of patents. The Group's patent protection strategy has generally involved filing US provisional applications to secure a priority date for inventive disclosure, followed by non-provisional applications and the filing of international patent applications complying with the Patent Cooperation Treaty. Further information on the Group's intellectual property and patents is detailed in Part IV of this document.

In addition to relying on its patent strategy, the Group will seek to establish market exclusivity for its product candidates in the US under the US Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which provides that newly approved drugs and indications in the US can benefit from a statutory period of marketing exclusivity, which is provided even in the absence of patent protection. During this exclusivity period, which is established by the FDA and is typically for a period of 3 to 5 years from first marketing, the approval of a generic competitor who seeks to rely upon data in the NDA is prohibited. In the case of a new indication or clinically-based differentiated labelling for an existing drug (including an isomer thereof), the period of exclusivity is typically 3 years from NDA approval.

There are similar provisions in Europe whereby a therapeutic drug product, regardless of its patent status, has an exclusivity period of ten years once it receives its marketing authorisation. As a result, a generic product which relies on the data used to support the marketing authorisation for the therapeutic drug product cannot be placed on the market during this period of exclusivity.

Regulatory Approvals

Regulation by government authorities is and will continue to be a significant factor in the development, manufacture and marketing of AGI's product candidates. All of the Group's product candidates will require regulatory approval by government agencies, such as the FDA in the US and equivalent agencies in other countries, prior to marketing. In particular, human therapeutic drug products are subject to rigorous pre-clinical studies and clinical trials and other approval procedures of such agencies. Various statutes and regulations also govern or influence testing, manufacture, safety, labelling, storage and record-keeping relating to such products and their marketing. The process of obtaining the approvals of these agencies for the marketing of human therapeutic drug products requires the expenditure of substantial time and financial resources.

Once developed, the Group's product candidates are expected to be filed for approval in the US through the NDA 505(b)(2) regulatory process, and its equivalent outside the US. The US NDA 505(b)(2) regulatory process provides a specific regulatory pathway to seek approval for new or improved uses of already approved drugs, including isomers and controlled release formulations thereof, typically with a reduced requirement to reproduce existing safety and toxicology information, which can be referenced. This can lead to a reduction in both the time and cost of the clinical development and regulatory approval process for products which qualify for filing as a NDA 505(b)(2). The Directors believe that the NDA 505(b)(2) process is particularly suited to KME products and to AGI's current product candidates and the Executive Management Team has substantial experience in the development and regulatory approval of KME-based therapeutic drug products through the NDA 505(b)(2) process.

Licensing and other Commercialisation Strategies

AGI will seek to enter into partnerships and alliances, such as licensing agreements, with appropriate pharmaceutical companies to provide for further development, funding and marketing of a number of its

product candidates by such partners, as well as providing future revenues for the Group. The Group has commenced preliminary discussions with potential partners in relation to the licensing of some of its product candidates.

As part of any licensing agreement, AGI may retain some marketing rights to certain product candidates within its portfolio, in particular AGI-003 and AGI-001, and will review the possibility of developing in the future a direct sales and marketing capability and infrastructure in the US, directed primarily at the specialist gastroenterologist community. The Directors believe that the retention of a certain level of control over in-market activities with its key product candidates and a larger share of the potential in-market revenues will improve the Group's ability to generate and sustain growth of its business in a more predictable way.

(5) THE GROUP'S PRODUCT CANDIDATES

AGI-003 — Diarrhoea-predominant Irritable Bowel Syndrome ("d-IBS")

AGI-003 is an oral dosage form of the R-isomer of verapamil which is being developed by AGI for the treatment of diarrhoea-predominant irritable bowel syndrome ("d-IBS") in both men and women.

IBS is a functional disorder (i.e. an abnormality or disturbance of normal function which cannot be directly attributed to anatomical or biochemical defects) that comprises a cluster of gastrointestinal symptoms which are likely to be life long and can include diarrhoea, constipation, abdominal pain and distension, which vary in intensity. Altered intestinal motility is a major component of IBS and patients are diagnosed and sub-typed according to their predominant symptom of bowel disturbance as either "d-IBS", constipation-predominant ("c-IBS") or mixed/alternating symptoms of diarrhoea and constipation ("m-IBS").

The prevalence of IBS has been estimated in US population-based studies at between 10 and 20 per cent and surveys conducted in Europe estimate a similar range of IBS prevalence there. It is estimated that there is an approximate equal prevalence of each of the d-IBS, c-IBS and m-IBS sub-types. IBS is reported to be about twice as prevalent in women as in men. While an estimated 75 per cent or more of current sufferers remain undiagnosed and untreated, IBS remains the most common diagnosis made by gastroenterologists and leads to a substantial reduction in quality of life, accompanied by considerable socio-economic and psychological consequences.

AGI-003 is being targeted to compete in the diarrhoea-predominant segment of the IBS market, which is estimated to account for approximately one third of all IBS patients. The annual market for prescription therapeutic drug products for IBS in the US was estimated at more than US$350 million in 2003 and is predicted to grow rapidly to more than US$1 billion by 2010. These sales are currently largely for products treating the c-IBS component, and whose use is currently restricted to women only. The Directors believe that there are market opportunities for new d-IBS therapeutic drug products.

A solid oral dosage form of AGI-003 has been developed and a Phase II clinical trial evaluating the efficacy of AGI-003 in the treatment of non-constipation predominant irritable bowel syndrome is currently ongoing. This trial is a randomised, double-blind, placebo-controlled, parallel group, dose escalation trial conducted at multiple sites in Europe in a total of 128 non-constipation predominant IBS patients. This study is fully enrolled and the treatment phase is now complete. It is expected that a final clinical report will be available in Q2/Q3 2006.

The Group currently anticipates that, dependent on the results of the ongoing Phase II clinical trial, it will develop AGI-003 for the treatment of d-IBS as a lead product candidate and that it will complete a Phase III programme and NDA filing in the US. The design of this Phase III programme, which remains subject to discussion and agreement with the FDA, is currently planned to include 1,400 patients, each treated for 12 weeks. An additional safety/exposure study in up to 300 patients will provide data from 6 months of drug exposure. These studies are expected to be multinational and conducted at multiple centres in both the USA and Europe. In addition, it is planned that two human pharmacokinetics studies will be required and provision has been made for a third such study, if required.

Assuming the results of the ongoing Phase II trial support the further development of AGI-003 for d-IBS, AGI expects that it would commence discussions with the FDA to finalise the design of a Phase III clinical programme and other NDA requirements and that the Phase III clinical programme would commence in Q1/Q2 2007. Based on the experience of the Executive Management Team in conducting clinical trials in IBS, the Directors anticipate that this Phase III programme will be completed in the second half of 2008 and, in the event the programme results are supportive, a NDA can be filed for AGI-003 in the US prior to the end of 2008.

The Group expects to retain all rights to AGI-003 until this Phase III programme is completed and, dependent on the results of this programme, will then seek to enter into a licensing or other appropriate partnership agreement with a suitable pharmaceutical company where AGI may retain certain marketing rights for the US and possibly other countries to facilitate the Group's objective to participate to a greater degree in the commercial exploitation of certain of its product candidates.

AGI-001 — Functional Dyspepsia

AGI-001 is an oral dosage form of the S-isomer of pindolol which is being developed for the treatment of functional dyspepsia, a functional disorder of the upper GI tract, in both men and women.

Functional dyspepsia, also referred to as non-ulcer dyspepsia or NUD, is a cluster of chronic or recurrent upper GI symptoms, including early satiety, abdominal distension and fullness and discomfort and pain, not associated with any known structural abnormality.

Estimates as to the prevalence of functional dyspepsia vary, with some studies suggesting that it affects up to 25 per cent of the US population annually and accounts for up to 5% of all visits to primary care physicians, while other studies report a prevalence of between 10 and 20 per cent of the population in the US and Europe. The incidence of functional dyspepsia in men and women is similar. No prescription therapeutic drug products have been found to have a high success rate in the treatment of functional dyspepsia and there are as yet no therapeutic drug products approved for its treatment in the US. The Directors believe that functional dyspepsia represents an unmet medical need and that there are market opportunities for new functional dyspepsia therapeutic drug products.

The Group has developed a solid oral dosage form of AGI-001 and a Phase II clinical trial evaluating the efficacy of AGI-001 in the treatment of functional dyspepsia is currently ongoing. This trial is a randomised, double-blind, placebo-controlled, parallel group, dose escalation trial conducted at multiple sites in Europe in a total of 133 functional dyspepsia patients. The trial is fully enrolled and the treatment phase is now complete. It is expected that a final clinical report will be available in Q2/Q3 2006.

Dependent on the outcome of the current Phase II clinical trial, the Group will seek to enter into licensing agreements with one or more pharmaceutical companies for AGI-001 which will provide for the funding by its partner(s) of additional clinical and regulatory development and for the subsequent commercial marketing of this product candidate by its partner(s). AGI may retain certain marketing rights to AGI-001 to facilitate the Group's objective to participate to a greater degree in the commercial exploitation of certain of its product candidates.

AGI-001 — Irritable Bowel Syndrome

AGI-001 is also being developed by AGI for the treatment of irritable bowel syndrome in both men and women. The Directors believe that there are market opportunities for new IBS therapeutic drug products.

The Group has developed a solid oral dosage form of AGI-001 and a Phase II clinical trial evaluating the efficacy of AGI-001 in the treatment of irritable bowel syndrome is currently ongoing. This is a randomised, double-blind, placebo-controlled, parallel group, dose escalation trial conducted over multiple sites in Ireland in a total of 67 patients. It is expected that treatment of the last patient in the trial will be completed in Q1/Q2 2006 and that a final clinical report will be available in Q3/Q4 2006.

Dependent on the outcome of the current Phase II clinical trial, the Group will seek to enter into licensing agreements with one or more pharmaceutical companies for AGI-001 which will provide for the funding by its partner(s) of additional clinical and regulatory development and for the subsequent commercial marketing of this product candidate by its partner(s). AGI may retain certain marketing rights to AGI-001 to facilitate the Group's objective to participate to a greater degree in the commercial exploitation of certain of its product candidates.

AGI-004 — d-IBS

AGI-004 is a controlled release transdermal patch containing mecamylamine which is being developed by the Group for the treatment of diarrhoea-predominant irritable bowel syndrome ("d-IBS") in both men and women. The Directors believe that there are market opportunities for new d-IBS therapeutic drug products.

AGI-004 is a controlled release form of mecamylamine with a lower peak-to-trough drug exposure profile which, coupled with a reduction in daily dosage, has demonstrated marked GI effects and a reduction of

the traditional non-GI ganglion blocking effects. AGI has developed a controlled-release transdermal dosage form of AGI-004 and a Phase II clinical trial evaluating the efficacy of AGI-004 in the treatment of functional diarrhoea is currently ongoing. This trial is a randomised, double-blind, placebo-controlled, parallel group, dose escalation trial conducted at multiple sites in the US and Israel. It is intended to randomise a total of 78 patients and the trial is continuing to enroll patients. Completion of enrollment is targeted for Q1/Q2 2006 and it is expected that a final clinical report will be available in Q4 2006/Q1 2007. In the event that AGI-004 is successful in the current clinical trial, the Group expects that this product candidate will thereafter be developed for the treatment of d-IBS.

Dependent on the outcome of the current Phase II clinical trial, the Group will seek to enter into licensing agreements with one or more pharmaceutical companies for AGI-004 which will provide for the funding by its partner(s) of additional clinical and regulatory development for d-IBS and for the subsequent commercial marketing of this product candidate by its partner(s).

AGI-006 — Functional Dyspepsia

AGI-006 is an oral dosage form of the R-isomer of baclofen which is being developed by AGI for the treatment of functional dyspepsia in both men and women. The Directors believe that functional dyspepsia represents an unmet medical need and that there are market opportunities for new functional dyspepsia therapeutic drug products.

A solid oral dosage form of AGI-006 has been developed and a Phase II clinical trial evaluating the efficacy of AGI-006 in the treatment of functional dyspepsia in both men and women is currently ongoing. This is a randomised, double-blind, placebo-controlled, parallel group, dose escalation trial conducted at multiple sites in Europe. Completion of enrollment is targeted for Q2/Q3 2006 and it is expected that a final clinical report will be available in Q4 2006/Q1 2007.

Assuming the results of the ongoing trial support the further development of AGI-006 for functional dyspepsia, AGI intends to undertake a further Phase II clinical trial for AGI-006 in functional dyspepsia patients in order to more definitively investigate its use in this clinical indication. AGI does not currently anticipate it will enter into commercial or licensing agreements for AGI-006 until such time as this further Phase II clinical trial has been completed, which is currently estimated to occur before the end of 2008.

AGI-010 — Gastro-Esophageal Reflux Disease (Nocturnal Acid Breakthrough)

AGI-010 is a delayed/controlled release formulation of the proton pump inhibitor drug ("PPI"), omeprazole which is being developed by AGI for the treatment of Gastro-Esophageal Reflux Disease ("GERD"), and in particular for the treatment of Nocturnal Acid Breakthrough ("NAB"), a poorly controlled aspect of GERD.

GERD results in the reflux of gastric contents into the esophagus, causing symptoms (e.g. heartburn or acid regurgitation) that are sufficient to interfere with quality of life. NAB is defined as the presence of at least 60 continuous minutes of intragastric pH < 4 during the overnight period (10pm – 6am) in patients taking a ("PPI") drug twice daily before meals.

GERD is the most common of the major target GI disorders and it is estimated that its prevalence in the general population ranges from 20 to 40 per cent Proton pump inhibitors are commonly used drugs in the treatment of GERD and are one of the largest selling drug classes with global annual sales of US$21 billion. One of the most commonly prescribed PPI drugs is omeprazole, which was reported to have a 29 per cent share of the PPI market in 2003. GERD patients may be h.pylori positive or h.pylori negative. NAB is estimated to occur in more than 70 per cent of *h.pylori*-negative and in up to 50 per cent of *h.pylori*-positive patients on PPI therapy. Modification of the dosage regime of existing PPIs has only had limited success in controlling the symptoms of NAB despite improving acid suppression. The Directors believe that currently available PPI drugs do not adequately address the problem of NAB, which is a prevalent aspect of GERD, and that there are therefore market opportunities for improved PPI formulations.

AGI has developed CHRONAB, an approach to the formulation of PPIs to specifically address NAB. AGI's lead CHRONAB formulation is AGI-010, a delayed/controlled release formulation of omeprazole. This is designed to be taken once-daily at night-time and to release the drug over a 6-8 hour period, which the Directors believe may improve acid suppression during the night-time hours.

An oral delayed release/controlled release formulation of AGI-010 with the desired in vitro characteristics has been developed and a combined human pharmacokinetics and pharmacodynamics study has commenced. It is expected that a final clinical report will be available in Q3/Q4 2006.

Dependent on the outcome of the current clinical trial, the Group will seek to enter into licensing agreements for AGI-010 with one or more pharmaceutical companies which will provide for the funding by its partner(s) of additional clinical and regulatory development and for the subsequent commercial marketing of this product candidate by its partner(s).

AGI-022 — Ulcerative Colitis

AGI-022 is a delayed/controlled release oral formulation of 4-aminosalicylic acid ("4-ASA") which is being developed by AGI for the induction and maintenance of remission of mild to moderate ulcerative colitis ("UC").

Inflammatory bowel disease is a chronic inflammatory disorder of the digestive tract and is manifest as two distinctive and overlapping forms, Crohn's disease and ulcerative colitis. Although both forms share many characteristics, they are regarded and treated as separate diseases. UC is a chronic, recurrent, relapsing and remitting inflammatory disease of the colon and/or rectum.

The prevalence of UC is estimated at almost 1 million patients across the seven major pharmaceutical markets (US, Japan, Germany, UK, France, Italy and Spain) and the incidence of new cases in these countries is estimated at 50,000 per annum. The aminosalicylate class of anti-inflammatory drugs is used to treat UC and many of those currently marketed are presented as modified release oral formulations. Global annual sales of aminosalicylate drug products in IBD are currently estimated to be at least US$700 million annually. 4-ASA is an aminosalicylate drug which is not currently available in an oral modified release form for the treatment of UC. The Directors believe that there are market opportunities for new modified release oral formulations of 4-ASA for the treatment of ulcerative colitis.

AGI has completed a human pharmacokinetics trial to demonstrate the potential of AGI-022 in the treatment of ulcerative colitis where the new formulation has achieved the desired pharmacokinetic profile. AGI-022 is a reformulation of an existing approved drug, 4-ASA, and this product candidate is now ready to progress to planning for a Phase III programme for the treatment of ulcerative colitis.

AGI will seek to enter into licensing agreements with one or more pharmaceutical companies which will provide for the funding by its partner(s) of additional clinical and regulatory development of AGI-022 and for the subsequent commercial marketing of this product candidate by its partner(s).

(6) INTELLECTUAL PROPERTY AND PATENTS

The Directors place great emphasis on the creation, development and protection of the Group's intellectual property in the area of gastrointestinal therapeutic drug products. An independent report which provides, *inter alia*, an overview of patent protection generally and of AGI's patent strategy, patent applications made and patents granted on its product candidates and other additional compounds is set out in Part IV of this document (the "Patent Agents' Report").

The Group's patent protection strategy has generally involved filing US provisional applications to secure a priority date for inventive disclosure, followed by non-provisional applications and the filing of international patent applications complying with the Patent Cooperation Treaty. As part of this strategy, the Group is the beneficial owner of patent applications for the following of its clinical product candidates:

Product Candidate	***Patent Title***
AGI-003	Treatment of abnormal increases in gastrointestinal motility with (R)-verapamil.
AGI-001	Treatment and prevention of gastrointestinal disease using antagonist or partial agonists of 5HT1a receptors.
AGI-004	Treatment of Intestinal Conditions with N-2,3,3-Tetramethylbicyclo[2.2.1]Heptan-2-Amine.
AGI-006	Treatment of Gastroparesis and Non-ulcer Dyspepsia with GABAb Agonists.
AGI-010	Proton Pump Inhibitor Formulations, and Methods of Preparing and Using Such Formulations.
AGI-022	Formulations and Methods of Treating Inflammatory Bowel Disease.

The Group has progressed the filings in the US for the above product candidates to non-provisional application status and has been granted a US patent (No. 6,849,661) for its AGI-003 product candidate. AGI is also the owner of a granted US patent (No. 5,892,093) and equivalent granted patents in five other

European countries, all of which relate to AGI-003. In addition, provisional patent applications have also been made for the following compounds:

Product Candidate	*Patent Title*
AGI-007	Use of Delayed Release Metformin to Treat Constipation.
AGI-008	Use of Modified Release Acarbose to Treat Constipation.

A summary of AGI's pending patent applications and issued patents owned by or assigned to AGI including filing dates, application numbers, application and/or patent issue dates, patent numbers and relevant countries is provided in the appendix to the Patent Agent's Report. Prospective investors should read the whole of this document including the Patent Agents Report in Part IV, and not rely solely on this summary.

(7) THE PLACING

The Company is proposing to raise approximately €39.8 million (net of expenses) through a conditional placing arranged by Davy of 33,730,159 new Ordinary Shares at €1.26 (Stg£0.865) per share. The Placing is not being underwritten by Davy.

Pursuant to the Placing Agreement, Davy has agreed with the Company, on and subject to the terms set out therein, to use all reasonable endeavours to procure investors to subscribe for 33,730,159 new Ordinary Shares at the Placing Price. The Placing has been conditionally completed and no offer of any participation in the Placing is being made by means of this document or otherwise.

The Placing is conditional, *inter alia*, on:

(a) the Placing Agreement becoming unconditional and not having been terminated in accordance with its terms prior to Admission;

(b) Admission being effective on or before 27 February 2006 or such later date as Davy and the Company may agree (but in any event not being later than 15 March 2006).

Subject to the fulfilment of the conditions set out above and the other conditions in the Placing Agreement, it is expected that the new Ordinary Shares will begin trading on AIM and on the IEX on 27 February 2006. Settlement of the Placing is also expected to occur on the 27 February 2006. CREST accounts of Placing participants holding their new Ordinary Shares in uncertificated form will then be credited on or around 27 February 2006 and Placing participants holding their new Ordinary Shares in certified form will be despatched share certificates by 13 March 2006. Upon Admission, the new Ordinary Shares being issued pursuant to the Placing will rank *pari passu* in all respects with the Existing Issued Share Capital.

(8) USE OF PROCEEDS

The net proceeds of the Placing, amounting to approximately €39.8 million, will be used as follows:

(i) Approximately €21 million to fund a Phase III Clinical Programme on a lead product candidate;

(ii) Approximately €2 million to fund a further Phase II clinical trial on AGI-006; and

(iii) Approximately €16.8 million to fund the Group's research and development activities, corporate development and business and other overheads through to 2008.

(9) SUMMARY FINANCIAL INFORMATION

Financial information on AGI Therapeutics plc and AGI Therapeutics Research Limited in Part V and VI of this document has been prepared in accordance with International Financial Reporting Standards. Following Admission, the Group will prepare its financial information in accordance with IFRS and will report in accordance with IFRS for the year ended 31 December 2006. The following table which has been extracted without material adjustment from the Accountants' Report contained in Part VI of this document and comprises financial information on the Group for the period/year ended 31 December 2003 and 2004 and for the 9 months ended 30 September 2005. Prospective investors should read the whole of this document and not rely solely on this summary.

	3 months ended 31 December 2003 *€*	*Year ended 31 December 2004* *€*	*9 months ended 30 September 2005* *€*
Revenue	—	—	—
Operating loss	—	(2,703,364)	(3,416,051)
Loss for the period	—	(3,121,433)	(3,858,529)

Further financial information on the Group is set out in Parts V and VI of this document.

(10) CURRENT TRADING AND PROSPECTS

The Group currently has no trading income and expenditure relates to costs associated with clinical trials, research and development, working capital and general and corporate overheads. The Directors believe that, dependent on the outcome of current ongoing clinical trials, it may be possible to develop revenues through the out-licencing of certain of the Group's product candidates to pharmaceutical companies.

(11) DIRECTORS, SENIOR MANAGEMENT AND SCIENTIFIC ADVISER

Directors

Ronan Lambe BSc MSc PhD (aged 66), Non-Executive Chairman
Dr Lambe was appointed non-executive chairman of the Group in January 2006. Dr Lambe is a co-founder of ICON plc and served as chairman from June 1990 to November 2002 and continues to serve as an executive director. Dr Lambe has over 21 years of experience in the contract research industry in Europe and attended the National University of Ireland where he received his BSc in chemistry in 1959, his MSc in biochemistry in 1962 and was conferred with a PhD in pharmacology in 1976.

John Devane CDip (A&F) BSc PhD (aged 49), Chief Executive Officer
Dr Devane has been the chief executive officer of the Group since its formation in 2003 and was chief executive officer of Athpharma Limited from 2001 to 2005. Prior to this, Dr Devane worked in a number of roles in research and development, clinical and regulatory affairs and product development for Élan Corporation plc (1981-2001) and its subsidiary companies including executive vice president, R&D, Élan Drug Delivery (1996-2001); vice president, R&D, Élan Corporation plc (1993-1996); vice president, regulatory & clinical affairs, Élan Pharma USA (1990-1993) and director, product development, Élan Corporation plc (1987-1990). Dr Devane studied pharmacology at University College Dublin and received his BSc (Hons) in 1978 and was conferred with a PhD in 1982 also from UCD. Dr Devane also holds a certified diploma in accounting and finance (Association of Certified Accountants), has published in the scientific area, is the author of a number of book chapters and has been an invited speaker at international scientific/technical conferences.

Mary Martin CDip (A&F) BSc PhD (aged 41), Chief Operating Officer
Dr Martin has been chief operating officer of the Group since 2004. Prior to this Dr Martin worked in a number of roles in pharmaceutical research and development, project and portfolio management and other roles for Élan Corporation plc and its subsidiary companies including managing director, Élan Biotechnology Research (2000-2003); senior vice president, project & portfolio management, Élan Drug Delivery (1996-2000); head of biological sciences, Élan Drug Delivery (1994-1996) and manager technical data/director device development, Élan Corporation plc (1989-1994). Dr Martin is a pharmacologist and holds a PhD in pharmacology (University College Dublin, 1989), a BSc (hons) in pharmacology and toxicology (University College, Dublin, 1985) and a certified diploma in accounting and finance (ACCA, 1991).

Patrick Ashe BSc MBA (aged 43), Senior Vice President, Business Development
Mr Ashe has been senior vice president, business development of the Group since 2004 and has over 19 years of experience in business and commercial development roles in the pharmaceutical industry. Mr Ashe was senior vice president, business development of Athpharma Limited from 2002 to 2005. Prior to this, Mr Ashe worked in a number of commercial development roles for Élan Corporation plc and its subsidiary companies including vice president, commercial development, Élan Pharma USA (1994-2001); director, commercial development, Élan Corporation plc (1989-1994); and manager, commercial development, Élan Corporation plc (1986-1989). Mr Ashe graduated with a BSc in pharmacology from University College Dublin in 1985 and received his Masters in Business Administration in 1994 from Dublin City University.

John O'Sullivan BComm CDipFM (aged 38), Non-Executive Director
Mr O'Sullivan was appointed as a non-executive Director of the Group in 2004 following the equity investment in the Group by ACT. He is a partner in ACT and has over fifteen years experience in business development and venture capital investing. He is currently responsible for ACT's investments in Intense Photonics Limited, Adeptra Limited, Ultrasonic Scientific Limited and Silicon and Software Systems Limited. He joined ACT in 1998. Prior to this he held a number of business development and operational roles with Kindle Banking Systems (1990-1995), now a division of Misys plc., and worked with a range of industrial start ups with Enterprise Ireland (1995-1998). Mr O'Sullivan holds a BComm from University College Cork (UCC, 1990) and a Certified Diploma in Financial Management from the Association of Chartered Certified Accountants (ACCA, 1993). He is a guest lecturer with the UCC Faculty of Management and Marketing.

Peter Sandys BBS FCA (aged 49), Non-Executive Director
Mr Sandys was appointed as a non-executive Director of the Group in 2004 following the equity investment in the Group by Seroba BioVentures. Mr Sandys co-founded Seroba Bioventures in 2001 which manages the Irish BioSciences Venture Capital Fund, an Irish venture capital fund exclusively dedicated to the life science and medical device sectors on the island of Ireland. Mr Sandys is a chartered accountant and a founder director and former managing director of ABN Amro Corporate Finance (Ireland) Limited with over 20 years' experience in equity fund raising, company development and venture capital. He previously worked with Ernst & Young in Dublin and London and with 3i Venture Capital in Dublin.

Frank Kenny BComm MEconSc MBA (aged 61), Non-Executive Director
Mr Kenny was appointed as a non-executive Director of the Group in 2004 following the equity investment in the Group by Delta Partners. Mr Kenny founded Delta Partners in 1994, having previously worked in the venture capital industry in Boston from 1983 to 1993. He was on the board of many private technology companies in the U.S.A. and was on the board of two NASDAQ quoted companies, Abacus Direct Corporation and Vivid Technologies Inc. Mr Kenny currently serves on a number of private boards, including Advanced Surgical Concepts, Kelvinside, Qumas, Neurocure, Neoss, Xancom and Dublin Molecular Medicine Centre. Mr Kenny has a BComm and a MEconSc. from University College Dublin and an MBA from the University of Chicago.

Senior Management

Jackie Butler BSc PhD (aged 47), Senior Vice President, Biopharmaceutics
Dr Butler has been senior vice president, biopharmaceutics of the Group since 2004 and was senior vice president, Biopharmaceutics of Athpharma Limited from 2002 to 2005. Prior to this Dr Butler was head, biopharmaceutics & pharmacokinetics for Élan Corporation plc (1991-2001). Between 1984 and 1991 Dr Butler was a post-doctoral research fellow at University College Galway. Dr Butler received her BSc (Hons) in biochemistry from University College Cork in 1980 and was conferred with a PhD in 1984 from University College Dublin and the Royal College of Surgeons in Ireland.

Paul Stark BSc (aged 44), Senior Vice President, Pharmaceutical Development
Mr Stark has been senior vice president, pharmaceutical development of the Group since 2004 and was senior vice president, pharmaceutical development of Athpharma Limited from 2002 to 2005. Prior to this Mr Stark was vice president, pharmaceutical R&D, Élan Corporation plc (1994-2001); group leader, formulation process & analytical development, Mallinckrodt US (1992-1994); head, formulations & process development – Europe, Pitman Moore Europe, senior formulations scientist, SmithKline Beecham (1986-1990), product development scientist at the Spillers Research Centre, Cambridge, UK (1982-1986), and a formulation scientist with Reckitt & Colman from 1977 to 1982. Mr Stark has a BSc from the University of Leicester and is a member of the Royal Society of Chemistry and a Chartered Chemist.

The Group has used appropriately qualified professionals on an ongoing basis to satisfy its financial control. Following Admission, the Group will continue to retain an interim chief financial officer so as to satisfy its financial control and reporting requirements. When appropriate, it is the intention of the Directors to secure the appointment of a permanent chief financial officer, with appropriate financial and industry qualifications and expertise.

Interim Chief Financial Officer & Consultant

Paul Donnelly BComm FCA (aged 44)
Mr Donnelly is an independent financial consultant, trading as P&G Donnelly & Co.. He is engaged by the Group as Interim Chief Financial Officer until the recruitment of a permanent CFO. Mr Donnelly has extensive financial experience in the US multinational IT business environment and was until recently CFO and Company Secretary of Arnotts plc, a company that was listed on the official list of the Irish Stock Exchange. He received his BComm (Hons) from University College Dublin in 1981 and is a Fellow of the Institute of Chartered Accountants in Ireland.

Chief Scientific Adviser & Consultant

John Kelly BSc PhD FPSI (aged 57)
Professor Kelly is presently the director of the School of Pharmacy, Royal College of Surgeons of Ireland, a post he has held since 2000. Professor Kelly was chief scientific officer, Athpharma Limited from 2002 to 2005; head of research, Norbrook Laboratories (1998-2000); chief executive officer, Irish Medicines Board & EMEA board member (1995-1998); and chief scientific officer, Élan Corporation plc (1985-1995). Professor Kelly received a BSc (Pharmacy), first class honours, from Queen's University, Belfast, in 1969 where he was also conferred with a PhD in pharmacology in 1972. Professor Kelly is a Fellow of the Pharmaceutical Society of Ireland.

(12) REASONS FOR ADMISSION

The Directors believe that Admission is central to development of a successful business and will enable the Group to progress its business strategy described above.

The Board believes that Admission will have a number of other benefits, including the following:

- Admission will facilitate the ability of the Group to access the capital markets and take advantage of possible future acquisition and development opportunities, as and when they arise;
- Admission is expected to enhance the profile of the Group both among current and potential investors and the pharmaceutical industry in general;
- The provision of a share based incentive scheme to assist in the recruitment, incentivisation, reward and retention of high calibre employees; and
- To expand the Company's shareholder base, providing liquidity for current and future shareholders in the Company.

(13) LOCK-IN AND ORDERLY MARKET AGREEMENTS

At Admission, John Devane, Mary Martin, Patrick Ashe, Jackie Butler, Paul Stark and John Kelly, and their related parties/families (as defined in the AIM and IEX Rules) will be interested in an aggregate of 16,391,988 Ordinary Shares, representing approximately 24.3 per cent of the Enlarged Issued Share Capital. They have undertaken not to sell, transfer or otherwise dispose of any Ordinary Shares or any interest in Ordinary Shares held immediately following the Admission for a period of 12 months from the date of Admission (except in limited circumstances, including a takeover, death and court orders). In addition, they are, where they decide to sell Ordinary Shares within 12 months of the expiry of this lock-in period, obliged to sell the Ordinary Shares through Davy (or the Company's then broker).

In addition, ACT, Seroba, Delta and Merlin (the "Syndicate Investors") have undertaken in respect of in aggregate, 19,870,001 Ordinary Shares, representing approximately 29.5 per cent of the Enlarged Issued Share Capital not to dispose of such Ordinary Shares for a period of 12 months from the date of Admission (except in limited circumstances, including, a takeover and court orders). In addition, the Syndicate Investors, are, where they decide to sell Ordinary Shares within 12 months of the expiry of this lock-in period, obliged to sell the Ordinary Shares through Davy (or the Company's then broker).

(14) DIVIDEND POLICY

The Company is at a development stage and may require additional investment which could be financed from the raising of equity finance and/or from the reinvestment of future profits should they occur. It is not expected that dividends will be paid to Shareholders in the foreseeable future.

(15) DEALING ARRANGEMENTS

CREST is a paperless settlement system enabling securities to be evidenced otherwise than by certificate and transferred otherwise than by written instrument in accordance with the CREST Regulations. The

articles permit the holding of Ordinary Shares to be evidenced in uncertificated form and settlement of transactions in the Ordinary Shares may, following Admission, take place within the CREST system if Shareholders so wish.

CREST is a voluntary system and holders of Ordinary Shares who wish to receive and retain share certificates will be able to do so.

(16) TAXATION

All information in relation to taxation in this document is intended only as a general guide to the current tax position in Ireland or the United Kingdom. If you are in any doubt as to your own tax position, or are subject to tax in a jurisdiction other than Ireland or the United Kingdom, you should consult your own independent professional adviser immediately. The attention of prospective investors is drawn to the taxation section in section 13 of Part VII of this document.

(17) TRENDS

Save as set out in this document, there are no known trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on the Group's prospects for at least the current year.

(18) CORPORATE GOVERNANCE

The Directors intend to develop appropriate measures (having regard to the current stage of development of the Company), to comply as far as is practicable with the Combined Code, as applicable to listed companies and set out in the Listing Rules of the UK Listing Authority and the Listing Rules of the Irish Stock Exchange.

The Board is comprised of 3 executive directors and 4 non-executive directors. The Company will hold Board meetings throughout the year at which reports relating to the Group's operations, together with financial reports, will be considered. The Board is responsible for formulating, reviewing and approving the Group's strategy, budgets, major items of capital expenditure and acquisitions.

The Board has, conditional on Admission, established an audit committee and a remuneration committee with formally delegated duties and responsibilities. The remuneration committee comprises Frank Kenny, Ronan Lambe and John O'Sullivan and is responsible for determining the terms and conditions of service, including remuneration and other benefits granted or proposed to be granted by the Company. The audit committee, comprising of John O'Sullivan and Peter Sandys, has primary responsibility for monitoring the quality of internal controls, ensuring that the financial performance of the Group is properly measured and reported on, and for reviewing reports from the Group's auditors relating to the Group's accounting and internal controls.

The Directors intend to comply with Rule 21 of the AIM Rules and Rule 21 of the IEX Rules relating to directors' dealings as applicable to AIM and IEX companies respectively and will take all reasonable steps to ensure compliance by the Group's applicable employees.

(19) FURTHER INFORMATION

Your attention is drawn to the additional information set out in Part VII of this document.

(20) RISK FACTORS

The AIM and IEX markets are designed primarily for emerging or smaller companies to which a higher investment risk than that associated with larger or more established companies tends to be attached. A prospective investor should be aware of the potential risks of investing in such companies and should make the decision to invest only after careful consideration and, if appropriate, consultation with an independent financial adviser being, in the case of persons resident in the United Kingdom, a person authorised under the Financial Services and Markets Act 2000 and, in the case of persons resident in Ireland, a person authorised or exempted under the Investment Intermediaries Act 1995 or the Stock Exchange Act 1995 of Ireland.

Your attention is drawn to the Risk Factors set out in Part II of this document.

PART II — RISK FACTORS

In evaluating the Group as an investment proposition, the Directors consider that prospective investors should take account of all the information set out in this document and the risks attaching to an investment in the Group, including, in particular, the risks described below, prior to making any investment decision. The information below does not purport to be an exhaustive list or summary of the risks which the Group may encounter. Investors and prospective investors should consider carefully whether an investment in the Group is suitable for them in light of the information in this document and the financial resources available to them.

The Group's business, financial condition or results of operations could be materially and adversely affected by any of the risks described below. In such case, the market price of the Ordinary Shares may decline due to any of these risks and investors may lose all or part of their investment. Additional risks and uncertainties not presently known to the Directors, or that the Directors currently deem immaterial, may also have an adverse effect on the Group.

(A) CLINICAL TESTING AND REGULATORY ENVIRONMENT

The clinical evaluation, development, manufacturing and marketing of the Group's product candidates are and will be subject to extensive regulation by government and regulatory agencies in all the countries in which it intends to test or market them. Of particular importance is the requirement to obtain and maintain approval for its product candidates from the applicable regulatory authorities to enable them to be marketed. Such approval requires the clinical evaluation of data relating to the safety, quality and efficacy of a product candidate. Many countries, including the US, have very high standards of technical appraisal. Accordingly, the clinical trials process, and the obtaining of regulatory approval, are, in most cases, costly and very lengthy, and the time necessary to obtain regulatory approval, which varies among product candidates and between countries, is affected by numerous factors, most of which are beyond the Group's control.

The Group has not yet completed the development of any of its product candidates. The GI therapeutic categories and clinical indications to which the Group is targeting its product candidates represent areas of significant clinical and regulatory challenges in terms of establishing efficacy and safety for therapeutic drug products, and many other drug products in development by other companies for these GI clinical indications have to date failed in either the clinical or regulatory process. This is particularly so in the case of the functional GI disorders, where most of the Group's current product candidates are targeted, where the diseases and disorders, their aetiologies and underlying mechanisms, are themselves poorly defined and understood, and have proven difficult to accurately diagnose. There can be no assurance that any of the Group's product candidates will complete the required clinical trials process successfully or that regulatory approvals to manufacture and market its product candidates will be obtained in a timely manner or at all.

Clinical trials have a high risk of failure and negative results can occur in advanced clinical trials even after promising results in earlier trials. Further, even if granted, the terms of any product approval may be more restrictive than the Group desires and could affect the marketability of the relevant product. Furthermore, if regulatory approval is obtained, the relevant product, and its manufacture, will be subject to continual review and there can be no assurance that required approvals will not be withdrawn or restricted. Even if the Group receives regulatory approvals, once marketed its products may exhibit adverse effects that limit or prevent their widespread use or that cause the products to lose their approvals and force them to be withdrawn from the market. This risk may be increased where a product had been granted orphan drug status as a result of the more limited clinical testing which may be conducted prior to marketing approval being granted, further post-clinical marketing studies for these products may be required and there can be no guarantee that such studies will corroborate the results of earlier trials. Furthermore, the market use of such products may show different safety and efficacy profiles to those demonstrated in the trials on which marketing approval was based. Such circumstances could lead to the withdrawal or suspension of marketing approval for affected products.

There can also be no guarantee that the facilities at which the Group's products are manufactured or tested will achieve compliance with required standards to enable their use in trials or their approval for sale.

In addition the Group cannot predict the extent to which it may be affected by legislative and regulatory developments affecting its product candidates and the healthcare field generally. In particular there can

be no guarantee that the regulations or policies applied by the regulatory authorities will not change and any such change may render the Group's trials and programmes inadequate for their intended purpose and/or require the Group to undertake additional work, which may not be successful in complying with revised standards.

(B) DEPENDENCE ON THIRD PARTY SERVICE PROVIDERS

The Group uses various service providers to conduct the various synthesis, formulation, manufacturing, clinical and regulatory work to its specifications as required. The Group has no such facilities of its own and therefore depends and will continue to depend upon third parties for their services. The Group may well experience difficulties in obtaining access to these services at an acceptable cost or current arrangements with service providers may be terminated at short notice which could seriously inhibit the evaluation and development of the Group's product candidates or otherwise have a material adverse effect on the Group's operating results and financial condition. The Group will be reliant on such service providers maintaining sufficient and adequate quality control and assurance systems and general compliance with regulatory and statutory standards and requirements and any or all of the development, regulatory approval and continued market supply of the Group's product candidates may be adversely affected in the event that its service providers fail to meet and maintain such standards and requirements.

(C) DEPENDENCE ON LICENSING PARTNERSHIPS

A significant part of the Group's strategy is to enter into partnerships and alliances, such as licensing agreements, with appropriate pharmaceutical companies to provide for the further development, funding and commercial exploitation of its product candidates by its partners, as well as providing future sources of revenues for the Group. The Group has no such arrangements at present and the Group's future results of operations will, therefore, depend to a significant extent upon its ability to secure such arrangements on satisfactory terms. Given the unpredictability of pharmaceutical product development and acceptance, in particular, in the context of some of the diseases and clinical indications at which the Group's product candidates are targeted, attracting appropriate partners on satisfactory terms may be difficult, especially with product candidates that are not totally new entities. There can be no guarantee that the Group will be able to secure any such arrangements for its product candidates, or that potential or then existing licensing partners will not enter into exclusive relationships with the Group's competitors. Failure to secure such licensing agreements for its product candidates or the loss of any then existing licensing partners could have a materially adverse effect on the Group's business, financial condition or results of operations.

The Group anticipates that many of its product candidates will be developed under such partnership arrangements where the future control, timing and funding of the further development of these product candidates may be fully or substantially in the control of the partner, and be subject to the partner's ability to provide adequate resources for the development and regulatory process, and therefore the timing of key development processes, clinical trials, regulatory filings and market introduction of its product candidates may be significantly and negatively affected, including the timing of dependent revenues for the Group, in the event the partners' resources or capabilities are inadequate to meet the development timelines anticipated by the Group.

(D) COMPETITION AND MARKET ACCEPTANCE

The healthcare market is increasingly competitive and the Group expects competition for its product candidates which are under development currently. Competition may come from companies which have greater research, development, marketing, financial and personnel resources than the Group. Competitors may precede the Group in development and receiving regulatory approval or may succeed in developing products that are more effective or economically viable than product candidates developed by the Group. Such activities could render the Group's product candidates obsolete and/or otherwise uncompetitive. The Group's strategy of focussing on a single, therapeutic area may magnify the competitive risk.

Even if regulatory approval is obtained for its product candidates, the success of the Group will also depend on the market acceptance of those products and there can be no guarantee that this acceptance will be forthcoming. A number of the Group's product candidates are targeted at diseases and clinical indications which are currently poorly understood, making it difficult to predict which therapeutic drug products will ultimately be widely used and which will fail. Furthermore, it can be more difficult to achieve

acceptance of what is perceived as an "old product" in a new indication. Notwithstanding the technical merits of any product candidate(s) which may be developed by the Group, there can be no assurance that medical practitioners will adopt such product candidates as a standard means of medical practice or that the clinical indications and associated medical procedures to which the Group's product candidates are targeted will maintain market acceptance. Even if the Group's product candidates achieve market acceptance, the market may not be large enough to allow it to generate an adequate return. The failure of the Group's product candidates to achieve market acceptance would prevent it from ever generating meaningful product revenues from those product candidates.

Your attention is drawn to the Experts' Report contained in Part III of this document.

(E) INTELLECTUAL PROPERTY RIGHTS

The Group's ability to commercialise its product candidates and to compete effectively with other companies depends, *inter alia*, on its generation, maintenance, protection and exploitation of its intellectual property relevant to its product candidates. However, competitors may have already developed, or may develop, substantially equivalent information or techniques, or otherwise gain access, to the Group's technology, or otherwise exploit its intellectual property. Those of the Group's patent applications now pending, or which may be applied for in the future, may not lead to patents being granted, and patents already granted, or which may be granted in the future, in respect of the Group's product candidates may not be sufficiently broad in their scope to provide protection for the Group against third party competition.

There cannot be any assurance as to the ownership, validity or scope of any patents which have been, or may in the future be, issued to the Group, or of its patent applications, or that the claims of its patents and patent applications will not be contested by other parties or that they will not be revoked or refused. Despite the efforts the Group may make to enforce its intellectual property, third parties may attempt to infringe, and succeed in infringing, its intellectual property, or may obtain and use information which the Group considers proprietary. Substantial costs may be incurred and resources depleted, if the Group challenges the proprietary rights of others or is required to defend its own proprietary rights.

The commercial success of the Group will also depend upon its not infringing the intellectual property of third parties who may have filed applications, or who have obtained or may obtain patents, which might inhibit the Group's ability to develop or exploit its own product candidates. In particular, the Group may have to obtain alternative products or technology, or reach commercial terms, on the exploitation of other parties' intellectual property rights. There can be no assurance that the Group will be able to obtain alternative products or technology or, if any licences are required, that the Group will be able to obtain any such licence on terms acceptable to the Group, if at all, such that it may have to cease the development or use of affected product candidates or expend significant resources in developing or acquiring alternative products. This could have a material adverse effect on the business of the Group. The Group may also have to pay significant damages and legal and other costs if it infringes third party intellectual property. Defending allegations of intellectual property infringement may also be extremely protracted and expensive, even if not ultimately proven.

The Group also relies on unpatented proprietary information, which it generally seeks to protect by confidentiality agreements with its employees, consultants and third party service providers and potential licensing partners. Nevertheless, these agreements may not effectively prevent disclosure of the Group's confidential information and may not provide the Group with an adequate remedy in the event of an unauthorised disclosure of such information. If such parties develop inventions or processes independently that may be applicable to the Group's product candidates, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become the Group's property, but may remain the property of those parties. Protracted and costly litigation could be necessary to enforce and determine the scope of the Group's proprietary rights. Failure to obtain or maintain patent and confidential information, for any reason, could have a material adverse effect on the Group's business, results of operations and financial condition.

Certain intellectual property rights acquired by the Group contain obligations and performance requirements which if not met or fulfilled, may result in the loss of the intellectual property rights and products.

Your attention is drawn to the Patent Agents' Report in Part IV of this document.

(F) THE NEED FOR ADDITIONAL CAPITAL IN THE FUTURE

The Directors believe that the net proceeds of the Placing will meet the Group's current funding requirements, that is for at least the next twelve months. However, the Group's capital requirements depend on numerous factors, including the rate of market acceptance of its products and its ability to establish, maintain and expand its licensee/partner base, the progress of clinical testing and development of its product candidates, the costs and timing of seeking regulatory approvals of its product candidates, the Group's ability to obtain the necessary regulatory approvals, the Group's degree of success in entering into satisfactory partnerships and alliances with other pharmaceuticals companies to provide for the commercialisation of its product candidates. Other factors include potential costs in filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights as well as more general factors such as changes in economic, regulatory or competitive conditions.

Significant additional capital is likely to be required if in the future the Group were to seek to establish its own direct sales and marketing capability and infrastructure in the US to commercialise one or more of its product candidates. It is difficult for the Directors to predict the timing and amount of the Group's capital requirements with accuracy. If its capital requirements vary materially from its plans, the Group may require further financing in addition to amounts raised in the Placing. There can be no guarantee that any such financing will be available to the Group, or, if available, that it will be available on acceptable terms. The Group's ability to raise additional financing will be adversely affected if the results of ongoing or future clinical trials are not favourable or if regulatory approval for any of its product candidates is not obtained. Any additional equity financing may be dilutive to shareholders of the Group, and debt financing, if available, may involve restrictions on financing and operating activities. The Group may be required to obtain additional financing through arrangements with future collaborative partners or others that may require it to relinquish rights to some or all of its product candidates. If the Group is unable to obtain additional financing as needed, it may be required to reduce significantly the scope of its operations.

(G) DEPENDENCE ON KEY EXECUTIVES AND PERSONNEL

Whilst the Group has entered into employment arrangements with each of its key personnel with the aim of securing their services, the retention of their services cannot be guaranteed. The loss of any member of the Executive Management Team or key consultants could harm or delay the plans of the business either whilst management time is directed to finding suitable replacements or if no suitable replacement is available to the Group. In either case, this may have a material adverse effect on the future of the Group's business.

(H) HISTORY OF OPERATING LOSSES AND ACCUMULATED DEFICIT

The Group has a history of operating losses and the Company has not traded since its incorporation. As at 30 September 2005, AGI Therapeutics Research Limited's retained losses as extracted from the Accountants' Report set out in Part VI of this document were €6,979,962. The Group expects to incur further substantial operating losses for the foreseeable future as its research and development activities continue and increase. There can be no assurance that the Group will ever achieve revenues or profitability.

(I) FOREIGN CURRENCY EXCHANGE RATE RISK

Changes in currency exchange rates may harm the financial condition of the Group through both transaction and translation risks. If the Group succeeds in licensing or commercialising any product candidate, a large part of its revenues and costs will be outside Ireland and the Group may be affected by currency fluctuations. In particular, changes in the US dollar – euro exchange rate will affect the translation into euro of any future US dollar based revenues and costs.

(J) PRODUCT LIABILITY/INSURANCE RISKS

Clinical testing, manufacturing, marketing and selling of pharmaceutical products entails a risk of product liability. In recent years, the healthcare environment has become increasingly litigious and awards and settlements may be substantial. Clinical trial insurance and product liability insurance coverage is difficult to obtain and expensive. The nature of the Group's business means that the Group may be exposed to potentially substantial liability for damages during clinical trials, in the event of product failure or adverse

side effects. Any such liability could have a material adverse effect on the Group's business and financial condition. There can be no assurance that future necessary insurance cover will be available to the Group at an acceptable cost, if at all, nor that in the event of any claim, the level of insurance carried by the Group now or in the future will be adequate or that a clinical trial product liability or other claim would not materially and adversely affect the business and financial condition of the Group.

The Group's operations are also subject to environmental and safety laws and regulations. The cost of compliance with these and similar future regulations could be substantial and the risk of accidental contamination or injury from the biological and other hazardous materials with which it works cannot be eliminated. If an accident or contamination occurred, the Group would likely incur significant costs associated with civil damages and penalties or criminal fines, and in complying with environmental laws and regulations. The Group's insurance may not be adequate to cover the damages, penalties and fines that could result from an accident or contamination and the Group may not be able to obtain adequate insurance at an acceptable cost or at all. The Group does not currently manufacture any pharmaceutical products internally.

(K) PHARMACEUTICAL PRICING ENVIRONMENT

If regulatory approval is obtained for its product candidates, the ability of the Group and its partners to market those product candidates successfully will depend in part on the extent to which reimbursement for the cost of such product candidates and related treatments will be available from government health administration authorities, private health coverage insurers and other organisations. Third party payers are increasingly challenging the pricing of therapeutic drug products. There is significant uncertainty as to the reimbursement status of newly approved healthcare products, and there is no assurance that adequate health administration or third party coverage will be available for the Group or its licensees to obtain satisfactory price levels for its product candidates to realise an appropriate return on its investment. In addition, there is increasing pressure by certain governments to contain healthcare costs by limiting both the extent of coverage and the level of reimbursement for new therapeutic drug products, and by refusing in some cases to provide coverage for uses of such products for disease conditions for which the relevant regulatory agency has not granted marketing approval.

(L) INVESTMENT IN AIM AND/OR IEX QUOTED SECURITIES

The value of the Ordinary Shares may go down as well as up. Furthermore, an investment in an ordinary share or other security that is traded on AIM and/or IEX is likely to carry a higher risk than an investment in a share or other security listed on the Official Lists. The market price of the Ordinary Shares may not reflect the underlying value of the assets of the Group. The market in the Ordinary Shares may be illiquid, may not have sufficient market makers giving a quotation, have a large bid offer spread, may be subject to sudden or large fluctuations and it may therefore be difficult for investors to sell their Ordinary Shares and they may receive less than the amount originally invested.

The share price of publicly traded biotechnology and/or pharmaceutical companies can be highly volatile. The price at which the Ordinary Shares will be quoted and the price which investors may realise for their Ordinary Shares will be influenced by a large number of factors, some specific to the Group and its operations and some which may affect the quoted biotechnology and pharmaceutical sector, or quoted companies generally. These factors could include the performance of the Group's research and development programmes, large purchases or sales of the securities, legislative changes in the healthcare environment and general economic conditions.

Admission should not be taken as implying that there will be a liquid market for the Ordinary Shares. It may be more difficult for an investor to realise his investment on AIM or IEX than to realise an investment in a company whose shares or the securities are quoted on the Official Lists.

The investment offered in this document may not be suitable for all of its recipients. Investors are accordingly advised to consult an independent financial adviser, who in Ireland, is an organisation or firm authorised or exempted pursuant to the Investment Intermediaries Act 1995 or the Stock Exchange Act 1995, and in the UK, is authorised under the Financial Services and Markets Act 2000 who or which specialises in investments of this kind before making any decision to invest in Ordinary Shares.

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21 February 2006

Dear Sirs

Bridgehead International Limited ("Bridgehead") is a privately owned Company established in 1995. It is a leading consultancy specialising in the assessment of healthcare companies, projects, products and markets and assisting in their development. Over the past 10 years Bridgehead has prepared reports for public and private placing documents for development stage biotechnology, pharmaceutical and life sciences companies. In addition many due diligence assignments have been successfully completed on behalf of international investors. Bridgehead employs specialists with knowledge of science, technology, product development, markets and business issues in medicine and life sciences.

Bridgehead has been instructed on behalf of AGI Therapeutics plc and its subsidiary companies ("AGI" or "the Group") and Davy to assess and review certain aspects of AGI's business plan and product candidates, namely:

- The merits and current status of the Group's product candidates;
- Certain relevant aspects of the Group's business plan, including the critical path and timescale to development and commercial exploitation of the Group's product candidates and current and any projections of the market potential for these product candidates; and
- Certain general risk factors which might affect the Group's product candidates.

Detailed assessment of the intellectual property position is specifically excluded from the report. Assumptions on patent expiry and freedom to use were provided by AGI.

Bridgehead International Limited
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In preparing this report, Bridgehead's consultants have conducted discussions with John Devane, Mary Martin, Patrick Ashe, Paul Stark, Jackie Butler and John Kelly, reviewed the documentation provided by AGI and assessed its activities with reference to the proprietary knowledge base possessed by Bridgehead. This report has been prepared with care and due diligence, based upon information provided to Bridgehead from the Group and from other public and private sources at the time of the report's preparation. Bridgehead has no reason to doubt the veracity of such information but Bridgehead has only verified it to the extent indicated above. Changes in circumstances may render such information invalid at any point hereafter. The scope of this report does not address the legal aspects of AGI's operations or its intellectual property. No audit or assessment of facilities was undertaken.

The Bridgehead Experts' Report is included in this Admission Document dated 21 February 2006. Bridgehead accepts responsibility for the information contained in this Part III of this document. To the best of the knowledge of Bridgehead (which has taken all reasonable care to ensure that such is the case), the information contained in this Part III of this document is in accordance with the facts and makes no omission likely to affect the import of such information.

Bridgehead consents to the issue of the Admission Document with the inclusion of its name and the contents of this report and the references to such report and its name in which they appear. The information contained in this Part III of the Admission Document accurately reproduces the contents of our report, and to the best of our knowledge, no facts have been omitted which would render any such information inaccurate or misleading.

Bridgehead confirms that its directors and employees are wholly independent from the Group and its product candidates. Except for the provision of professional services neither Bridgehead or any director or employee has any shareholding, commercial arrangement or any other interest in AGI Therapeutics plc or the Group's product candidates and neither the engagement to make the Experts' Report nor the compensation payable is contingent on the Experts' Report or future income or development for the Group's product candidates.

1.0 Overview

AGI is a speciality pharmaceutical company, focused exclusively on the mid-late stage development of product candidates in the gastroenterology area. Their portfolio is derived from the KME (Known Molecular Entity) approach to drug development. The Group has 7 clinical trials on 6 product candidates (3 single isomer products and 3 new formulation approaches), as follows:

Product candidate	*Description*	*Target indication*	*Clinical trial (ongoing)*	*Expected in-house development and completion timing:*	*Anticipated commercialisation route*
AGI-003	R-isomer verapamil	D-IBS	Phase II	End Phase III (Q3/4 2008)	Out-licence, reserving co-promotion rights in the US
AGI-004	Low dose CR mecamylamine	D-IBS	Phase II	End Phase II (Q4 2006/Q1 2007)	Out-licence
AGI-001	S-isomer pindolol	Functional dyspepsia	Phase II	End Phase II (Q2/3 2006)	Out-licence, reserving co-promotion rights in the US
AGI-001	S-isomer pindolol	IBS	Phase II	End first Phase II trial (Q3/4 2006)	Out-licence, reserving co-promotion rights in the US
AGI-006	R-isomer baclofen	Functional dyspepsia	Phase II	End second Phase II trial (Q3/4 2008)	Out-licence
AGI-010	DR/CR omeprazole	GERD/NAB	Human PK/PD	End Human PK/PD (Q3/4 2006)	Out-licence
AGI-022	DR/CR 4-ASA	Ulcerative colitis	End Human PK	End Human PK (Q1 2006)	Out-licence

In addition it is planned to develop another Delayed release/Controlled release ("DR"/"CR") proton pump inhibitor product based on the Group's "CHRONAB" drug delivery technology, and the Group is considering further opportunities for its IP.

2.0 AGI's capabilities and plans

Management

AGI has an experienced senior management team drawn from the pharmaceutical industry. Bridgehead believes that this management team brings appropriate expertise to key roles in drug development, clinical trials management, regulatory strategy and commercialisation for the types of product candidate under development by the Group.

R&D, clinical and regulatory affairs

Product candidates are selected, and the development strategy for these is determined by the management team who have extensive experience of the development of these types of products. The implementation of the development plan is then generally managed on a fee-for-service basis through third party laboratories, clinical research organisations and contract manufacturers. With regard to regulatory matters, production and control of key reports and documentation is retained in-house but submissions and regulatory interactions are managed through contract research organisations with Group involvement. In Bridgehead's opinion this is a reasonable model for a company of this type.

Regulatory strategy

By developing product candidates from KMEs, AGI will normally be able to cross refer to relevant existing toxicological and clinical data from previous approvals that AGI does not directly own or have access to. In the US this type of regulatory application is referred to as a 505(b)(2) application.

Manufacturing

The Group utilises a number of reputable contract manufacturers, with capacity, regulatory approvals and quality controls appropriate to the stage of development of the products. To date single sources are in place but Bridgehead believes that alternatives could be identified if this were necessary. In most cases the Group envisages that licensees will wish to manufacture to supply the market. This is a reasonable approach.

Commercialisation strategy

AGI's aim is develop further into a specialty pharmaceutical company which includes the possibility of developing a gastroenterology focused US specialist sales and marketing infrastructure post 2008. Up to 2008, it plans to continue to invest in development activities to support its portfolio of product candidates and it will then seek to out-licence its product candidates upon completion of various clinical trials.

AGI currently intends to fund only one product candidate through to regulatory filing; this is currently anticipated to be AGI-003 for d-IBS. As part of any licensing agreement, it will seek to retain co-promotion rights in the US for this product candidate. It will also seek to retain US co-promotion rights for AGI-001 in functional dyspepsia and IBS, though it will seek a licensee at the end of Phase II in both FD and IBS to fund the further development of the product candidate. The roles of the product candidates in this overall plan may change as their profiles develop, but the general approach is expected to remain similar.

The approach described follows a pattern now adopted by a number of new entrant and more established pharmaceutical companies, especially those targeting US markets. It reduces certain risks by ensuring that the most expensive and resource intensive part of the development of most product candidates is funded and directed by licensees, while retaining enough rights to ensure that the originator has a prospect of earning satisfactory revenues in the longer term. This strategy recognises the weaknesses of the total out-licence based approach which leaves the licensor with little development or marketing control over the product candidates and has typically yielded disappointing revenues.

The proposed approach is also very flexible in its structure in that the Group has not yet committed to a particular lead product candidate. This is a wise approach given the unpredictability of pharmaceutical

product development and the risks of development failure. This flexibility is possible because the Group has a number of product candidates in its pipeline that are at a broadly similar stage of development, which is more than is usually found in companies of this type.

The Group's proposed approach still carries some commercial risks. Appropriate partners must still be found, which may be rather more difficult with KME-based product candidates than for new chemical entities at a similar stage of development.

Although not intended to occur until post-2008, it must be noted that establishment of a US specialist sales and marketing base has also been problematic for a number of European entrants in the past, given the cost and know-how required. The Group has not put forward plans for establishing its US presence since this is likely to take place after 2009. Provisionally, however, Bridgehead believes that sufficient resources to address the specialist GI market of some 10,000 physicians in the US could be justified to support two product candidates, such as AGI-001 and AGI-003.

3.0 Programmes

3.1 AGI-003 for D-IBS

3.1.1 Description and rationale

AGI-003 is the R-isomer of verapamil, a calcium channel blocking agent, being developed by AGI as a prescription-only oral product for treatment of diarrhoea-predominant irritable bowel syndrome (D-IBS) in both men and women. It is currently in Phase II.

IBS is a functional disorder (i.e. an abnormality or disturbance of normal function which cannot be directly attributed to anatomical or biochemical defects) that comprises a cluster of gastrointestinal symptoms which are likely to be life long and can include diarrhoea, constipation, abdominal pain and distension, which vary in intensity. It is estimated that the D-IBS subtype affects approximately 30 per cent of the overall IBS patient population.

As a racemic mixture of the R- and S- isomers, verapamil is approved for the treatment of hypertension, angina and cardiac arrhythmias at doses of up to 480mg/day. It has also been used off-label in various motility/diarrhoea conditions in both males and females. The cardiovascular effects of verapamil predominantly reside in the S- isomer, whilst R-verapamil shows relative selectivity for colonic over vascular tissue. In clinical use constipation is one of the most frequently reported adverse effects of racemic verapamil. In addition verapamil has been reported to have beneficial effects in gastrointestinal conditions associated with diarrhoea, including IBS. Other actions of verapamil that may contribute to its gastrointestinal effects are effects via opioid receptors, reduction in enteral 5-HT release and 5-HT_2 or 5-HT_3 receptor antagonism

3.1.2 Clinical/regulatory status and plans

Phase II trial – ongoing

This is a randomised, double-blind, placebo-controlled clinical trial of AGI-003 in the treatment of non-constipation predominant irritable bowel syndrome. The primary objective of the trial is to determine the efficacy of R-verapamil in the treatment of IBS, based on the patient's global impression, relief of abdominal discomfort/pain and use of rescue medication. Patient inclusion criteria are based on modified Rome II criteria.

Following an 8-14 day run-in period, where eligibility to participate in the trial was determined, patients were randomised to receive AGI-003 or placebo for the first four weeks. In the protocol patients receiving AGI-003 had the dose doubled for a further four weeks and doubled again for the final four weeks, providing the previous dose was well tolerated.

The protocol aim was to randomise 125 patients to ensure completion of 100. Thirteen centres are participating, 9 in Poland (1 inactive) and 4 in Lithuania. Bridgehead understands that the trial, which seems to be adequately powered to give a statistically significant result, is fully recruited with 128 patients, all of whom have completed treatment. The results of the trial will be available in Q2/3 2006.

Planned studies

Subject to a satisfactory result from the ongoing Phase II trial, AGI plans to apply for a meeting with the FDA in Q2/3 2006 to discuss and agree the proposed Phase III programme in D-IBS. The current

estimation is that this programme will include two Phase III efficacy trials involving 1,400 patients, each treated for 12 weeks. An additional safety/exposure trial, in up to 300 patients, will provide data from 6 months of drug exposure. The trials are expected to be multicentre and multinational with centres in both the US and Europe. AGI estimate that two human pharmacokinetic trials will be required to bridge to the existing wealth of clinical and preclinical data on racemic verapamil. Provision has been made in the budget for a third pharmacokinetic trial, if required.

It is anticipated that the future programme will be agreed by end Q3/Q4 2006, so clearing the way for the Phase III trials to commence recruitment in Q1/2 2007 and complete 18 months later (Q3/4 2008). At this stage the timing and budget estimates seem reasonable but will be subject to the agreement of FDA to the planned programme and final negotiation of costs and timing with third party suppliers.

3.1.3 Market potential

Patient numbers

There are varying estimates of the incidence and prevalence of IBS, with population-based studies in the US estimating prevalence at 10-20 per cent. Incidence has been estimated at 1-2 per cent per year in Europe and the US. Overall only 10-25 per cent of all subjects with symptoms consistent with irritable bowel syndrome seek medical care.

Estimates of the relative prevalence of the subtypes vary. Frost and Sullivan, for example, have estimated that there is an equal prevalence of constipation predominant IBS (C-IBS), diarrhoea predominant IBS (D-IBS) and mixed symptom IBS (M-IBS). A National Opinion Polls survey sponsored by GlaxoSmithKline resulted in an estimate of prevalence of 28 per cent, 29 per cent and 33 per cent in each such category respectively, 10% were unclassified.

Current treatment

Treatment of IBS remains based around patient education, lifestyle and dietary changes. Initial drug treatment is usually directed at the predominant symptoms, for example, using laxatives, stool softeners and anti-diarrhoeals. Anti-cholinergics, anti-spasmodics and anti-depressants are also commonly used.

The 5-HT_3 receptors mediate physiological motor and secretory actions in the GI tract, and can therefore retard small bowel and colonic transit. The 5-HT_4 receptors mediate the peristaltic reflex, and can therefore accelerate the small bowel and colonic transit. 5-HT modulators are beginning to have an impact on IBS therapy, these include alosetron (Lotronex®, GlaxoSmithKline, for D-IBS) and tegaserod (Zelnorm®/Zelmac®, Novartis, for C-IBS). In Japan, mosapride (Gasmotin®, Dainippon) is also on the market. Each of these is discussed in more detail below. As things stand however, the only current competitor specifically in the D-IBS arena is Lotronex®, which is severely compromised as a result of its side effects.

Alosetron (Lotronex®) is a 5-HT_3 antagonist and is indicated for the treatment of women only with severe D-IBS. Initially launched in the US in 2000 it was voluntarily withdrawn due to reports of adverse events such as severe constipation or ischemic colitis, and patient deaths being ascribed to its use. It was re-launched in 2002, but with prescribing restrictions to prevent it being used as a first-line therapy. Recent sales are being reported at no more than $2 million per quarter.

Tegaserod (Zelnorm®/Zelmac®) is a prokinetic, partial agonist of 5-HT_4 receptors and is indicated for the short-term treatment of women with C-IBS. Although approved in the US, this product carries a warning regarding the serious consequences of diarrhoea associated with the medication and a precaution about ischemic colitis and other forms of intestinal ischemia. The FDA granted US approval in 2004 for the additional indication of chronic idiopathic constipation in both men and women under age 65. Novartis continues to seek approval in the EU. By 2004, annual sales of this product had reached almost US$300 million and Novartis is forecasting annual sales of US$1billion by 2007.

Mosapride (Gasmotin®) is a prokinetic which was approved in Japan in 1998 for lessening symptoms associated with chronic gastritis. It is a selective serotonin 5-HT_4 receptor agonist which enhances gastrointestinal motility and has been used off label for C-IBS. Sales for the year to end March 2005 were approximately US$140 million, doubling from the previous year.

Future competition

A large number of companies are developing products for the treatment of IBS, reflecting the high unmet medical need still remaining in the area. In addition to the AGI programmes, the following are reported to be in active clinical development for the treatment of D-IBS.

Generic name	*Originator*	*Status*	*Description*
cilansetron	Solvay	Phase III	5-HT_3 antagonist
ramosetron hydrochloride	Astellas	Phase III	5-HT_3 antagonist
dextofisopam	Vela Pharmaceuticals	Phase II	Benzodiazepine receptor agonist, GABA receptor agonist
piboserod	GlaxoSmithKline	Phase II	5-HT_4 antagonist
DDP-225	Dynogen	Phase II	5-HT_3 antagonist, noradrenaline reuptake inhibitor
E-3620	Eisai	Phase II	5-HT_3 antagonist/5HT_4 agonist
Xifaxan®	Salix	Phase IIb	Non-absorbed broad spectrum antibiotic

5-HT modulator approaches dominate. Cilansetron (Calmactin®) from Solvay is in the same class of 5-HT_3 antagonists as Lotronex®. Regulatory submissions were filed in 2004 in the US and Europe and the product has now been deemed non-approvable by both the FDA and European authorities due to safety concerns relating to severe ischaemic colitis, and approval will now be dependent on further clinical trials being undertaken. Solvay has indicated it will discontinue development of this product development for the US; its plans for Europe are not known.

Regulatory filing of ramosetron (Astellas/Yamanouchi) in Japan is expected by the end of Q1 of 2006.

Vela Pharma reported in 2005 that Phase II results with dextofisopam in D-IBS and "alternating-symptom" M-IBS in men and women were positive. This is a benzodiazepine and thus represents a different approach to 5-HT modulation.

Salix's Xifaxan® is an antibiotic currently marketed for treatment of traveller's diarrhoea. From a regulatory perspective, the potential of an antibiotic approach for treatment of a chronic condition is uncertain.

No recent progress has been reported on DDP-225 from Dynogen, or E-3620 from Eisai. GlaxoSmithKline's IBS programme for piboserod may also have been discontinued following out-licensing to Bio-Medsinisk for development for heart failure, in 2005.

Bridgehead has not identified any other company actively developing verapamil or its isomers for this indication or any other in the GI field. The off-label use of the racemate is unlikely to grow significantly due to the cardiovascular effects of this form, which are substantially absent from the R-isomer.

Market value

In the US, the market for prescription products for IBS (largely the C-IBS component) was estimated to have generated annual sales of more than US$350 million in 2003 and was predicted at that time to continue to grow rapidly to an estimated annual value of US$1.03 billion by 2010. The D-IBS sub-sector shows very low sales at present due to the absence of effective therapies.

The current pricing of Lotronex®, the only drug current approved for D-IBS, at 1mg daily is US$7.33 per day in the US. There are some limitations on reimbursement in the US, e.g. prior authorisation and limited duration under some plans.

3.1.4 Product merits

Clinical/regulatory

Racemic verapamil is a well established product with a good safety record.

As the dose of R-verapamil in the proposed product candidate will not exceed existing doses used in current treatment with racemic verapamil no regulatory safety concerns are expected to arise and therefore there should be no requirement for additional pre-clinical toxicology.

Reports of successful treatment of diarrhoeal conditions, including IBS with verapamil are encouraging.

This product candidate is differentiated in terms of mechanism from the specific 5-HT_3 and partial 5-HT_4 modulators that have been problematic in terms of toxicity. Safety of existing treatments has become a

significant issue and it is to be expected that the regulators will place significant burdens of proof of safety in the way of new chemical entities seeking approval. This may create an advantage for a known chemical entity in this indication.

Market/commercial

10-20 per cent of the US population are estimated to suffer from IBS, approximately 30 per cent having the D-IBS sub-type. Only 10-25 per cent of patients with IBS symptoms currently seek medical care, so there is growth potential.

There is a need for new treatments for patients with D-IBS and a poor pipeline of new drugs with a very limited range of modes of action represented.

If the efficacy and safety targets are met, AGI-003 would offer a competitive profile in this market for treatment of both men and women with D-IBS. Potentially it may also be used in patients with M-IBS which could expand the potential market considerably.

Taking the product candidate to the end of Phase III before partnering gives a good chance of finding an effective partner and offers greater earnings potential compared to partnering at the end of Phase II because, at that stage much will be known about performance and risks of failure will be low.

Pricing in the IBS market is at reasonably attractive levels, offering good margins and is unlikely to be affected by generic activity in the sector. Reimbursement is currently cautious but may become more generous at least for moderate to severe patients as better drugs become available and the condition becomes better understood.

It is understood that if the scope of patent cover is maintained its broad enough to cover generic competition for a significant period. Significant off-label use of racemic verapamil or use of the S-isomer in the indication is not considered likely, given the different therapeutic profiles of these and the R-isomer.

3.1.5 Key risks

Clinical/regulatory

While the occurrence of constipation as a common adverse event with racemic verapamil and the reports of successful treatment of diarrhoeal conditions with verapamil are encouraging, there is no certainty that efficacy will be demonstrated in the ongoing Phase II clinical trial or in the subsequent Phase III programme. The absence of a specific pharmacological mechanism for the proposed efficacy in D-IBS increases the risk that R-verapamil may not be effective.

Although there is data supporting an effect of R-verapamil in IBS, this is from a non-randomised, uncontrolled study. Such data may not be reliable in predicting efficacy.

Although the cardiovascular effect of R-verapamil is less than S-verapamil and the doses proposed do not exceed those currently in use, unexpected cardiovascular or other adverse effects could still emerge in this population during the course of current and planned clinical studies.

Market/commercial

The policy of taking the product candidate to the end of Phase III before partnering is relatively high risk, since by that point the product candidate will be expected to have generated convincing proof of its safety and efficacy. Any meaningful shortfall in this profile will mean that a licensing deal may not be achieved.

3.2 AGI-004 for D-IBS/functional diarrhoea

3.2.1 Description and rationale

AGI-004 is a low dose presentation of mecamylamine, a ganglion blocking agent, being developed initially for delivery via a transdermal patch for the treatment of D-IBS/functional diarrhoea. A controlled release oral version may also be evaluated following the outcome of the current Phase II trial.

D-IBS has been described above. Functional diarrhoea is defined as “continuous or recurrent passage of loose or watery stools without abdominal pain”.

Mecamylamine is approved in the US for the treatment of moderately severe to severe hypertension. The most common adverse effects at antihypertensive doses include GI effects. Mecamylamine has more

recently been shown to block central neuronal acetylcholine receptors (nAChRs) at substantially lower concentrations than those required to achieve ganglion blocking activity, and as a result it has been investigated to treat a variety of conditions including Tourette Syndrome, bipolar disease, cocaine addiction and smoking cessation.

Support for the use of mecamylamine in functional diarrhoea/D-IBS is based on these significant GI effects, but otherwise good tolerability was observed following administration of daily doses of 5mg and 10mg of oral mecamylamine to the general smoking population and also of up to 6mg/day of low dose transdermal mecamylamine in smokers. There is no direct link between nAChR antagonism and the underlying pharmacological deficiency in D-IBS and functional diarrhoea, although nAchR receptors have been reported to modulate 5-HT.

3.2.2 Clinical/regulatory status and plans

Phase II trial – ongoing

This is a randomized, double-blind, placebo-controlled dose escalation clinical trial of AGI-004 in the treatment of functional diarrhoea to determine the efficacy of transdermal mecamylamine based on the patient's global impression, stool consistency and use of rescue medication.

The trial was initially planned to include male or female patients, aged between 18 and 50 years, who fulfilled Rome II criteria for functional diarrhoea, modified for the purpose of this trial. However, in discussion with their investigators, AGI modified the protocol inclusion criteria because patients with functional diarrhoea as defined were considered uncommon as most were clinically classified as D-IBS. The protocol was therefore amended to remove reference to the presence of abdominal pain and in addition the allowed age range was also modified to extend the upper limit to 70.

Patients first undergo an 8-14 day run-in period, where eligibility to participate in the trial is determined. Patients are randomized to receive transdermal mecamylamine or transdermal placebo for the first four weeks. Patients receiving mecamylamine have the dose adjusted upwards for a further four weeks and again for the final four weeks, providing the previous dose is well tolerated. If a dose is not well tolerated, it can be adjusted down for the remainder of the dose escalation phase of the trial. Seventy eight patients with functional diarrhoea/D-IBS are to be randomized to ensure completion of seventy patients, assuming a 10 per cent (approx) drop-out rate.

The trial is being conducted under an IND in the US, and was initiated in January 2005. There are 16 centres in the US and an additional 4 centres in Israel where screening of patients for the trial has commenced. Bridgehead understands that the trial, which seems to be adequately powered, has recruited 86 per cent of the required 78 patients. The trial is expected to complete recruitment in Q1/2 2006 and the results of the trial will be available in Q4 2006/Q1 2007.

Planned studies

Subject to a satisfactory result from the ongoing Phase II trial, AGI would plan to seek a licensee for this product candidate and envisage its licensee agreeing to fully finance a Phase III programme in D-IBS and to agree it with the FDA.

3.2.3 Market potential

As for AGI-003, there is a potential market opportunity in D-IBS. A further similar number of patients who experience diarrhoea as a symptom of M-IBS may also be targets and the product candidate may also have potential in treatment of patients with functional diarrhoea. The labelling will ultimately depend on the studies carried out, their outcome and discussions with the FDA. There is a poor pipeline of new drugs with a very limited range of modes of action represented.

Bridgehead has not identified any other company developing mecamylamine for this indication, although it is under Phase II development in the US by Targacept Inc (which markets Inversine® (mecamylamine HCl), for essential hypertension and uncomplicated cases of malignant hypertension), for patients with major depressive disorder who do not respond or do not fully respond to citalopram hydrobromide. Targacept is also developing TC-5214, one of the stereoisomers of mecamylamine hydrochloride, which has shown anti-depressant effects in several preclinical models.

3.2.4 Product merits

Clinical/regulatory

A substantial amount of data already exists on the safety and tolerability of transdermal mecamylamine.

The high level of reporting of constipation in the existing clinical studies could be indicative of a useful therapeutic effect in diarrhoeal conditions.

As the dose of mecamylamine in the proposed product candidate will be much lower than existing doses used in current treatment no regulatory safety concerns are expected to arise and therefore there should be no requirement for additional pre-clinical toxicology other than as referenced above.

Functional diarrhoea and D-IBS, like almost all of the functional GI disorders, represent areas of unfulfilled medical need.

As discussed above, safety of existing treatments for D-IBS has become a significant issue and it is to be expected that the regulators will place significant burdens of proof of safety in the way of new chemical entities seeking approval. This may create an advantage for a known chemical entity such as mecamylamine in this indication.

Market/commercial

10-20 per cent of the US population are estimated to suffer from IBS, approximately 30 per cent having the D-IBS sub-type and a further similar number of patients experience diarrhoea as a symptom of M-IBS. Only 10-25 per cent of patients with IBS symptoms currently seek medical care, so there is growth potential. The product candidate may also have potential in treatment of patient with functional diarrhoea.

There is a need for new treatments for patients with D-IBS, M-IBS and functional diarrhoea and a poor pipeline of new drugs with a very limited range of modes of action represented.

The transdermal approach may be attractive to a segment of the market and it may be possible to develop a complementary or alternative oral dosage form which would open up a larger segment of the market for this product candidate.

Pricing in the sector is attractive and reimbursement, at least for the more severely affected patients, is likely to be achieved.

Competition from off-label use of generic mecamylamine is unlikely as is that from other low dose controlled release forms assuming the patent application is granted and Bridgehead understands that the scope of AGI's patent application includes an oral controlled release presentation.

3.2.5 Key risks

Clinical/regulatory

There is no direct link between nAChR antagonism and the underlying pharmacological deficiency in functional diarrhoea, although nAChR receptors have been reported to modulate 5-HT.

The presence of a tendency to produce constipation in GI healthy subjects does not necessarily indicate useful effect in patients with D-IBS/functional diarrhoea.

In some of the studies with mecamylamine patches, constipation is not the only GI side effect to emerge. Flatulence, diarrhoea and abdominal pain have also been reported more frequently than in placebo treated subjects. It is difficult to predict how these other GI effects may manifest in patients with a functional GI disorder.

Following inclusion of patients who fall outside the precise Rome II definition of IBS in the Phase II trial, the precise definition of patients for the Phase III programme will be an important area for agreement with FDA. Reaching such agreement may take time and delay the programme. If the agreed patient definition is narrower than expected this may lead to an indication which is also narrow.

Market/commercial

Labelling, and thus the market potential, will ultimately depend on the studies carried out, their outcome and discussions with the FDA.

A patch presentation limits the overall potential of the product candidate to a sub-group of patients.

The oral form has not yet been tested.

Finding an appropriate licensee at the end of Phase II may be difficult. The product candidate is likely to be of more interest to mid-size pharmaceutical companies than to the majors. Potential partners may require greater proof of effectiveness and safety in a formally defined D-IBS population than will be possible at this the end of Phase II.

3.3 AGI-001 for functional dyspepsia

3.3.1 Description and rationale

AGI-001 is an oral dosage form of the S-isomer of pindolol under development by AGI as a prescription-only product for the treatment of functional dyspepsia (FD) in men and women.

FD, also referred to as non-ulcer dyspepsia or NUD, is a cluster of upper GI symptoms including early satiety, abdominal distension and fullness, discomfort and pain not associated with any structural abnormality.

Pindolol is a synthetic beta-adrenergic receptor blocking agent with intrinsic sympathomimetic activity. It is administered as a racemic mixture of the R- and S-isomers for the treatment of hypertension and angina. It is also a high affinity antagonist of 5-HT_{1a} receptors and, following oral administration, binds to $5HT_{1a}$ receptors in the brain. It has been reported that pindolol decreases the time to onset of selective serotonin reuptake inhibitor (SSRI) therapy by this mechanism.

5-HT is believed to have an important role in the regulation of gut physiology, including peristalsis and intestinal tone. Patients with FD have been shown to have enhanced central serotinergic responses and in support of this theory the hypersensitivity of central $5HT_{1a}$ receptors in FD has been demonstrated by a significantly exaggerated prolactin release response to a 5-HT agonist challenge in FD patients. This has led to the hypothesis that a centrally active 5-HT_{1a} receptor antagonist such as pindolol could be effective in treating the symptoms of FD.

The benefit of blocking $5HT_{1a}$ receptors has been demonstrated in a number of clinical studies with cyproheptadine, a non-selective 5-HT antagonist, and with both racemic and S-pindolol. Preclinical studies suggest that the S-isomer has relatively better penetration into brain tissue and is much more potent at the $5HT_{1a}$ receptors.

In summary, pindolol is a well established synthetic beta-adrenergic receptor blocking agent with intrinsic sympathomimetic activity which is also a high affinity antagonist of 5-HT_{1a} receptors. 5-HT is widely recognized as having an important role in the control of GI function and in functional GI disorders. There is evidence in support of "supersensitivity" of central 5-HT_{1a} receptors in patients with FD, which supports the rationale for treating such patients with a 5-HT_{1a} antagonist. Early clinical data with cyproheptadine and racemic pindolol are supportive of an effect. Preclinical data support the choice of S-pindolol based upon potency at $5HT_{1a}$ receptors and possibly better penetration into brain.

3.3.2 Clinical/regulatory status and plans

Phase II trial — ongoing

This is a randomised, double-blind, placebo-controlled trial in the treatment of functional dyspepsia. The primary objective of this trial will be to determine the efficacy of S-pindolol in the treatment of FD (NUD), based on the patient's global impression.

Patients first undergo an 8-14 day run-in period, where eligibility to participate in the trial is determined. Patients are randomised to receive S-pindolol or placebo for the first four weeks. Patients receiving S-pindolol have the dose doubled for a further four weeks and further increased for the final four weeks, providing the previous dose is well tolerated. Patients randomised to receive placebo continue to receive placebo for the duration of the dose escalation phase of the trial (12 weeks). Patients are down-titrated from trial medication over a one week period at the end of the trial. If the previous dose is not well tolerated, the dose can be adjusted down to the dose lower than the previous dose for the remainder of the dose escalation phase of the trial.

The protocol was to randomize 125 patients to ensure completion of 100 patients and the trial seems to be adequately powered. The trial is understood by Bridgehead to be fully randomized with 133 patients, all of whom have completed treatment. The results of the trial are expected in Q2/3 2006.

Planned studies

Subject to a satisfactory result from the ongoing Phase II trial in FD, AGI plans to seek a licensee for this product candidate and envisages its licensee agreeing to fully finance the Phase III programme and to agree it with the FDA.

3.3.3 Market potential

Patient numbers

Upper GI symptoms are reported (in the UK) to affect up to 40 per cent of adults in any one year, of whom about half self-medicate. About one in four consult a doctor. A number of studies have estimated that up to 60 per cent of patients whose dyspepsia is investigated (using upper endoscopy) will have FD, as now defined. The large degree of overlap with concomitant reflux symptoms continues to be problematic for effective diagnosis of FD.

Data suggests that some 7-10 million individuals may be appropriate candidates for therapy for FD in the US and *pro rata* more in Europe, but many in the target population will have relatively mild and occasional symptoms.

Current treatment

No prescription drug therapies have been found to have a high success rate in the treatment of functional dyspepsia. In general, cases of milder, uncomplicated FD self-medication and lifestyle are the cornerstone. If symptoms persist the patient may be tested for *Helicobacter pylori* and eradication may be attempted. If no infection is found, or eradication does not help, the common approach is acid suppression using either histamine receptor antagonists or proton pump inhibitors. There is not considered to be a significant difference in efficacy of these approaches, nor is there evidence that they benefit most patients to a significant extent.

Historically an alternative or complimentary approach has been an attempt to improve bowel motility using prokinetic drugs. They stimulate smooth muscle contraction and hence peristalsis. These drugs have, however, more recently become associated with significant safety concerns. Until its withdrawal from the market some years ago cisapride (Propulsid®, Johnson & Johnson, then approved for treatment of heartburn in patients with gastrointestinal reflux disease) was widely used off label, with total sales in excess of US$1billion. Domperidone and metoclopramide continue to be prescribed in some markets.

Future competition

There has been comparatively little new product development activity focused on FD in recent years and there are few mid- to late-stage drugs in active development. The primary focus is on prokinetics. The following are the most promising competing products known to be undergoing clinical development for FD:

Product	*Brand*	*Company*	*Mechanism of Action*	*Stage*
tegaserod	Zelnorm®	Novartis	Partial 5-HT_4 agonist (prokinetic)	Phase III
itopride	Itax®	Axcan	Dopamine D2 receptor antagonist A-cholinesterase inhibitor (prokinetic)	Phase III
Z 338/YM443		Zeria/Astellas	5-HT uptake stimulant (prokinetic)	Phase II
GTP-010		Gastrotech/Lilly	Glucagon-like peptide 1 agonist (smooth muscle relaxant)	Phase I/II

Tegaserod has been discussed above. Regulatory filing for FD is planned for 2007, suggesting a product launch in 2008 at the earliest.

Phase III results are expected for itopride (Itax®) in the first half of 2006. Data so far suggests that cardiotoxicity problems may be avoided, but drug interactions with (in particular) ranitidine may require further study. Given results as predicted, the product may reach the market at the end of 2007.

YM443 has been reported to be in Phase II for FD since 2002, when it was licensed by Zeria of Japan to Yamanouchi for development and marketing in the US and Canada. No progress has been reported.

GTP-010 is in Phase II for IBS. It is in late Phase I for FD. It is a smooth muscle relaxant, designed to reduce gastrointestinal motility, in contrast to the prokinetics discussed above. On November 2, 2005 DOR BioPharma, Inc. announced that it had entered into a binding agreement for the acquisition of Gastrotech at a reported consideration of US$9 million, satisfied by the issue of shares.

In addition to these clinical stage compounds a series of products are reported to be in pre-clinical development. Companies involved are Aryx (ATI-7505), Dainippon (mosapride/Gasmotin®), Microbia (MD-1100), Tranzyme (TZP-202), and Theravance (TD-2749). These are all believed to be prokinetics. In the majority of these cases, FD is not the primary indication.

AGI-001 represents a different approach from those described above in that it is expected to have its primary effect in the area of pain and discomfort.

Market value

Current therapies are inadequate and therefore do not represent the potential value of the market for effective treatments. Given the large patient numbers there is clearly potential for market growth if effective products are introduced.

3.3.4 Product merits

Clinical/regulatory

Pindolol is a well established product with a good safety record.

As the dose of S-pindolol in the proposed product candidate will not exceed existing doses in current treatment with racemic pindolol no regulatory safety concerns are expected to arise and therefore there should be no requirement for additional pre-clinical toxicology.

Reports of successful treatment of functional dyspepsia with racemic pindolol and S-pindolol, and pre-clinical data on S-pindolol, are encouraging though they do not provide evidence of efficacy.

Market/commercial

Data suggests that some 7-10 million individuals may be appropriate candidates for therapy for FD in the US and *pro rata* more in Europe. Although many in the target population will have relatively mild and occasional symptoms there is unmet medical need and a reasonable pricing and reimbursement environment.

The target profile, assuming it is achieved and current assumptions about disease mechanism hold good, may reasonably be expected to make the product candidate an effective competitor in the target market place.

Potential new-entrant competition comes from prokinetic drugs which address a different aspect of the condition to AGI-001, and therefore would be only indirectly challenging. In addition, most of these may be, to some extent, limited by association of their modes of action with past drug withdrawals and safety problems.

Competitive challenge from existing pindolol products is not considered likely due to the differences in binding and brain penetration of the isomers.

The proposal to find a strong marketing partner should be feasible, assuming the target Phase II profile is achieved. The intention to reserve some US rights is common practice and should not act as a significant deterrent to a partner. However, neither does it at this stage commit the Group to expenditure and effort which may be ill advised.

3.3.5 Key risks

Clinical/regulatory

While the reports of successful treatment of functional dyspepsia with pindolol is encouraging, there is no certainty that efficacy will be demonstrated in the ongoing Phase II or future Phase III clinical trials.

While 5-HT and 5-HT_{1a} receptors are clearly thought to play an important role in the control of the GI tract there is no formal data conclusively showing that blocking $5HT_{1a}$ receptors is an effective mechanism in the management of functional dyspepsia.

Although the doses of S-pindolol proposed do not exceed those currently in use, unexpected adverse effects could still emerge in this population during the course of the clinical studies.

Manufacturing

A stability issue was encountered with the drug product supplied for the Phase II clinical trial. A subsequent batch is stable to date, though it is being stored at low temperature as a precaution. An investigation is currently underway to determine the nature of the stability issue but there remains a small risk of problems arising in future.

Market/commercial

The market for FD is currently embryonic with limited big pharmaceutical company participation in product development. This factor may make finding a partner more challenging than is currently anticipated.

Given the large potential patient population this market may be expected to attract significantly more competitive attention as disease mechanisms become better understood and the market size is made more obvious. This will not have an effect in the immediate future, but could change the level of competition in the medium term.

3.4 AGI-001 for IBS

3.4.1 Description and rationale

AGI-001 is the S-isomer of pindolol under evaluation at proof of concept level for treatment of IBS, in particular the symptoms of pain and discomfort.

As 5-HT is considered to be important throughout the bowel, AGI believe that S-pindolol may have benefit in IBS in addition to that already discussed for functional dyspepsia.

3.4.2 Clinical/regulatory status and plans

Phase II trial – ongoing

This is a randomised, double-blind, placebo-controlled, proof of concept trial in the treatment of IBS. The primary objective of this trial will be to determine the efficacy of S-pindolol, based on the patient's global impression.

Patients first undergo an 8-14 day run-in period, where eligibility to participate in the trial is determined. Patients are then randomised to receive S-pindolol or placebo for the first four weeks. Patients receiving S-pindolol will have the dose doubled for a further four weeks and increased again for the final four weeks, providing the previous dose is well tolerated. Patients randomised to receive placebo will continue to receive placebo for the duration of the dose escalation phase of the trial (12 weeks). Patients will be down-titrated from trial medication over a one week period at the end of the trial. If the previous dose is not well tolerated, the dose can be adjusted down to the dose lower than the previous dose for the remainder of the dose escalation phase of the trial.

The trial, which seems to be adequately powered, is understood by Bridgehead to be fully enrolled, with 67 patients at 12 centres (3 of which are inactive) in Ireland and treatment is ongoing. The results of the trial are expected in Q3/4 2006.

Planned studies

Subject to a satisfactory result from the ongoing trial in IBS, AGI will seek to out-licence this product candidate. AGI anticipates its licensee will conduct and finance a further Phase II trial in IBS before progressing into a Phase III programme in this indication.

3.4.3 Market potential

It has already been seen above that there is a large patient population with IBS symptoms. Pain and discomfort, for which AGI proposes S-pindolol may be particularly useful, are key aspects of IBS and are found in the majority of patients and there is an associated unmet medical need.

The pipeline for drugs specifically addressing pain associated with IBS is relatively poor, with a limited range of modes of action represented. For pain predominant IBS there are three products in clinical development:

- Asimadoline (Merck KgaA/Tioga Pharmaceuticals), a peripheral kappa opioid receptor antagonist is in Phase II. A Phase IIa study suggested that the drug may be effective for IBS pain in men and women.
- Saredutant (sanofi-aventis), a non peptide NK2 antagonist which is proposed to reactivate inhibited motility or decrease inflammation- or stress-associated hypermotility in the gut, is in Phase II.
- Alvimopan (Adolor/GSK), an orally active, mu opioid antagonist with activity restricted to GI tract, in Phase I.

In addition there are products under development for treatment of symptoms of pain and discomfort associated with IBS e.g. Gastrotech (Sweden) is undertaking a Phase II trial of a glucagon-like peptide-1 analogue (GTP-1) in IBS patients with moderate to severe pain. GTP-1 is reported to act by reducing gastrointestinal motor activity. AstraZeneca has the serotonin modulator AZD-7371 in Phase II for IBS-related visceral hypersensitivity.

Drugs targeting D-IBS, C-IBS and M-IBS may also offer benefits in terms of pain reduction. With tegaserod, for example, there can be a reduction of pain and discomfort in the abdominal area, reduced bloating, as well as reduced constipation.

Bridgehead has not identified any other company actively developing pindolol or its isomers for this indication or any other in the GI field.

3.4.4 Product merits

Clinical/regulatory

Pindolol is a well established product with a good safety record.

As the dose of S-pindolol in the proposed product candidate will not exceed existing doses in current treatment with racemic pindolol, no safety concerns are expected to arise and therefore there should be no requirement for additional pre-clinical toxicology.

Safety of existing treatments has become a significant issue and it is to be expected that the regulators will place significant burdens of proof of safety in the way of new chemical entities seeking approval. This may create an advantage for a known chemical entity in this indication.

Market/commercial

10-20 per cent of the US population are estimated to suffer from IBS. Only 10-25 per cent of patients with IBS symptoms currently seek medical care, so there is growth potential. There is unmet medical need in the IBS market, and a large proportion of patients suffer pain and discomfort as a major component of their condition.

The pipeline of products that might compete is not large and there have been several failures in development and post marketing.

Pricing and reimbursement are positive in the sector.

Competition from racemic pindolol is possible but unlikely.

3.4.5 Key risks

Clinical/regulatory

In view of the lack of evidence that blockade of $5HT_{1a}$ receptors is an effective mechanism in the management of IBS, the investigation of S-pindolol in this indication is speculative.

Although the doses of S-pindolol proposed do not exceed those currently in use, unexpected adverse effects could still emerge in this population during the clinical studies.

AGI-001 would represent a novel approach to the indication, however it is not possible to predict at this stage how competitive its profile might be. The results of the Phase II trial may indicate a sub-set of patients that may benefit and this could narrow the target indication and potential market.

Market/commercial

Drugs in development targeting D-IBS, C-IBS and M-IBS may also offer benefits in terms of pain reduction with an impact on the potential market for this product candidate.

3.5 AGI-006 for functional dyspepsia

3.5.1 Description

AGI-006 is the R-isomer of baclofen that is in a Phase II clinical trial for the treatment of functional dyspepsia. Racemic baclofen is well established as a muscle relaxant and antispasmodic.

Baclofen is a gamma amino butyric acid receptor type B (GABA B) agonist. GABA is a major inhibiting neurotransmitter in the brain. However, GABA mechanisms have also been demonstrated in human and animal intestine. In addition to its known muscle relaxant and antispasmodic effects, baclofen also has activity on the GI tract, particularly on the gastro-esophageal junction, and is reported to promote gastric emptying in model systems.

The dominant GABA B agonist activity is associated with the R-isomer which is 4.2-9.2 -fold as active pharmacologically as the S-form, and 1.4-1.9 times as active as the racemate. R-baclofen has been suggested to be effective in treating gastroesophageal reflux disease (GERD) in view of its inhibitory effects on transient lower (o)esophageal sphincter relaxation in model systems. Further studies in patients with GERD have suggested beneficial effects.

The mechanism(s) responsible for the symptoms of FD are not understood and there is no published pharmacological basis for the use of R-baclofen in FD, however, the effects on the GI tract may be helpful in easing the symptoms of FD so a study to assess this is not unreasonable.

3.5.2 Clinical/regulatory status and plans

Phase II trial — ongoing

This is a multicentre, randomised, double-blind, placebo-controlled, dose escalation Phase II trial. R-baclofen will be dosed as immediate release tablets or multiples thereof three times daily up to a maximum daily dose. The total duration of treatment for the dose escalation phase will be six weeks. Individual dose upwards adjustment will only be allowed if serious or significant safety problems do not occur.

The primary assessment of effect will be based upon the patient's global impression of whether they feel better after the treatment. Secondary endpoints include patient's global severity of illness scale, severity of GI symptoms scale (upper abdominal pain/discomfort, upper abdominal fullness, early satiety, bloating, nausea) and quality of life (QOL).

Sixty six patients will be randomised at 10 centres in Ireland and 7 in Lithuania. The trial, which seems to be adequately powered, is reported to be 12 per cent enrolled from centres in Ireland. The Lithuanian centres were initiated in January 2006. The results of the trial are expected in by year end 2006.

Planned studies

Subject to a satisfactory result from the ongoing Phase II trial in FD, AGI plans to conduct a further Phase II trial with a larger population and more extended duration of treatment. AGI plans to start enrolment in Q3/4 2007 and results for the trial are expected in Q3/4 2008. Following this, and subject to a further satisfactory result, AGI plans to seek to out-licence the product candidate.

At this stage the timings and budget for the second Phase II trial seem reasonable.

3.5.3 Market potential

The broad FD market addressed by AGI-006 is the same as that targeted by AGI-001. Of significance in the competitive field for AGI-006 is the pro-drug form of R-baclofen in Phase I development by Xenoport

for GERD. If this is approved and marketed for GERD, there may be some "off-label" use in FD, although the timing of availability and likely pricing of this NCE form is not expected to provide for appreciable levels of off-label erosion of AGI-006 sales. It is likely, however, in contrast to AGI-001 which has applicability across the full FD indication, that AGI-006 will be used preferentially in the sub-group of FD patients (approximately 30 per cent) with delayed gastric emptying, given its prokinetic profile.

3.5.4 Product merits

Clinical/regulatory

Baclofen is a well established product with a good safety record, although it does have significant side effects at currently used doses, including sedation nausea and hypotension. These are, however, usually early during treatment and dose escalation.

As the dose of baclofen in the proposed product candidate will not exceed existing doses in current treatment with racemic baclofen, no safety concerns are expected to arise and therefore there should be no requirement for additional pre-clinical toxicology.

Reports of successful treatment of GERD with racemic baclofen are encouraging in that they suggest effects on the GI tract in humans, though they are not necessarily effects that will be beneficial in FD.

Market/commercial

Data suggests that some 7-10 million individuals may be appropriate candidates for therapy for FD in the USA and pro rata more in Europe. AGI-006 will address a sub-section of this market (some 30 per cent) in which motility is a key problem. Although many in the target population will have relatively mild and occasional symptoms there is unmet medical need and a reasonable pricing and reimbursement environment.

The target profile, assuming it is achieved, offers the possibility of providing an alternative mode of action for patients seeking a prokinetic effect, which may be expected to differentiate the product candidate from other products on the market and in development which claim similar therapeutic benefits.

The proposal to find a strong marketing partner should be feasible, assuming the target Phase II profile is achieved.

3.5.5 Key risks

Clinical/regulatory

The lack of a clear pharmacological rationale and animal models to demonstrate relevant pharmacological activity of R-baclofen, increases the risk that it be found not to be effective in this condition.

The lack of appropriate pharmacological models on which to base dose selection increases the risk that doses in the ongoing Phase II trial may not be optimal.

Timings for the further Phase II and Phase III studies are critically dependent on timely completion of the current Phase II trial. Timings are tight and assume good recruitment at the Lithuanian sites.

Although the doses of R-baclofen proposed do not exceed those currently in use, unexpected adverse effects could still emerge in this population during the course of the clinical studies.

Market/commercial

Given the patient numbers this market may be expected to attract significantly more competitive attention as disease mechanisms become better understood and its size is made more obvious. This will not have an effect in the immediate future, but could change the level of competition in the medium term.

The market is currently embryonic with limited big pharmaceutical company participation in product development. Finding a licensee may be more challenging than anticipated.

AGI anticipates that the pro-drug form of R-baclofen in Phase I development by Xenoport may, if it is approved and marketed for GERD, have some "off-label" use in FD although the timing of availability and likely pricing of this NCE form is not expected to provide for appreciable levels of off-label erosion of any future AGI-006 product candidate sales.

A limited degree of "off-label" competition from the marketed racemic forms of baclofen is expected due to the reduced GI-specificity and poorer tolerability of the racemate.

3.6 AGI-010 for GERD/NAB

3.6.1 Description and rationale

Gastro-esophageal reflux disease (GERD) results in the reflux of gastric contents into the oesophagus, causing symptoms (e.g. heartburn or acid regurgitation) that are sufficient to interfere with quality of life. Nocturnal acid breakthrough (NAB) is defined as the presence of at least 60 continuous minutes of intragastric pH <4 during the overnight period (10pm-6am) in patients taking a proton pump inhibitor twice daily before meals.

AGI-010 is a modified release capsule formulation of omeprazole, comprising both a delayed release and an extended release component, so that the product candidate works through the night. It is being developed for the treatment of heartburn and other symptoms of GERD, in particular for those symptoms experienced at night as Nocturnal Acid Breakthrough (NAB).

Omeprazole is a marketed proton pump inhibitor (PPI) indicated for the treatment of heartburn and other symptoms associated with GERD (20mg/day) and other conditions. Omeprazole Delayed-Release Capsules and Tablets contain an enteric-coated granule formulation of omeprazole (because omeprazole is acid-Labile), so that absorption of omeprazole begins only after the granules leave the stomach. Absorption is rapid, with peak plasma levels of omeprazole occurring within 0.5 to 3.5 hours.

The PPIs bind irreversibly to the acid (proton) pump in the lining of the stomach so inhibiting acid production. However, despite the success of PPI's, many patients recover acid secretion during the night even with twice-daily administration of PPI's. This phenomenon has been termed "nocturnal acid breakthrough" (NAB) and leads to symptom recurrence.

Modification of the dosage regimen of PPI's has only had limited success in controlling the symptoms of NAB despite improving acid suppression. Administration twice daily or at night is more effective than administration in the morning in that the percentage of time with gastric pH < 4 is reduced but by no means eliminated.

3.6.2 Clinical/regulatory status and plans

Ongoing Human PK/PD trial

A Human PK/PD proof of concept and formulation selection trial in healthy volunteers commenced in January 2006. It will assess the steady state pharmacokinetics and effect on intragastric pH of three modified release formulations of omeprazole, dosed as two capsules once daily at night for five days, compared to Losec® dosed twice daily in the evening before dinner and in the morning before breakfast for five days.

This trial is a multiple-dose randomized four way crossover trial, with at least a seven day washout period from the last dose in one period until the first dose of the subsequent period, in sixteen volunteers. Each treatment period will be 5 days following a baseline day. On the baseline day and day 5 of each treatment period 24-hour intragastric pH monitoring will be conducted. In addition on day 5 of each treatment period, plasma samples will be taken to characterise the steady-state pharmacokinetics.

Subject to a satisfactory outcome, AGI plans to seek a licensee for the product candidate. Possible development strategies have been identified by AGI, although responsibility for the further development plan and financing will rest with the licensee. AGI also has plans to use this delivery technology with a different PPI, where it plans to undertake a similar programme.

Following the initiation of the human PK/PD trial in January 2006, completion with results in Q3/4 2006 is reasonable. Further plans and timescales depend upon the results of the human PK/PD trial and the development strategy that is pursued.

3.6.3 Market potential

Patient population

Heartburn, a major symptom of GERD, affects an estimated 5 per cent to 7 per cent of the population once per day and 36-44 per cent of adults in the US experience heartburn at least once a month. Based on objective measures, such as endoscopic or histological examinations, it has been estimated that approximately 2 per cent of the adult population in the Western world suffers from GERD. NAB occurs

in more than 70 per cent of *H. pylori*-negative and in 0-50 per cent of *H. pylori*-positive subjects on PPI therapy. Barrett's oesophagus occurs in about 10 per cent of patients with chronic GERD[2] and can increase the risk of cancer of the oesophagus.

Management of GERD may include lifestyle changes, drug therapy and, in some cases, surgery. Initial treatment is guided severity then adjusted according to response. The fist line drug treatments are the PPIs (e.g. omeprazole, esomeprazole) which treat the symptoms of GERD but are also considered to be more effective than H_2-receptor antagonists at healing oesophagitis and in relieving symptoms in endoscopy-negative reflux.

Future competition

The following products that are known to be undergoing mid to late stage clinical development for GERD:

Product	*Company*	*Mechanism of Action*	*Stage*
Tenatoprazole	Negma	PPI with longer half life	Phase III
MR enantiomer of lansoprazole TAK-390MR	TAP	PPI modified release	Phase III
Revaprazan (YH1885)	YuHan Corp	Reversible acid pump antagonist	Phase III (Asia only)
Soraprazan	Altana	Acid pump antagonist	Phase IIb
ATI-7505	ARYx Therapeutics	Cisapride analogue (no cardiac issues to date)	Phase II
XP-19986	XenoPort	Transported prodrug of R-baclofen/ GABA receptor agonist	Phase II
Ilaprazole	TAP	PPI	Phase I/II

Compounds in development include new PPIs with a prolonged plasma half-life, a modified release enantiomer of the marketed PPI lansoprazole, and acid-pump antagonists which have a faster onset of action than PPIs. Also in early stage development are AstraZeneca's AZD3355 and AZD9343, inhibitors of transient lower oesophageal sphincter relaxations, another mechanism responsible for episodes of reflux.

Market value

The global annual market for PPIs is around US$21 billion, of which the US accounts for around 60 per cent. Omeprazole has a share of around 29 per cent of this market, with lansoprazole at 28 per cent. Pricing in the PPI market has been influenced by entry of generics and over-the-counter Prilosec® (US only). However, newer entrants such as Zegerid® (an immediate-release formulation of omeprazole), have achieved reasonable price levels (US$120-130 per month in the US). Therapies for GERD are widely reimbursed.

3.6.4 Product merits

Clinical/regulatory

Omeprazole is very well established and has a very good safety profile, as reflected in the recent OTC approval of omeprazole in the US.

There are clinical data indicating that modifying the timing of omeprazole administration reduced NAB.

24hr intragastric pH monitoring is an accepted method of determining the effect of acid inhibitors. The Human PK/PD trial therefore will give a good indication of the effectiveness on nocturnal acid secretion of the proposed formulations.

Market/commercial

Approximately 2 per cent of the adult population in the Western world suffers from GERD and at least 50 per cent of those treated with PPI's experience NAB.

The target profile, assuming it is achieved, may reasonably be expected to make the product candidate an effective competitor in its target market in that it addresses a specific unmet need which is present in a large proportion of patients using PPIs.

If the "CHRONAB" drug delivery technology employed in AGI-010 with omeprazole proves successful, there may be further opportunities throughout the PPI product class.

3.6.5 Key risks

Clinical/regulatory

Although 24 hr intragastric pH monitoring is an accepted method of determining the effect of acid inhibitors and will give a good indication of the effectiveness on nocturnal acid secretion of the proposed formulations, it is not clear from prior studies that symptom relief will necessarily correlate well with this effect.

Aggressive regimens of omeprazole (8 hourly) and long half-life PPI (tenatoprazole) shorten the duration of NAB but there are data suggesting that symptom control is not dependent on the degree of NAB elimination.

While the different clinical development options provide products with increasing differentiation it should be noted that the risk of failure to demonstrate a differentiated profile increases proportionately, as do the complexity and risks to timings and budgets.

The technology is at an early stage and is not yet tested in larger scale clinical trials.

Market/commercial

Newer PPIs in development e.g. tenatoprazole, which is in a Phase III programme, have a much longer half life than omeprazole (7-fold longer). This will increase the level of competition for AGI-010's target patients, but the magnitude of this effect is difficult to predict at this stage

Other approaches to the treatment of GERD are in development which may replace the need for current PPIs in certain patients.

Price competition is evident in the PPI marketplace following the patent expiry of Losec®/Prilosec®, which sets a very low price background. Reimbursement agencies will need to be convinced that the benefit to patients offered by the product candidate is substantial if the target price is to be achieved, and it is likely that reimbursement will be limited to rather more severe patients.

Given the highly competitive nature of the market, commercial prospects for the product candidate will be heavily dependent on securing an appropriate licensee. A potential licensee will need to be convinced that the release profile will lead to an improvement in symptoms, and that the IP protection is sufficient to prevent the copying of the technology or the development of parallel technology which offers the same end result. Achieving agreement with an appropriate partner could present a challenge.

3.7 AGI-022 for ulcerative colitis

3.7.1 Description and rationale

AGI-022 is an oral modified release formulation of the sodium salt of 4-aminosalicylic acid (4-ASA) that incorporates both delayed (time-based) and controlled release components to target colonic delivery. The target indication is for the induction and maintenance of remission of mild to moderate ulcerative colitis (UC), a chronic, recurrent, relapsing and remitting inflammatory disease of the colon and/or rectum

4-ASA is closely related to 5-ASA, which is an established treatment for ulcerative colitis. 4-ASA has a well established safety profile from use over a number of years at high dose in the treatment of tuberculosis. It has also been shown to be effective by rectal administration in distal ulcerative colitis. It may have advantages over 5-ASA in terms of better penetration into colonic cells and in terms of renal toxicity.

3.7.2 Clinical/regulatory status and plans

Completed studies

A pharmacokinetic trial in healthy volunteers has recently completed. This was an open label, 4 treatments, 4 periods, randomized crossover trial, with at least a 7 day washout between each dose. The objective of this trial was to determine the single-dose fasting pharmacokinetics of AGI-022 (three

modified release formulations of 4-ASA) in healthy volunteers. A total of 16 subjects were enrolled and were dosed on at least 3 occasions and 14 subjects completed the trial and received all 4 treatments. 4-ASA and its metabolite, N-acetyl-p-aminosalicyclic acid, were measured in plasma and urine samples.

The trial, which was formally reported in January 2006, has shown that the formulation technology can delay the release of 4-ASA.

Planned studies

AGI is currently seeking licensees for this product candidate. The development and the financing of the Phase III programme will be the responsibility of the licensee and should be discussed with the FDA.

3.7.3 Market potential

Patient numbers

The prevalence of UC is estimated at almost 1 million patients in the seven major pharmaceutical markets (US, UK, Germany, France, Italy, Spain and Japan) and the incidence of new cases is nearly 50,000 per annum in these markets. Relapses of UC are common, with annual relapse rates ranging from 70-80 per cent without treatment, to 20-30 per cent in patients treated with 5-ASA.

Current treatment

The goal of drug therapy in UC is first to induce remission and then to maintain it. Aminosalicylates are available for oral or rectal delivery, are generally considered to be safe and are often used to induce and maintain remission. However, efficacy may be variable and side effects can be a problem. Corticosteroids are available for oral or rectal delivery and may be used in acute episodes to induce remission but are not generally regarded as being safe for chronic use. Modified-release formulations of oral corticosteroids (e.g. AstraZeneca's Entocort®) are claimed to have lower systemic side-effects than conventional products, but are only indicated for Crohn's Disease. Newer biologicals, such as infliximab (Remicade®, Centocor), are generally only used in severe cases and/or where cheaper drugs have failed.

Future competition

Tacrolimus (Prograf® from Astellas) is an oral formulation of an immunosuppressive which has completed development in Japan and is currently awaiting approval. The product is positioned for use in moderate to severe ulcerative colitis in steroid-resistant patients for the induction of remission. Astellas has not developed Prograf® for ulcerative colitis in either the US or Europe, although it is on the market for other indications in those markets.

The following products are also known to be in mid- to late-clinical development for the treatment of ulcerative colitis:

Product	*Company*	*Mechanism of action*	*Stage*
SPD-476	Giuliani/Shire	Anti-inflammatory/5-ASA	Phase III
OPC-6535	Otsuka	Phosphodiesterase 4 inhibitor	Phase III
Ecabet	Tanabe, aaiPharma	Anti-inflammatory/5-ASA	Phase III
Alicaforsen sodium (enema)	ISIS Pharma	RNAse antisense inhibitor to (ICAM)-1	Phase II
MLN02	Millennium/ Genentech	Binds to T-cell integrin	Phase II
Cronaze (BNP-166)	IVAX	"Soft" steroid	Phase II
Basiliximab	Novartis	MAb for CD25, used in comb with steroid	Phase II
RDP-58	P&G	TNF, interferon-gamma, IL-2, IL-12 inhibitor	Phase II
Kappaproct*	Serono/Index	Antisense-NF-KBp65 oligonucleotide	Phase II

Product	*Company*	*Mechanism of action*	*Stage*
Nolpitantium	sanofi-aventis	Non-peptide NK1 receptor antagonist	Phase II

* A Phase II study of Kappaproct® did not reach its primary endpoint in terms of clinical remission vs. placebo. However, Serono and InDex ''remain committed to the development of Kappaproct®''

Market value

The worldwide annual market for inflammatory bowel disease (IBD) therapies (both ulcerative colitis and Crohn's disease) was estimated to be US$1.3 billion in 2002 and forecast to grow to US$2.3 billion by 2010. In terms of patient numbers, the split of the IBD market is approximately 60 per cent with ulcerative colitis and 40 per cent with Crohn's disease. Annual sales of the leading 5-ASA product Asacol® were reported to be US$500 million in 2003, for both acute and maintenance indications.

Currently pricing in this market ranges from very low generic 5-ASA and oral steroid prices, through moderate prices for the branded, mostly modified-release products (around US$100-250 per month) through to very high prices for products such as Remicade® (>US$10,000 per year in the US). Therapies for ulcerative colitis are widely reimbursed.

3.7.4 Product merits

Clinical/regulatory

4-ASA is a well established product although in a different indication.

In the treatment of tuberculosis the recommended dose of 4-ASA is 4g t.i.d. This is significantly higher than that proposed for ulcerative colitis, providing reassurance about the likely safety in this indication.

4-ASA has shown efficacy in the treatment of distal ulcerative colitis by the rectal route, though these studies usually included relatively small numbers of patients.

It may now be possible to move straight to pivotal Phase III clinical trials following the Human PK trial.

Market/commercial

The ulcerative colitis market is relatively large (>US$1 billion) and it is estimated that there is potential for this market to grow (to >US$2 billion) as diagnosis improves and newer therapies are introduced.

Aminosalicylates remain the first line choice for the treatment of ulcerative colitis, despite the availability of newer therapies.

Because modified release characteristics are key to effective therapy, pricing for branded modified release products in the market is attractive and reimbursement is generally not a significant issue.

There remains unmet need in the treatment of acute ulcerative colitis and potentially a much larger opportunity for a maintenance treatment, which the proposed profile would go some way to addressing through its reduced side effect impact and easier dosing regime.

If successful in ulcerative colitis, the product candidate could potentially be developed further for other disorders of the colon.

Oral products are generally more attractive to patients than, e.g., injections and enemas.

3.7.5 Key risks

Clinical/regulatory

The model on which the timed/controlled release of 4-ASA is based is rational but hypothetical at this stage and may not lead to the expected levels of efficacy. Consistent and complete delivery of drug to the colon via a timed release mechanism can be difficult to achieve.

Clinical trials to date have not indicated superiority of 4-ASA over 5-ASA, but these studies have not included the proposed modified release technology.

Colonic delivery is technically challenging. Many groups have worked on colon-targeted delivery in the past, but few have achieved what they set out to do, and even fewer have got to market.

The plan to move straight to pivotal Phase III trials following the Human PK trial without clinical trial data indicating that the selected doses are effective, provides a faster route to NDA submission. However, the Phase III studies may include more dose levels as the dose justification has not been established. This increases the cost and risk of failure at Phase III though it shortens the time to NDA filing.

There are differences in approaches to the management of ulcerative colitis and associated regulatory views across Europe and the US, which may have implications for development and approval.

Market/commercial

The inflammatory bowel disease market is highly competitive and there are a large number of aminosalicylate-based products already on the market.

Without patient data on efficacy it may be challenging to convince potential partners that the AGI-022 product candidate will offer sufficient improvements over current and possible future ASA-based therapies to be an attractive commercial prospect.

The possibility of similar products being generated and entering the market may take on a larger dimension than currently thought, putting pressure on market share and possibly price over time.

4.0 General clinical, manufacturing and commercial risk factors

Bridgehead considers that AGI will face certain general clinical, manufacturing and commercial risks that may impact on the realisation of its business plan. The industry area addressed by the Group is fast moving, and certain aspects, such as the legislative, regulatory and market environment, are outside the control of the Group and may render some or all of its information invalid or incomplete or its products obsolete in the future.

Clinical

As for any pharmaceutical product failure may occur at any stage during development and post marketing, due to safety or clinical efficacy issues. The underlying rationale for development of each of AGI's products is acceptable and the risks of failure on toxicity grounds is relatively low, but the direct evidence available to date to support efficacy is not substantial.

Several of the product candidates are under development for treatment of functional disorders (IBS, functional diarrhoea and FD) where clinical development is known to be high risk, due to placebo effects and difficulties of clinical trial design due to lack of objective end points.

The Rome Criteria have greatly advanced the ability to categorise functional GI disorders but differentiation in clinical application can be lead to problems with recruitment of appropriate patients into clinical studies. Failing to achieve this can potentially have efficacy, safety and/or regulatory impacts.

The clinical development programmes may encounter delays due to, for example, capacity/performance issues with selected CROs and other third parties, obtaining the required regulatory and ethics approvals, patient recruitment to trials, preparation of product supplies for trials. AGI is managing its exposure to risks in this respect by using a number of reputable vendors.

Results emerging from trials may necessitate further preclinical or clinical testing; this could lead to delays and additional costs.

AGI has a reasonable portfolio of development programmes and technologies and is not dependent on any single product candidate however, as for any pharmaceutical company, there is a risk that not all the product candidates will be developed successfully.

Regulatory

Due to safety issues which emerged post approval with certain competing products targeting, for example, IBS, regulators are likely to be highly cautious in their assessment of any new products for functional indications. They will also give considerable critical attention to trial design in indications, such as the majority involved here, where endpoints are largely subjective.

In general there is a risk that regulatory approval may be delayed, limited or denied for a number of reasons. Different regulatory bodies around the world have different requirements for approval of

therapeutics and this may result in demands for additional data leading to delays and additional costs. Approvals may vary in terms of the indications for use of the product.

After product candidate approval, safety or efficacy issues may emerge during post-marketing surveillance which may result in withdrawal or restriction of the product licence.

Manufacturing

AGI uses a number of contract manufacturers and suppliers. If these were to cease supply at short notice this could result in delays in product development and increase costs.

Commercial

Lack of understanding of the aetiology of IBS, functional diarrhoea and FD makes it difficult to predict which drugs will in the end be widely used and which will fail. The landscape is likely to change in unpredictable ways over the next decade, making forecasts made today relatively unreliable.

AGI is not developing new chemical entities and therefore is relying on patent protection relating to, for example, new uses of stereoisomers and new formulations. In the pharmaceutical sector such patent protection is not generally considered as strong a barrier to generic competition as a composition of matter patent and there is the possibility of attempted generic challenge, especially in the larger of the markets targeted by AGI. This aspect may also make it more likely that the company will need to conclude a number of regional deals rather than a single global deal for each product, addition to cost, complexity and risk of the out-licencing activity.

Before the product candidates face the market of patients, prescribers and payers they will face the market of potential licensees. There can be no guarantee that appropriate licensees will be found as planned. This may be for a variety of reasons, including, for example, the data available being unconvincing or changes in the competitive situation or overall market sentiment.

Once approval is obtained for a product there is no certainty that the products will achieve commercial success since several factors will determine this, including, clinical performance of the product (which is difficult to predict even through good clinical studies), approved indication, competitive environment, performance of the licensee, pricing and reimbursement.

There is no guarantee that, after regulatory approval, reimbursement agencies will agree to cover the cost of the product. Delays in reimbursement or its denial will limit adoption of the product in the market. Particularly in the markets for functional disorders such as IBS, functional diarrhoea and FD, where patient numbers are potentially very large, reimbursement agencies may become sensitised to the huge potential demand and become more restrictive about re-imbursement over time, limiting value and volume potential to a degree.

5.0 Summary

AGI is a speciality pharmaceutical company, focused exclusively on the mid-late stage development of product candidates in the gastroenterology area. Since its formation, AGI has been focused on developing products for the treatment and management of gastrointestinal disease to address areas of high unmet clinical need.

AGI-003, the R-isomer verapamil, is in Phase II development for treatment of D-IBS. The Group plans to develop this through Phase III and then seek a licensee, reserving co-promotion rights in the US. The potential market is attractive with unmet medical needs. There is a reasonable rationale for development of R-verapamil in this indication but no clinical proof of efficacy to date. Safety is not expected to be an issue. A good indication of the efficacy of the drug in non-constipation predominant IBS should emerge from the current Phase II clinical trial. This will support a decision on whether or not to progress to Phase III in D-IBS.

AGI-004 is a low dose CR presentation of mecamylamine, which is in Phase II development as a transdermal patch, for the treatment of D-IBS and functional diarrhoea. Subject to a satisfactory result from the trial in Q3/4 2006, AGI would plan to seek a licensee. The rationale for this indication is based on a tendency for the drug to produce constipation in GI healthy subjects and on modulation of 5-HT, both potential indicators of efficacy in the target patient population. The transdermal approach may be attractive to a segment of the market and it may be possible to develop a complementary, or alternative, oral dosage form which would open up a larger segment of the market for this product candidate.

AGI-001 is the S-isomer of pindolol. It is in Phase II development for FD, an indication with high unmet need. Subject to a satisfactory result from the trial (Q2/3 2006) AGI would seek to out-licence, reserving

co-promotion rights in the US. The potential market is attractive, though it is currently embryonic with limited pharmaceutical company activity. S-pindolol has greater potency at $5HT_{1a}$ receptors and, possibly, better penetration into brain compared with R-pindolol. There are reports of successful treatment of FD with racemic pindolol and S-pindolol, and pre-clinical data on S-pindolol which support the development of AGI-001. However, there is no evidence of efficacy to date, this will only emerge as the clinical development programme evolves.

AGI-001 is also in Phase II for IBS and, subject to a satisfactory result from the current trial (Q2/3 2006), AGI would seek to out-licence, probably to the same licensee as for functional dyspepsia, again reserving co-promotion rights in the US. As 5-HT is considered to be important throughout the bowel, AGI believe that S-pindolol may have benefit in IBS, but to date there is no specific evidence that blockade of 5HT1a receptors is an effective mechanism in the management of IBS. Evidence of efficacy and the patient population that may benefit, will only emerge as the clinical development programme progresses.

AGI-006, the R-isomer baclofen is in Phase II development for FD. AGI plans to complete the current Phase II trial and carry out a larger, second trial before seeking to out-licence this product candidate in late 2008. The dominant GABA B agonist activity of baclofen is associated with the R-isomer and reports of successful treatment of GERD with racemic baclofen are encouraging in that they suggest effects on the GI tract in humans, though they are not necessarily effects that will be beneficial in FD. However, there is no clear rationale for relevant pharmacological activity in FD and there are no model systems to enable such activity to be demonstrated. The outcome of the current trial will give some indication of the potential of this product candidate.

AGI-010 is a CHRONAB based DR/CR version of the proton pump inhibitor, omeprazole, in development for GERD/NAB. AGI plans to complete the current Human PK / PD trial (Q1 2006) and seek to out-licence the product candidate. The target profile, assuming it is achieved, may reasonably be expected to make the product candidate an effective competitor in its target market, in that it addresses a specific unmet need which is present in a large proportion of the many patients using PPIs. The technology is, however, at an early stage and is not yet tested in larger scale clinical trials; and while study methods used to date will give a good indication of the effectiveness on nocturnal acid secretion of the proposed formulations, it is not clear from prior studies that symptom relief will necessarily correlate well with this effect. If the CHRONAB approach is shown to be effective with omeprazole, AGI's plan to apply it to another PPI is sound.

AGI-022 is a DR/CR version of 4-ASA in development for UC. AGI has completed a Human PK/PD trial and is now seeking to out-licence the product candidate. The model on which the timed/controlled release of 4-ASA is based is rational but hypothetical at this stage, and may not lead to the expected levels of efficacy. The inflammatory bowel disease market is highly competitive and there are a large number of aminosalicylate-based products already on the market.

In Bridgehead's opinion, AGI's portfolio of product candidates has the potential to produce commercially attractive therapeutic drug products with competitive advantages. However, development of any pharmaceutical product carries a high degree of risk, and both safety and efficacy in pivotal clinical trials remain to be proven for all AGI's products. To a great extent these risks are common to all companies developing therapeutics, and AGI's risks are balanced across a reasonable portfolio.

Bridgehead believes that AGI's management have the relevant skills and experience to implement the Group's plan.

For and on behalf of Bridgehead International Ltd.

Fiona J Paton PhD

PART IV — PATENT AGENTS' REPORT

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Dear Sirs:

21 February 2006

In accordance with your request on behalf of AGI Therapeutics, plc and its subsidiary, AGI Therapeutics Research Limited ("AGI" or "the Group"), we have prepared a summary of AGI's worldwide patent portfolio for inclusion in an admission document relating to the proposed admission of AGI's entire issued share capital to the AIM of the London Stock Exchange and the Irish Enterprise Exchange of the Irish Stock Exchange. In preparation of this summary, we have reviewed our internal files for AGI's patent applications and issued patents and consulted publicly available sources for current and confirmatory application and patent status information.[1]

To the best of our knowledge, based upon reasonable inquiry and research, this summary covers the complete patent portfolio of pending patent applications and issued patents assigned to AGI Therapeutics Research Limited (previously known as AGI Therapeutics Limited). This summary has been prepared diligently and we have no reason to doubt the accuracy of any of the information provided. The information provided herein has only been verified to the extent indicated above. Changes in circumstances, in particular the passage of time, will likely result in the expiration of the accuracy of the portfolio status information provided.

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP ("Finnegan Henderson") first began providing patent related legal services to the executives presently at AGI in 2002, when they were with a predecessor company, Athpharma Limited ("Athpharma"). In March 2004, when AGI became the assignee of intellectual property assets from Athpharma, Finnegan Henderson was retained as intellectual property counsel and has since managed the majority of the Group's worldwide patent portfolio in conjunction with select international patent agents and firms. Since the Group's inception, Finnegan Henderson has drafted and prosecuted AGI's patent applications worldwide in consultation with AGI's executives and technical experts. In addition, Finnegan Henderson has advised AGI on general patent-related matters surrounding their intellectual property in the general areas of acquiring patent

1 Finnegan Henderson currently manages AGI's entire worldwide patent portfolio with the exception of one pending US non-provisional patent application, entitled "Proton Pump Inhibitor Formulations, and Methods of Preparing and Using Such Formulations." The information related to this application presented herein was obtained from the law firm (Greenblum & Bernstein, PLC) handling the prosecution of this application and through publicly available sources.

rights and evaluating opportunities for licensing relationships, as well as regarding various patentability, infringement and validity issues surrounding the Group's patent portfolio.

Finnegan Henderson is a United States ("US") law firm, practicing US law and has over four decades of experience specializing in intellectual property ("IP") law. The firm offers full-service IP protection and counseling in virtually every technology and product category ranging from consumer goods, electronics, medical devices, biotechnology and manufacturing to pharmaceuticals and nanotechnology. Finnegan Henderson employs over 300 lawyers focused on IP law only. They are supported by an IP infrastructure of over 500 professionals and support staff that include dedicated docketing, research, graphics, and technology specialists. During a typical year, Finnegan Henderson handles more than 3,000 patent applications, which include new US applications, continuations, divisionals, foreign-origin applications, and their filing and prosecution domestically and abroad.

Finnegan Henderson is headquartered in Washington, DC with offices located in growing research and technology centers such as Cambridge, Massachusetts; Palo Alto, California; Reston, Virginia; and Atlanta, Georgia. As more markets emerge on every continent and as the protection of IP grows increasingly valuable and complex, Finnegan Henderson has expanded their global presence through their Brussels, Taipei, and Tokyo offices and their network of international affiliates.

In surveys conducted over the past several years, American Lawyer Media has consistently ranked Finnegan Henderson as one of the top law firms that Fortune 250 corporations rely on for IP counseling and litigation. Most recently, in *The American Lawyer's* annual survey for 2005, Finnegan Henderson was awarded the title of Best Intellectual Property Litigation Department of the Year. In *Managing Intellectual Property's* 2002, 2003/2004, and 2005 World IP surveys of 4,000 global practitioners, the firm was ranked as the number one US law firm for patent litigation and non-contentious patent work, e.g., prosecution, opinions and patent portfolio management. The same publication ranked Finnegan Henderson as the first- or second-place US firm for trademark litigation in its 2002, 2003/2004, and 2005 surveys. In the rankings for non-contentious trademark work, Finnegan Henderson has risen from fifth place (2002) to third place (2003/2004) and currently is tied for second place (2005).

Finnegan Henderson consents to the issue of the Admission Document with the inclusion of its name and the contents of this report. The information contained in Part IV of the Admission Document accurately reproduces the contents of our report, and to the best of our knowledge, no facts have been omitted which would render any such information inaccurate or misleading. Finnegan Henderson accepts responsibility for the information which is contained in Part IV of the Admission Document.

I. PATENT OVERVIEW

A. Patent Protection Generally

1. United States[2]

Under US law, a patent for an invention is the grant of a property right to the inventor(s), which is issued by the United States Patent and Trademark Office ("the USPTO"). Generally, the term of a newly issued patent is 20 years from the date on which the application for the patent was filed in the United States ("US") or, in special cases, from the date of filing of an earlier related application, subject to the payment of maintenance fees. All patents require the USPTO approval of a non-provisional application that includes at least one claim. AGI utilizes two general types of patent applications in their US patent portfolio: provisional and non-provisional patent applications.

a.) Provisional Patent Applications

Provisional patent applications were designed to provide a lower cost, and perhaps less detailed, original patent filing opportunity in the US and to give US applicants parity with foreign applicants having priority application opportunities. In addition, provisional applications provide the means to establish an early effective filing date for a related, subsequently filed non-provisional patent application and permit the term "Patent Pending" to be applied in connection with the covered invention.

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2 The material discussed under this heading has been obtained from the USPTO website under ''General Information Concerning Patents'' found at www.uspto.gov/web/offices/pac/doc/general/index.html.

With provisional applications, the applicant has up to 12 months from their filing to file a related non-provisional application for patent, as described below. The claimed subject matter in the later filed non-provisional application can be entitled to the benefit of the filing date of the provisional application, if it has full Title 35, Section 112 of the United States Code ("U.S.C.") statutory support in the provisional application.

It is important to note that provisional applications are not examined on their merits, nor are they required to include any claims. A provisional application will become abandoned by the operation of law 12 months from its filing date. The 12-month pendency for a provisional application is not counted toward the 20-year term of a patent granted on a subsequently filed non-provisional application, which claims benefit of the filing date of the provisional application.

b.) Non-Provisional Patent Application

Non-provisional applications are the traditional patent applications and are distinct from provisional applications in that a non-provisional application is examined on its merits and can mature into an issued US patent. A non-provisional application includes: (1) a written document which comprises a specification (description and claims), and an oath or declaration; (2) a drawing in those cases in which a drawing is necessary; and (3) payment of required filing, search, and examination fees.

The specification must conclude with at least one claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention. The portion of the application in which the applicant sets forth the claim or claims is an important part of the application, as it is the claims that define the scope of protection afforded by a granted patent.

More than one claim may be presented provided they differ from each other. Claims may be presented in independent form, e.g., the claim stands by itself, or in dependent form, referring back to and further limiting another claim or claims in the same application.

The filing date of a non-provisional application for patent is the date on which a specification (including at least one claim) and any drawings necessary to understand the subject matter sought to be patented are received in the USPTO; or the date on which the last part completing the formal application requirements is received in the case of a previously incomplete or defective application.

c.) Patentability

In order for a non-provisional application to mature into a patent, it must undergo "prosecution" before the USPTO. Prosecution ensures that certain formal and disclosure requirements are satisfied. 35 U.S.C. § 112. Prosecution also ensures that the invention is new, as defined in the patent laws, which provide that an invention cannot be patented if: "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States. . ." 35 U.S.C. § 102.

If the claimed invention has been described in a printed publication anywhere in the world, or has been in public use or on sale in the US more than one year before the date on which an application for patent is filed in the US, a patent cannot be obtained. In this evaluation, it is immaterial when the claimed invention was made, or whether the printed publication or public use was by the inventor himself/herself or by someone else. If an inventor describes an invention in a printed publication or uses an invention publicly, or places it on sale, he/she must apply for a patent on that invention before one year has passed, otherwise any right to a patent in that invention will be lost. The inventor must file for a patent on the date of public use or disclosure, however, in order to preserve patent rights in many foreign countries, i.e., outside the US. Otherwise, the inventors' own activities can become patent defeating prior art.

Even if the subject matter sought to be patented is not exactly shown in the prior art, and involves one or more differences over the closest similar thing already known, a patent may still be refused if the differences with the prior art would be obvious. The subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be nonobvious to a person having ordinary skill in the area of technology related to the invention. 35 U.S.C. § 103.

d.) Time Of Pendency

The time period that it takes from the filing of a non-provisional patent application to issuance of a US patent can vary greatly depending on a number of factors, such as the scope of protection sought and the

technological area of the invention. For example, an application in the biotechnology or organic chemistry technology centers takes, on average, 23 months to receive a first office action on the merits (*e.g.*, an action addressing patentability issues).[3] Peggy Focarino, *Patent Operations FY 05 Results*, AIPLA Annual Meeting, October 28, 2005. Similarly, an application in the same technology centers generally takes, on average, 32.3 months to mature into an issued patent.[4] *Id*. These time periods, however, change drastically if one were to follow an application that was recently filed, *e.g.*, on or after January 2005. *Id*. In this case, assuming production rates remain the same, a new application directed to pharmaceuticals or bio-affecting and body treatments filed on or after January of 2005 would take approximately 57-65 months to obtain a first office action on the merits. *Id*. These production rates assume no changes in USPTO production due to hiring, attrition, changes to examination processing or examination efficiencies, and that applications are taken in the order of filing in the given art unit. *Id*. The USPTO is taking aggressive steps to ensure changes that will significantly lower the inventory rates, but as one can see, pendency can vary greatly. Accordingly, it is difficult to predict how long an application will remain in prosecution before it matures into a patent.

Estimated pendency time periods indicated below for AGI's pending patent applications are based on current predictions by the USPTO of 23 months to receive a first Office Action and 56 months to issuance (i.e., 23 months to first Office Action and an additional 32.3 months to issuance, totaling 55.3 months) from a non-provisional application's filing date. As noted, these pendency time periods are estimates only and are in no way guarantees regarding issuance of any of the claims or applications mentioned in this summary during the projected time periods or that a patent containing even one claim will issue at all.

2. International Applications[5]

The Patent Cooperation Treaty ("PCT") is an international treaty administered by the World Intellectual Property Organization ("WIPO"), between more than 125 Paris Convention member countries. The PCT makes it possible to seek patent protection for a claimed invention simultaneously in each of a large number of countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. The granting of individual patents, however, remains under the control of national or regional offices in what is called the "national phase" of the PCT process.

The following outline briefly describes the PCT prosecution procedure:

Filing: An international patent application is filed by complying with the PCT formality requirements, including filing in an acceptable language and paying one set of fees.

International Search: An "International Searching Authority" (i.e., one of the world's major patent offices) performs a prior art search and identifies the published documents that may have an influence on whether an invention is patentable and provides an opinion on the claimed invention's potential patentability. A PCT international search is generally deemed a high quality search of the relevant patent documents and other technical literature in those languages in which most patent applications are filed (*e.g.*, English, French and German, and in certain cases, Chinese, Japanese, Russian and Spanish).

International Publication: Approximately 18 months after an application's effective filing date, the content of the international patent application generally publishes. The WIPO generally publishes international applications together with the international search report.

International Preliminary Examination: An "International Preliminary Examining Authority" (i.e., one of the world's major patent offices), at an applicant's request, carries out a more focused patentability analysis, often on an amended version of the originally filed application.

National Phase: Following the international phase of the PCT process, an applicant can pursue grant of a patent directly before the national (or regional) patent offices of the PCT member countries in which patent protection is desired.

Normally, an applicant has 18 months from the time the international patent application is filed (or 30 months for the filing date of the original patent application to which an applicant claims priority)

3 Average first action pendency is the average age from filing to first office action for a newly filed application, completed during July-September Fiscal Year 2005. Peggy Focarino, *Patent Operations FY 05 Results*, AIPLA Annual Meeting, October 28, 2005.

4 Average total pendency is the average age from filing to issue or abandonment of a newly filed application, completed during July-September Fiscal Year 2005. *Id.*

5 The material discussed under this heading has been obtained from the brochure entitled "Protecting Your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT)" distributed by the World Intellectual Property Organization.

before one has to begin the national phase procedures with individual patent offices. Once in the national phase, each patent office is responsible for examining the application in accordance with its respective national or regional patent laws, regulations, and practices resulting in, if all things are favorable, the grant of a national or regional patent. The time required for examination and grant of a patent varies across patent offices. Because of the disparity in pendency for national phase applications, an estimated time period to grant is not provided.

B. AGI's Patent Strategy

The following description highlights the general approach taken for the protection of AGI's intellectual property in the area of gastrointestinal disorder therapeutics. Based on prior art searches performed by and invention disclosures prepared by AGI executives and scientists, Finnegan Henderson drafts provisional and non-provisional US patent applications in consultation with AGI regarding the various technical aspects of their inventions.

AGI's patent protection strategy generally involves first filing US provisional applications to secure a priority date for each inventive disclosure. Within one year of the first filed application, a US non-provisional and/or an international application under the PCT are filed claiming the benefit of the provisional application filing date. In instances where AGI filed a non-provisional US application first, an international application was subsequently filed within one-year of the non-provisional application filing, and claims priority benefit of the non-provisional application filing date as its effective US filing date. To maintain a solid international patent prosecution strategy and adjust to changes in the technical as well as legal fields, AGI and Finnegan Henderson continually optimize this general approach by taking into consideration evolving case law, varying domestic and international patent practices, and changing laws and regulations.

Regarding the non-US applications, Finnegan Henderson works, on AGI's behalf, in consultation with well-established patent agents and firms knowledgeable in the patent laws of the countries where AGI seeks patent protection. In the international arena, AGI typically designates all PCT contracting states and often nationalize at least in the following countries: Australia, Canada, European Patent Organization ("Europe") (i.e., member countries of the European Patent Organization include: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Monaco, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and United Kingdom), Israel, Japan, Mexico, Norway, New Zealand, and South Africa. During the prosecution of these international applications as well as with issued US patents, an annuity service (Computer Patent Annuities Limited Partnership) is generally used to pay associated fees for maintaining the pendency of these applications and issued patents.

II. SCOPE OF SUMMARY

In preparation of this summary, we have reviewed our internal files of AGI related to both domestic and foreign patent application filings and issued patents. From these files, communications between the various patent offices around the world and foreign counsel and ourselves were reviewed. Based on these communications and official domestic and international patent office issued documents, a summary of the status of AGI's currently pending applications and issued patents is provided below. We have also consulted publicly available sources for current and confirmatory information regarding AGI's patents and patent applications.

We have verified the facts presented in this summary to the extent possible via such sources, which facts must be noted to be of limited temporal accuracy. Thus, changes in circumstances, in particular the passage of time, will likely result in the expiration of the accuracy of the various status details presented herein. This document excludes the identification and substantive review of any prior art cited during the prosecution of the respective patent applications and excludes any analysis of the patentability, validity, strength and/or enforceability of any of the claims of the respective listed patent applications and issued patents. Accordingly, this document does not contain any legal opinion as to the patentability, validity, strength or enforceability of any of the patent and application claims mentioned herein.

In the following section, Core Patent Portfolio, each family of applications is identified by the title of the US patent application along with a brief description of the application's disclosure. The descriptions of the respective disclosures included herein were obtained from the abstracts filed with each respective US

patent application. These descriptions should not be relied upon as providing a complete or wholly accurate description of any of the disclosures, or the patent protection sought or obtained with respect to the particular application.

Following the description of each inventive disclosure, a table is provided entitled "Patent Application Filings and Issued Patents" directed to each particular family of applications. The tables summarize the countries, filing dates, patent application numbers, patent issue dates (patent application publication dates), and patent numbers (patent application publication numbers) for each disclosure. In circumstances where an application has not matured into an issued patent and is presently undergoing prosecution or will undergo prosecution, the issue date and patent number column is indicated with the designation "currently being prosecuted" by "CBP." In other instances where an issue date and patent number are not given, *e.g.*, with the filing of a US provisional application, these columns are indicated with the designation "not applicable" by "N/A." An appendix is provided at the end of the summary that merges the tables of all the families of applications into one.

A discussion of the current status of each domestic and foreign application and patent within a particular family follows the corresponding "Patent Application Filings and Issued Patents" table. These discussions are organized by country and provide a synopsis of the status of the application in each respective country where an application was filed. The current status of the application is subject to change at any time and thus, may only be applicable as of the date of this report. The synopsis of the current status of each application should not be relied upon as providing a complete or wholly accurate description of the entire prosecution in that particular country. Furthermore, when presently pending claims are mentioned or discussed, there is no related opinion or guarantee provided as to the strength of those claims or the likelihood that any of the presently pending claims will issue in their present form, or even at all. The discussion of the current status of any pending application or patent, moreover, should not be relied upon as an opinion as to the validity, patentability, strength or enforceability of any of the pending or issued claims in the respective applications and patents.

III. CORE PATENT PORTFOLIO

AGI's inventive pursuits have generally been focused on therapeutics for gastrointestinal disorders and in particular, on functional disorders, such as irritable bowel syndrome, functional dyspepsia, functional diarrhea and gastroparesis, and acid-related disorders, such as gastro-esophageal reflux disease, and inflammation diseases, such as ulcerative colitis. The invention disclosures and corresponding patent applications and patents are identified chronologically by family in the following discussion.

A. AGI-001: Treatment and Prevention of Gastrointestinal Disease Using Antagonist or Partial Agonists of 5HT1a Receptors

i. Description

This disclosure is directed to a method for treating gastrointestinal disease comprising administering a composition consisting essentially of an effective amount of S(-) pindolol, or a salt thereof, to a subject in need thereof, wherein the gastrointestinal disease is chosen from gastrointestinal motility disorders and functional gastrointestinal disorders.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	10/22/99	60/161,117	N/A	N/A
US	10/13/00	09/687,384	CBP	CBP
PCT	10/11/01	PCT/IB01/02759	CBP (4/18/02)	(WO 02/30406)
Canada	4/11/03	2,425,910	CBP	CBP
Europe	5/12/03	01986602.9	CBP (4/21/04)	CBP (EP 1 408 937)
Japan	4/14/03	2002-533849	CBP (4/8/04)	CBP (2004-510814)

iii. Current Status

a. US — Provisional

A provisional application was filed with the USPTO on October 22, 1999, and assigned Application No. 60/161,117. Within one year of filing the provisional application, a fully developed US non-provisional

patent application was filed claiming the benefit of the provisional application filing date. No further action is required on behalf of AGI or the USPTO.

b. US — Non-provisional

This application was filed on October 13, 2000, with the USPTO and was accorded Application No. 09/687,384. The inventors (T.G. Dinan and P.W.N. Keeling) assigned the application originally to G.I. Pharmaceuticals, Limited, an Irish company. By a subsequent assignment, Athpharma was assigned the application, which application was then assigned to AGI. The assignment transferring rights to AGI was duly recorded at the USPTO on August 8, 2004, at Reel/Frame: 015076/0001.

Most recently in this case, the USPTO issued an Office Action on August 17, 2005. An Examiner Interview was conducted on October 5, 2005, and AGI timely filed a response to the Office Action on November 7, 2005. A telephone interview was conducted with the Examiner on December 9, 2005. The USPTO issued on 3 February 2006, a Notice of Allowance with an Examiner's Amendment to the claims of this application. The allowed claims with the Examiner's Amendment read as follows:

1. A method for treating at least one gastrointestinal disease comprising administering a composition consisting essentially of an effective amount of S(-) pindolol, or a salt thereof, as the sole active agent to a subject in need of said treatment, wherein the effective amount of S(-) pindolol, or a salt thereof, ranges from greater than 3 mg/per day to about 50 mg/per day in a single or divided dose, wherein the at least one gastrointestinal disease is chosen from non-ulcerative dyspepsia, irritable bowel syndrome, cancer chemotherapy-associated disorders of motility, and combinations thereof. AGI awaits further substantive action from the USPTO.

2. The method according to claim 1, wherein an effective amount of S(-) pindolo, or a salt thereof, is administered in a pharmaceutical dosage form that permits rapid release of the S(-) pindolol.

3. The method according to claim 1, wherein an effective amount of the S(-) pindolol, or a salt thereof, is administered in a pharmaceutical dosage form that releases the S(-) pindolol in a slow or controlled fashion.

4. The method according to claim 1, wherein the cancer chemotherapy-associated disorder of motility is nausea.

c. PCT

Within one year of filing the US non-provisional application, AGI filed an international application under the PCT on October 11, 2001. The PCT application claimed benefit of the US non-provisional application, was accorded Application No. PCT/IB01/02759, and published on April 18, 2002, as WO 02/30406. AGI timely initiated national stage applications in Canada, Europe, and Japan. With nationalization, the PCT application is now complete and no further action is required.

d. Canada

Based on the PCT application, AGI nationalized in Canada on April 11, 2003. The Canadian Patent Office assigned Application No. 2,425,910 to the application. To date, all the procedural aspects of the application are in order and AGI must request substantive examination by October 11, 2006.

e. Europe

AGI also nationalized the PCT application in Europe on May 13, 2003. The European Patent Office accorded Application No. 01986602.9 to the application. The PCT claims were amended to conform to European patent practice. The application published on April 21, 2004, as EP 1 408 937. To date, all the procedural aspects of the application are in order and AGI awaits substantive action by the European Office Action.

f. Japan

From the PCT application, AGI nationalized in Japan on April 14, 2003, and the Japanese Patent Office assigned Application No. 2002-533849 to the presently pending application. The application published on April 8, 2004, as publication No. 2004-510814. On September 27, 2004, AGI filed a Request for Examination and amended the claims to conform to Japanese patent practice. At this time, AGI awaits further action by the Japanese Patent Office.

B. AGI-003: Treatment of Abnormal Increases in Gastrointestinal Motility with (R)-Verapamil

i. Description

This disclosure is directed to methods of treating, preventing, and/or managing abnormal increases in gastrointestinal motility, and intestinal conditions that cause the same. Such conditions include irritable bowel syndrome (IBS), infectious diseases of the small and large intestines, and symptoms of any of the foregoing. In particular, family of applications discloses methods of using enriched (R)-verapamil, as well as compositions and formulations containing the same.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US	9/27/02	10/256,261	Abandoned (5/15/03)	(2003/0092765)
	10/15/02	10/294,692	2/1/05 (4/1/04)	6,849,661 B2 (2004/0063784)
PCT	11/15/02	PCT/IB/05140	(4/22/04)	(WO 04/032919)
Australia	11/15/02	2002351118	CBP	CBP
Canada	3/16/05	2,499,290	CBP	CBP
Europe	3/31/05	02785831.5	CBP (6/22/05)	CBP (EP 1 542 673)
Israel	3/16/05	167,482	CBP	CBP
Japan	3/28/05	2004-542687	CBP	CBP
Mexico	3/23/05	PA/a/2005/003177	CBP	CBP
New Zealand	3/23/05	539059	CBP	CBP
Norway	4/27/05	20052026	CBP	CBP
South Africa	3/18/05	2005/02306	CBP	CBP

iii. Current Status

a. US

1. Application No. 10/256,261

The first US application in this family was filed as a nonprovisional application on September 27, 2002. The USPTO assigned Application No. 10/256,261 to the application. This application published on May 15, 2003, as US Patent Application Publication No. 2003/0092765. The application, however, was subsequently abandoned in view of a continuation-in-part application filed on October 15, 2002, i.e., Application No. 10/294,692.

2. Application No. 10/294,692

Based on Application No. 10/256,261, AGI filed a continuation-in-part application on November 15, 2002, and the USPTO assigned Application No. 10/294,692 to this application. This application published on April 1, 2004, as US Patent Application Publication No. 2004/0063784. AGI secured allowance of the subject matter covered by the pending claims following substantive examination. The USPTO issued a Notice of Allowance on August 30, 2004. Accordingly, Application No. 10/294,692 matured into US Patent No. 6,849,661 ("the '661 patent"), which issued on February 1, 2005.

The '661 patent has a term extending twenty-years from its earliest effective filing date and thus, expires on November 24, 2022 (including a patent term adjustment of 58 days), assuming the payment of all maintenance fees. The '661 patent recites 29 claims of which claims 1, and 27-29 are independent. These independent claims recite:

1. A method for treating an increase in gastrointestinal motility in a subject in need of said method: comprising administering a therapeutically effective amount of enriched (R)-verapamil, or a pharmaceutically acceptable salt thereof, to said subject, wherein the (R)-verapamil is at least about 98 per cent enriched with respect to its (S) stereoisomer.

27. A method for preventing an increase in gastrointestinal motility in a subject in need of said method: comprising administering a therapeutically effective amount of enriched (R)-verapamil, or a pharmaceutically acceptable salt thereof, to said subject wherein the (R)-verapamil is at least about 98 per cent enriched with respect to its (S) stereoisomer.

28. A method for managing an increase in gastrointestinal motility in a subject in need of said method: comprising administering a therapeutically effective amount of enriched (R)-verapamil, or a pharmaceutically acceptable salt thereof, to said subject, wherein the (R)-verapamil is at least about 98 per cent enriched with respect to its (S) stereoisomer.

29. A method for reducing an increase in gastrointestinal motility in a subject in need of said method: comprising administering a therapeutically effective amount of enriched (R)-verapamil, or a pharmaceutically acceptable salt thereof, to said subject, wherein the (R)-verapamil is at least about 98 per cent enriched with respect to its (S) stereoisomer.

b. PCT

Under the PCT, an international application was filed on November 15, 2002, in conjunction with the filing of the US non-provisional application. The international application, i.e., Application No. PCT/IB02/05140, claimed the benefit of US non-provisional patent Application No. 10/256,261 and was published on April 22, 2004, as WO 04/032919. National stage applications were initiated in Canada, Israel, Japan, Mexico, Norway, Australia, Europe, New Zealand, and South Africa. With nationalization, the PCT case is now complete and no further action is required.

c. Australia

From the PCT application, AGI nationalized in Australia on November 15, 2002. The Australian Patent Office accorded Application No. 200235118 to the present application. The first annuity fee will be due November 15, 2007. AGI awaits instructions from the Australian Patent Office that examination must be requested, at which time AGI will have six-months to request examination.

d. Canada

Based on the PCT application, AGI nationalized in Canada on March 16, 2005. The Canadian Patent Office assigned Application No. 2,499,290 to the present application. With all procedural requirements having been fulfilled, AGI must request substantive examination by November 17, 2007.

e. Europe

AGI also designated Europe for entry into the national phase from the PCT application. The application was filed with the European Patent Office on March 31, 2005, and the application has been assigned Application No. 02785831.5 with an effective filing date of November 15, 2002 (i.e., the PCT filing date). With national phase entry, the PCT claims were amended to conform to European practice, i.e., method claims were converted to "second medical use" claims. The European Patent Office recently issued a Communication that the present application published on June 22, 2005, under publication number EP 1 542 673. AGI awaits substantive action by the European Patent Office.

f. Israel

National phase entry was also sought in Israel from the PCT application. The Israeli Patent Office accorded Application No. 167,482 to the present application having an effective filing date of November 15, 2002 (i.e., the PCT filing date). AGI submitted an executed Authorization of Agent Form with the Israeli Patent Office. The application is expected to remain dormant for about four years, from the submission date of the executed Authorization of Agent Form, until its turn for substantive examination. As such, AGI presently awaits action by the Israeli Patent Office.

g. Japan

The PCT application was nationalized in Japan on March 28, 2005. This application has been accorded Application No. 2004-542687. To date, the PCT claims were amended to conform with Japanese patent practice and a Request for Examination has been filed. AGI awaits substantive action from the Japanese Patent Office.

h. Mexico

AGI nationalized the PCT application in Mexico on March 23, 2005. The Mexican Patent Office assigned Application No. PA/a/2005/003177 to the application. To perfect the filing, AGI submitted assignment documents issued by the USPTO. AGI awaits further action by the Mexican Patent Office.

i. New Zealand

Based on the PCT application, AGI nationalized in New Zealand on March 23, 2005. The New Zealand Patent Office accorded Application No. 539059 to the application. To date, claim amendments were filed

to bring the PCT claims in conformance with New Zealand patent practice. With all procedural requirements having been fulfilled, AGI must request acceptance of the application by November 25, 2006.

j. Norway

From the PCT application, AGI nationalized in Norway on April 27, 2005. The Norwegian Patent Office accorded Application No. 20052026 to the application. AGI has fulfilled the procedural requirements with the Norwegian Patent Office and the annuity fees for the first through third years have been paid. AGI awaits action by the Norwegian Patent Office.

k. South Africa

From the PCT application, AGI nationalized in South Africa on March 18, 2005. The South African Patent Office assigned Application No. 2005/02306 to the present application. At this time, AGI awaits action from the South African Patent Office.

C. AGI-004: Treatment of Intestinal Conditions with N-2,3,3-Tetramethylbicyclo[2.2.1]Heptan-2-Amine

i. Description

This disclosure is directed to methods and formulations for reducing, preventing, and/or managing abnormal increases in gastrointestinal motility, and intestinal conditions that cause the same. Methods of using N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine and formulations comprising N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine are included.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	3/14/03	60/454,527	N/A	N/A
US	3/12/04	10/798,421	CBP (10/21/04)	CBP (2004/0209961)
PCT	3/12/04	PCT/IB04/01134	(9/23/04)	(WO 04/080446)
Australia	3/12/04	2004218899	CBP	CBP (2004218899)
Canada	9/7/05	2,518,385	CBP	CBP
Europe	10/7/05	04720110.8	CBP (12/14/05)	CBP (EP 1603544)
Israel	9/6/05	170,688	CBP	CBP
Mexico	9/9/05	PA/a/2005/009640	CBP	CBP
New Zealand	9/6/05	542260	CBP	CBP
Norway	10/11/05	20054670	CBP	CBP
South Africa	9/6/05	2005/07159	CBP	CBP

iii. Current Status

a. US — Provisional

A provisional application was filed with the USPTO on March 14, 2003, and assigned Application No. 60/454,527. Within one year of filing the provisional application, AGI filed a US non-provisional application and an international (PCT) application claiming the benefit of the US provisional application filing date. No further action is required on behalf of AGI or the USPTO.

b. US — Non-provisional

Within one year of the provisional application filing, AGI filed a non-provisional application on March 12, 2004, and it was assigned Application No. 10/798,421. The application published on October 21, 2004, as US Patent Application Publication No. 2004/0209961. To date, AGI has met all the procedural requirements for the application and awaits substantive action from the USPTO. Based on the USPTO promulgated pendency rates discussed above, a first Office Action may be reasonably expected around the second or third quarter of 2006 and prosecution may reasonably be expected to be completed around the fourth quarter of 2008.

The presently pending independent claims recite:

1. A method of reducing gastrointestinal motility in a subject suffering from an abnormal increase in gastrointestinal motility, said method comprising administering to said subject a gastrointestinal motility reducing amount of N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine, or a pharmaceutically acceptable salt thereof.

30. A pharmaceutically acceptable formulation comprising N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine, or a pharmaceutically acceptable salt thereof, in the form of a modified-release formulation for oral, intra-nasal, or transdermal administration.

65. A pharmaceutically acceptable transdermal formulation, comprising N-2,3,3-tetramethylbicyclo[2.2.1]heptan-2-amine, or a pharmaceutically acceptable salt thereof, that when tested using modified Franz diffusion cells of human epidermis, in phosphate buffer at a pH of about 4 to about 7, at about 32 °C, exhibits a permeation rate in which less than about 50 per cent of said N-2,3,3-tetramethylbicyclo[2.2.1]heptan-2-amine is released in less than about 2 hours, greater than or equal to about 40 per cent is released in about 12 or more hours, and about 70 per cent or more is released in about 24 or more hours.

c. PCT

Under the PCT, an international application was filed on March 12, 2004, concurrently with the filing of the US non-provisional application. The international application, i.e., Application No. PCT/IB04/01134, claims the benefit of the US provisional application and was published on September 23, 2004, as WO 04/080446. National stage applications were initiated in Canada, Israel, Japan, Mexico, Norway, Australia, Europe, New Zealand, and South Africa. With nationalization, the PCT case is now complete and no further action is required.

d. Australia

From the PCT application, AGI sought national phase entry in Australia. The Australian Patent Office assigned Application No. 2004218899 to the pending application. The annual fee will become payable on March 12, 2009. At this time, AGI awaits a Direction that examination must be requested, at which time AGI will have six-months to request substantive examination.

e. Canada

The present application was nationalized in Canada from the PCT application on September 7, 2005. The Canadian Patent Office issued a Notice of National Entry and the application has been accorded Application No. 2,518,385. A request for substantive examination in Canada is due by March 12, 2009.

f. Europe

AGI also designated Europe for entry into the national phase. The application was filed with the European Patent Office on October 7, 2005, and the application has been assigned Application No. 04720110.8 with an effective filing date of March 12, 2004 (i.e., the PCT filing date). To maintain the pendency of the application, the first renewal fee is due on March 31, 2006. In addition, the European Patent Office issued a Communication that the present application published on December 14, 2005, under the publication number EP 1 603 544. From the European application, AGI must designate whether to record in Hong Kong by June 14, 2006. AGI awaits further action by the European Patent Office.

g. Israel

The PCT application was also nationalized in Israel on September 6, 2005. The Israeli Patent Office assigned Application No. 170,688 to the application with an effective filing date of March 12, 2004 (i.e., the PCT filing date). The application is expected to remain dormant for about four-years, until its turn for examination. To that end, AGI awaits further action by the Israeli Patent Office.

h. Mexico

The PCT application was also nationalized in Mexico on September 9, 2005. The Mexican Patent Office has assigned Application No. PA/a/2005/009640 to the application. At this time, AGI is in the process of filing certified copies of assignments and power of attorney to comply with the procedural requirements of the Mexican Patent Office. Once these procedural requirements are fulfilled, AGI will await substantive action by the Mexican Patent Office.

i. New Zealand

Based on the PCT application, AGI nationalized in New Zealand on September 6, 2005, and the New Zealand Patent Office accorded Application No. 542260 to the application. AGI has perfected the filing of this application with the submission of an executed copy of Request for Entry into National Phase. At this time, AGI awaits further action by the New Zealand Patent Office.

j. Norway

AGI also nationalized the PCT application in Norway on October 11, 2005. The Norwegian Patent Office assigned Application No. 20054670 to the present application. AGI filed an executed Right to the Invention and Power of Attorney perfecting the filing of the application. As such, AGI awaits further action from the Norwegian Patent Office.

k. South Africa

From the PCT application, AGI nationalized in South Africa on September 6, 2005, and was assigned Application No. 2005/07159 to the present application. AGI filed declaration and power of attorney documents with the South African Patent Office in order to perfect the filing of this application. In addition, certain claims that were filed with the PCT application were amended to conform with South African patent practice. To date, AGI awaits further action by the South African Patent Office.

D. AGI-022: Formulations and Methods of Treating Inflammatory Bowel Disease

i. Description

This disclosure is directed to methods and formulations for treating inflammatory bowel disease. The methods and formulations include methods and formulations for delivering effective concentrations of 4-aminosalicylic acid and/or 5-aminosalicylic acid to affected areas of the intestine. The methods and formulations comprise modified-release elements, providing for drug delivery to the affected or desired area. Diseases and conditions treatable with the present methods and formulations include Crohn's disease and ulcerative colitis.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	9/3/03	60/499,365	N/A	N/A
US	9/1/04	10/930,743	CBP (4/28/05)	CBP (2005/0090473)
	CIP — TBA	TBA	N/A	N/A
PCT	9/2/04	PCT/IB04/003059	(3/10/05)	(WO 05/021009)

CIP = Continuation-In-Part Application; TBA = To Be Announced

iii. Current Status

a. US — Provisional

In pursuing patent protection for this invention, a provisional patent application was first filed on September 3, 2003, having Application No. 60/499,365. Within one year of filing the provisional application, AGI filed a US non-provisional application and an international (PCT) application claiming benefit of the filing date of the US provisional application. No further action is required on behalf of AGI or the USPTO.

b. US

1. Application No. 10/930,743

Within one year of filing the provisional application, a non-provisional application was filed on September 1, 2004, claiming priority to the provisional application. The non-provisional application is identified as Application No. 10/930,743, and was published on April 28, 2005, as US Patent Application Publication No. 2005/0090473. To date, AGI has met all the procedural requirements for the application and awaits substantive action from the USPTO. Based on the USPTO promulgated pendency rates discussed above, a first Office Action may reasonably be expected around the second or third quarter of 2006 and prosecution may reasonably be expected to be completed around the second or third quarter of 2009.

The presently pending independent claims recite as follows:

1. Disodium 4,4'-azo-bis salicylate.

2. A pharmaceutical composition comprising 4,4'-azo-bis salicylic acid, or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient.

5. A pharmaceutical composition comprising: a salicylate and/or salicylic acid chosen from 4-amino salicylic acid, 5-amino salicylic acid, pharmaceutically acceptable salts thereof, and pro-drugs thereof, and at least one pharmaceutically acceptable excipient, formulated as a modified-release pharmaceutical composition, wherein the composition exhibits a delay in release that is dependent on surrounding pH.

8. A pharmaceutical composition comprising: a salicylate and/or salicylic acid chosen from 4-amino salicylic acid, 5-amino salicylic acid, pharmaceutically acceptable salts thereof, and pro-drugs thereof, and at least one pharmaceutically acceptable excipient, formulated as a modified-release pharmaceutical composition, wherein the composition exhibits a drug-release profile that is independent of surrounding pH.

16. A method of treating inflammatory bowel disease comprising administering an effective amount of 4,4'-azo-bis salicylic acid to a subject in need of such treatment.

2. CIP Application

AGI anticipates filing a continuation-in-part ("CIP") application based on the parent non-provisional application, i.e., Application No. 10/930,743, in the first quarter of 2006. This application will be focused on data from the clinical trials outlined in the parent non-provisional application.

c. PCT

Under the PCT, an international application was filed in conjunction with the non-provisional application filed in the US. The international application, identified as Application No. PCT/IB04/003059, claims the benefit of the US provisional application and was published on March 10, 2005, as WO 2005/021009. AGI recently instructed its various foreign patent agents in the following countries to proceed with nationalization. Australia, Canada, Europe, Israel, Japan, Mexico, Norway and South Africa. AGI awaiting confirmation of nationalization in each country.

E. AGI-006: Treatment of Gastroparesis and Non-ulcer Dyspepsia with GABAb Agonists

i. Description

This disclosure relates to formulations comprising a therapeutically effective amount of baclofen or (R)-baclofen, or pharmaceutically acceptable salts thereof, and methods of their use. The disclosed formulations and methods are designed to release a therapeutic amount of baclofen in a manner that maximizes its therapeutic effect. The methods and formulations are especially suitable for treating gastroparesis and non-ulcer dyspepsia.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	9/12/03	60/502,242	N/A	N/A
	3/18/04	60/553,940	N/A	N/A
US	9/8/04	10/935,176	CBP (4/28/05)	CBP (2005/0090554)
PCT	9/10/04	PCT/IB04/003299	(3/24/05)	(WO 05/025559)

iii. Current Status

a. US — Provisional

A first provisional patent application was filed in the USPTO on September 12, 2003, identified as Application No. 60/502,242, and directed generally to the above-described subject matter. In addition, a second provisional patent application was field on March 18, 2004, assigned Application No. 60/553,940. Within one year of filing the first provisional application, AGI filed a US non-provisional application and an international application claiming the benefit of both first and second provisional applications. No further action is required on behalf of AGI or the USPTO.

b. US — Non-provisional

Within one year of filing the first provisional application, a non-provisional application was filed on September 8, 2004, claiming priority to and including the disclosure of both first and second provisional applications. The pending application is identified as Application No. 10/935,176, which was published on April 28, 2005, as US Patent Application Publication No. 2005/0090554. To date, AGI has met all the

procedural requirements for the application and awaits substantive action from the USPTO. Based on the USPTO promulgated pendency rates discussed above, a first Office Action may reasonably be expected around the second or third quarter of 2006 and completion of prosecution may reasonably be expected around the second or third quarter of May 2009.

The presently pending independent claims recite:

1. A method of treating gastroparesis in a subject in need of such treatment, comprising administering to said subject an effective amount of baclofen, or a pharmaceutically acceptable salt thereof, wherein at least one symptom of gastroparesis other than vomiting is relieved.

11. A method of treating nonulcer dyspepsia in a subject in need of such treatment, comprising administering to said subject an effective amount of baclofen, or a pharmaceutically acceptable salt thereof, wherein at least one symptom of nonulcer dyspepsia other than vomiting is relieved.

21. A pharmaceutically acceptable formulation comprising enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, in the form of a pharmaceutical dosage form for oral, intra-nasal, buccal, transdermal, parenteral, or sublingual administration.

30. A method of treating gastroparesis comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such a treatment, wherein the subject obtains a therapeutic benefit resulting from the administration of enriched (R)-baclofen or substantially pure (R)-baclofen, and wherein the amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or pharmaceutically acceptable salt thereof, is less than the amount of racemic baclofen required to achieve the same therapeutic benefit.

31. A method of treating nonulcer dyspepsia comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such a treatment, wherein the subject obtains a therapeutic benefit resulting from the administration of enriched (R)-baclofen or substantially pure (R)-baclofen, and wherein the amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or pharmaceutically acceptable salt thereof, is less than the amount of racemic baclofen required to achieve the same therapeutic benefit.

32. A method of reducing one or more side effects associated with racemic baclofen comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such a reduction, wherein one or more side-effects are reduced relative to those resulting from the administration of an equivalent amount of racemic baclofen.

34. A method of reducing one or more drug interactions associated with administration of racemic baclofen comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such a reduction, wherein one or more drug interactions are reduced relative to those resulting from the administration of an equivalent amount of racemic baclofen.

36. A method of extending the therapeutic effect of a treatment for gastroparesis comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such treatment, wherein the administration of enriched (R)-baclofen, substantially pure (R)-baclofen, or pharmaceutically acceptable salt thereof, provides a therapeutic effect that lasts longer than the therapeutic effect achieved by administration of an equal amount of racemic baclofen.

38. A method of extending the therapeutic effect of a treatment for nonulcer dyspepsia comprising administering a therapeutically effective amount of enriched (R)-baclofen, substantially pure (R)-baclofen, or a pharmaceutically acceptable salt thereof, to a subject in need of such treatment, wherein the administration of enriched (R)-baclofen, substantially pure (R)-baclofen, or pharmaceutically acceptable salt thereof, provides a therapeutic effect that lasts longer than the therapeutic effect achieved by administration of an equal amount of racemic baclofen.

c. PCT

Under the PCT, an international application, Application No. PCT/IB04/003229, was filed on September 10, 2004. The international application claims priority to both of the US provisional applications. The international application published on March 24, 2005, as WO 05/025559. AGI recently

instructed its various foreign patent agents in the following countries to proceed with nationalization: Australia, Canada, Europe, Israel, Japan, Mexico, New Zealand, Norway and South Africa. AGI awaits confirmation of nationalization in each country.

F. AGI-010: Proton Pump Inhibitor Formulations, and Methods of Preparing and Using Such Formulations [currently being prosecuted by Greenblum & Bernstein, PLC]

i. Description

This disclosure is directed to pharmaceutical formulations comprising at least one proton pump inhibitor structured and arranged to provide an initial pH independent time-based delayed-release, and a subsequent extended-release of the at least one proton pump inhibitor.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	9/3/03	60/499,362	N/A	N/A
US	9/2/04	10/932,098	CBP (10/20/05)	CBP (2005/0232992)
	CIP — TBA	TBA	N/A	N/A
PCT	9/2/04	PCT/EP04/009806	(3/10/05)	(WO 05/020954)

CIP = Continuation-In-Part Application; TBA = To Be Announced

iii. Current Status

a. US — Provisional

A provisional application was filed with the US Patent and Trademark Office on September 3, 2003, and assigned Application No. 60/499,362. Within one year of filing the provisional application, AGI filed a US non-provisional application and an international application claiming the benefit of the filing date of the provisional application. No further action is required on behalf of AGI or the USPTO.

b. US — Non-provisional

1. Application No. 10/932,098

Within one year of filing the provisional application, AGI filed a non-provisional application on September 2, 2004, claiming benefit of the filing date of the provisional application. The non-provisional application is identified as Application No. 10/932,098. On October 20, 2005, this application published as US Patent Application Publication No. 2005/0232992. To date, AGI has met all the procedural requirements for the application and awaits a substantive action from the USPTO. Based on the USPTO promulgated pendency rates discussed above, a first Office Action may reasonably be expected around the second or third quarter of 2006 and prosecution may reasonably be expected to be completed by around the second or third quarter of 2009.

The presently pending independent claims recite:

1. A pharmaceutical formulation comprising at least one proton pump inhibitor structured and arranged to provide an initial pH independent time-based delayed-release, and a subsequent extended-release of the at least one proton pump inhibitor, said initial pH independent time-based delayed-release period of the at least one proton pump inhibitor comprising release of at most about 20 per cent of the at least one proton pump inhibitor during a period of about 1 to 4 hours, and the subsequent extended-release of the proton pump inhibitor being over a period of about 3 to 12 hours, and providing an hourly increase in percent release of the at least one proton pump inhibitor during any and all one hour periods of time of less than about 35 per cent.

25. A proton pump inhibitor formulation having a dissolution profile, using a rotating paddle apparatus (USP II) using 900 ml of USP phosphate buffer (pH 6.8) at 37°C and an agitation speed of 50 rpm of: 2 hours $\leq$30 per cent, 3 hours $\leq$ 60 per cent, 6 hours $\geq$ 20 per cent, 8 hours $\geq$ 40 per cent, and 12 hours $\geq$ 70 per cent.

30. A method of treating nocturnal acid breakthrough comprising orally administering a pharmaceutical formulation to a mammal, wherein said pharmaceutical formulation comprises at least one proton pump inhibitor structured and arranged to provide an initial pH independent time-based delayed-release, and a subsequent extended-release of the at least one proton pump inhibitor.

38. A formulation including at least one proton pump inhibitor, said formulation having a T_{max} of greater than 3.5 hours.

2. CIP Application

AGI anticipates filing a continuation-in-part ("CIP") application based on the parent non-provisional application, i.e., Application No. 10/932,098, in the second quarter of 2006. This application will be focused on data from the clinical trials outlined in the parent non-provisional application.

c. PCT

Under the PCT, an international application, Application No. PCT/EP04/009806, was filed on September 2, 2004. The international application published on March 10, 2005, as WO 05/020954. By February of 2006, AGI must file national phase applications in any of the designated PCT contracting states.

G. AGI-007: Use of Delayed Release Metformin to Treat Constipation

i. Description

The disclosure is directed to methods and formulations for treating chronic constipation. The methods and formulations include methods and formulations for delivering effective concentrations of metformin for treating chronic constipation and further comprise at least one pharmaceutically acceptable ingredient to control the release of the metformin, wherein following administration, the release of metformin is distal to the gastrointestinal sites to achieve systemic absorption of metformin. The disclosure is also directed to treating constipation as a symptom associated with other diseases and conditions such as irritable bowel syndrome.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	3/18/05	60/662,920	N/A	N/A

iii Current Status

a. US — Provisional

A provisional application was filed on March 18, 2005, directed to the above-described disclosure. The USPTO assigned Application No. 60/662,920 to the application. Within one year of filing the provisional application, AGI can file a non-provisional application and/or an international application claiming the benefit of the filing date of the provisional application. Accordingly, AGI has until March 18, 2006, to file a non-provisional application and/or international application to obtain the priority benefit of the US provisional application filing date.

H. AGI-008: Use of Modified Release Acarbose to Treat Constipation

i. Description

This disclosure is directed to a method for treating chronic constipation in a subject in need of such treatment comprising administering to the subject a dosage formulation comprising a therapeutically effective amount of acarbose, or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable ingredient to control the release of the acarbose, wherein following administration, the dosage formulation releases acarbose distal to the gastrointestinal sites at which acarbose is absorbed.

ii. Patent Application Filings and Issued Patents

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — Provisional	4/12/05	60/670,265	N/A	N/A

iii Current Status

a. US — Provisional

A provisional application was filed on April 12, 2005, directed to the above-described disclosure. The USPTO assigned Application No. 60/670,265 to the application. Within one year of filing the provisional application, AGI can file a non-provisional application and/or an international application claiming the benefit of the filing date of the provisional application. Accordingly, AGI has until April 12, 2006, to file a non-provisional application and/or an international application claiming the benefit of the US provisional application filing date.

I. Future Disclosures

AGI continues to innovate and evaluate research opportunities for the development of gastrointestinal disorder therapeutics for the preparation and filing of further patent applications.

IV. ADDITIONAL PATENTS IN AGI'S PORTFOLIO

In addition to the patent applications and patents identified above in its core portfolio, AGI, pursuant to transfer agreements between Arakis Limited and Athpharma and subsequently between Athpharma and AGI, is the assignee of the following patents generally directed to verapamil, entitled "Resolution of 4-cyano-4-(3,4-diemthoxyphenyl)-5-methylhexanoic Acid."[6] These patents are directed to a reproducible process for preparing a substantially single enantiomer (R or S) of 4-cyano-4-(3,4-diemthoxyphenyl)-5-methylhexanoic acid, or an analogue thereof, thereby providing a single enantiomeric acid for the first time. The disclosed process proceeds via a classical salt resolution employing a resolving agent selected from an enantiomer (R or S) of a 1-arylalkylamine and (-)-quinine, and provides novel salts that are readily convertible to verapamil.

Subject to the agreements between Arakis Limited, Athpharma and AGI, the chart below identifies the patents assigned to AGI:

Country	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
US — provisional	5/7/96	60/016,536	N/A	N/A
	5/7/96	60/016,987	N/A	N/A
US	2/7/97	08/796,358	4/6/99	5,892,093
France	10/2/97	97904517.6	1/24/01	EP 0 879 225
Germany	10/2/97	97904517.6	1/24/01	EP 0 879 225
Italy	10/2/97	97904517.6	1/24/01	EP 0 879 225
Switzerland	10/2/97	97904517.6	1/24/01	EP 0 879 225
United Kingdom	10/2/97	97904517.6	1/24/01	EP 0 879 225

As identified above, US Patent No. 5,892,093 ("the '093 patent"), was filed on February 7, 1997, and claims the benefit of US Provisional Application No. 60/016,536, filed on May 7, 1996, and US Provisional Application No. 60/016,987, filed on May 7, 1996. The '093 patent has a term extending twenty-years from its first effective filing date and thus, expires February 7, 2017, assuming the payment of all maintenance fees. The '093 patent contains three independent claims:

> substantially single isomer of 4-cyano-4-(3,4-dimethoxyphenyl)-5-methylhexanoic acid, or an analogue thereof, which proceeds by means of a classical salt resolution employing an enantiomer, R or S, of a resolving agent selected from the group consisting of 1-phenylethylamine, 1-(1-naphthyl)ethylamine, and (-)-quinine.
>
> 2. A process for the synthesis of substantially single enantiomer, R or S, verapamil, or an analogue thereof, comprising preparing a substantially single isomer of 4-cyano-4-(3,4-dimethoxyphenyl)-5-methylhexanoic acid, or an analogue thereof, by means of a classical salt resolution employing an enantiomer, R or S, of a resolving agent selected from the group consisting of 1-phenylethylamine, 1-(1-naphthyl)ethylamine, and (-)-quinine; and subsequent conversion of the product obtained to verapamil, or an analogue thereof.
>
> 3. An enantiomeric salt, R or S, of 4-cyano-4-(3,4-dimethoxyphenyl)-5-methylhexanoic acid, or an analogue thereof, wherein the counterion is resolved by employing an enantiomer, R or S, of a resolving agent selected from the group consisting of 1-phenylethylamine, 1-(1-naphthyl)ethylamine, and (-)-quinine.

6 Finnegan Henderson did not participate in the preparation or prosecution of any of these patent applications and/or later, issued patents.

Counterpart international patents in France, German, Italy, Switzerland and the United Kingdom also issued in 2001. To the best of our knowledge, based upon reasonable inquiry and research, each of these patents is presently in force.

V. THIRD PARTY RIGHTS/INFRINGEMENT

To date, we are not aware of any third parties conducting activities that may infringe any of AGI's issued US patents and/or the provisional rights associated with the publication of any of AGI's application claims. Our advice to AGI regarding third party rights has been limited to US legal questions. In addition, Finnegan Henderson is not currently aware of nor has ever been made aware of any US patent claims or US published application claims of any third parties that may be infringed by AGI.

VI. OVERVIEW OF PROSECUTION PROGRESS

Based on the facts available to us at this time and based upon reasonable inquiry and research, we have identified and summarized the existence and status of the pending patent applications and issued patents within AGI's core patent portfolio. The prosecution of these pending applications, managed by Finnegan Henderson, is being undertaken in a timely and consistent manner according to current US patent prosecution practice, and in accordance with the patent laws of those countries where AGI's applications are pending, as counseled by well-established foreign prosecution counsel. To that end, the above-identified applications are proceeding through their respective prosecution processes both domestically and internationally.

Within AGI's core patent portfolio, AGI-003 entitled "Treatment of Abnormal Increases in Gastrointestinal Motility with (R)-Verapamil" was the first application to reach allowance in the US, maturing into US Patent No. 6,849,661 on February 1, 2005. In a similar manner, AGI recently received on February 3, 2006, a Notice of Allowance from the USPTO for AGI's patent application directed to AGI-001 entitled "Treatment and Prevention of Gastrointestinal Disease Using Antagonist or Partial Agonist of 5HT1a Receptors". AGI's remaining pending patent applications in its core patent portfolio continue to progress through the early stages of prosecution and based on current projected pendency time periods within the USPTO, are reasonably anticipated to proceed through substantive prosecution, which may reasonably be expected to conclude around late-2008 to mid-2009.

This "Overview of Prosecution Progress" should not be viewed as an exhaustive overview of the details related to the pending applications or issued patents, nor should it be interpreted as any form of opinion related to any of the claims of the pending applications or issued patents.

With best regards,

Sincerely,

Michele C. Bosch

APPENDIX: AGI's Patent Portfolio

AGI Product Number: Title	*Country*	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
AGI-001: Treatment and Prevention of Gastrointestinal Disease Using Antagonist or Partial Agonists of 5ht1a Receptors	US — Provisional	10/22/99	60/161,117	N/A	N/A
	US	10/13/00	09/687,384	CBP	CBP
	PCT	10/11/01	PCT/IB01/02759	(4/18/02)	(WO 02/30406)
	Canada	4/11/03	2,425,910	CBP	CBP
	Europe	5/12/03	01986602.9	CBP (4/21/04)	CBP (EP 1 408 937)
	Japan	4/14/03	2002-533849	CBP (4/8/04)	CBP (2004-510814)
AGI-003: Treatment of Abnormal Increases in Gastrointestinal Motility with (R)-Verapamil	US	9/27/02	10/256,261	Abandoned (5/15/03)	(2003/0092765)
		10/15/02	10/294,692	2/1/05 (4/1/04)	6,849,661 B2 (2004/0063784)
	PCT	11/15/02	PCT/IB/05140	(4/22/04)	(WO 04/032919)
	Australia	11/15/02	2002351118	CBP	CBP
	Canada	3/16/05	2,499,290	CBP	CBP
	Europe	3/31/05	02785831.5	CBP (6/22/05)	CBP (EP 1 542 673)
	Israel	3/16/05	167,482	CBP	CBP
	Japan	3/28/05	2004-542687	CBP	CBP
	Mexico	3/23/05	PA/a/2005/003177	CBP	CBP
	Norway	4/27/05	20052026	CBP	CBP
	New Zealand	3/23/05	539059	CBP	CBP
	South Africa	3/18/05	2005/02306	CBP	CBP
AGI-004: Treatment of Intestinal Conditions with N-2,3,3-Tetramethylbicyclo [2.2.1]Heptan-2-Amine	US — Provisional	3/14/03	60/454,527	N/A	N/A
	US	3/12/04	10/798,421	CBP (10/21/04)	CBP (2004/0209961)
	PCT	3/12/04	PCT/IB04/01134	(9/23/04)	(WO 04/080446)
	Australia	3/12/04	2004218899	CBP	CBP
	Canada	9/7/05	2,518,385	CBP	CBP
	Europe	10/7/05	04720110.8	CBP (12/14/05)	CBP (EP 1603544)
	Israel	9/6/05	170,688	CBP	CBP
	Mexico	9/9/05	PA/a/2005/009640	CBP	CBP
	Norway	10/11/05	20054670	CBP	CBP
	New Zealand	9/6/05	542260	CBP	CBP
	South Africa	9/6/05	2005/07159	CBP	CBP
AGI-022: Formulations and Methods of Treating Inflammatory Bowel Disease	US — Provisional	9/3/03	60/499,365	N/A	N/A
	US	9/1/04	10/930,743	CBP (4/28/05)	CBP (2005/0090473)
		CIP — TBA	TBA	N/A	N/A
	PCT	9/2/04	PCT/IB04/003059	(3/10/05)	(WO 05/021009)
AGI-006: Treatment of Gastroparesis and Non-ulcer Dyspepsia with GABAb Agonists	US — Provisional	9/12/03	60/502,242	N/A	N/A
		3/18/04	60/553,940	N/A	N/A
	US	9/8/04	10/935,176	CBP (4/28/05)	CBP (2005/0090554)
	PCT	9/10/04	PCT/IB04/003299	(3/24/05)	(WO 05/025559)
AGI-010: Proton Pump Inhibitor Formulations, and Methods of Preparing and Using Such Formulations [prosecuted by Greenblum & Bernstein, PLC]	US — Provisional	9/3/03	60/499,362	N/A	N/A
	US	9/2/04	10/932,098	CBP (10/20/05)	CBP (2005/0232992)
		CIP — TBA	TBA	N/A	N/A
	PCT	9/2/04	PCT/EP04/009806	(3/10/05)	(WO 05/020954)

AGI Product Number: Title	*Country*	*Filing Date (MM/DD/YY)*	*Application No.*	*Patent Issue Date (Patent Application Publication Date)*	*Patent No. (Patent Application Publication No.)*
AGI-007: Use of Delayed Release Metformin to Treat Constipation	US — Provisional	3/18/05	60/662,920	N/A	N/A
AGI-008: Use of Modified Release Acarbose to Treat Constipation	US — Provisional	4/12/05	60/670,265	N/A	N/A
	US — provisional	5/7/96	60/016,536	N/A	N/A
		5/7/96	60/016,987	N/A	N/A
Resolution of 4-cyano-4-(3,4-diemthoxyphenyl)-5-methylhexanoic Acid	US	2/7/97	08/796,358	4/6/99	5,892,093
	France	10/2/97	97904517.6	1/24/01	EP 0 879 225
	Germany	10/2/97	97904517.6	1/24/01	EP 0 879 225
	Italy	10/2/97	97904517.6	1/24/01	EP 0 879 225
	Switzerland	10/2/97	97904517.6	1/24/01	EP 0 879 225
	United Kingdom	10/2/97	97904517.6	1/24/01	EP 0 879 225

NOTE: The above table summarizes the countries, filing dates, patent application numbers, patent issue dates (patent application publication dates), and patent numbers (patent application publication numbers) for each disclosure. In circumstances where an application has not matured into an issued patent and is presently undergoing prosecution or will undergo prosecution, the issue date and patent number column is indicated with the designation "currently being prosecuted" by "CBP." In other instances where an issue date and patent number are not given, *e.g.*, with the filing of a US provisional application, these columns are indicated with the designation "not applicable" by "N/A." The designation "CIP" stands for continuation-in-part application and "TBA" stands for "to-be-announced." The current status of the application is subject to change at any time and thus, may only be applicable as of the date of this report.

CBP = Currently Being Prosecuted;
N/A = Not Applicable;
CIP = Continuation-In-Part Application; and
TBA = To-Be-Announced.

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The Directors
AGI Therapeutics plc
Adelaide Chambers
Peter Street
Dublin 8
Ireland

The Directors
Davy
Davy House
49 Dawson Street
Dublin 2
Ireland

21 February 2006

Dear Sirs:

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP ("Finnegan Henderson") consents to the inclusion of its name and the contents of this report in the Admission Document. The information contained in Part IV of the Admission Document accurately reproduces the contents of our report, and to the best of our knowledge, no facts have been omitted, which would render any such information inaccurate or misleading. Finnegan Henderson accepts responsibility for the information that is contained in Part IV of the Admission Document.

With best regards,

Sincerely,

Michele C. Bosch

PART V — FINANCIAL INFORMATION ON AGI THERAPEUTICS PLC

(formerly AGI Therapeutics Limited)

KPMG
Chartered Accountants
1 Stokes Place
St. Stephen's Green
Dublin 2
Ireland

The Directors
AGI Therapeutics plc
Adelaide Chambers
Peter Street
Dublin 8
Ireland

21 February 2006

Dear Sirs

Accountant's Report on AGI Therapeutics plc (formerly AGI Therapeutics Limited) ("the Company") for the period from the date of incorporation, 16 December 2005 to 31 December 2005.

We report on the financial information set out in Part V in respect of the Company. This financial information has been prepared for inclusion in the Admission Document dated 21 February 2006 of AGI Therapeutics plc on the basis of the accounting policies set out in note 1 to the financial information. This report is required by paragraph (a) of Schedule Two of the AIM Rules and by paragraph (a) of Schedule Two of the IEX Rules and is given for the purpose of complying with those paragraphs and for no other purpose.

Responsibilities

The Directors of the Company are responsible for preparing the financial information on the basis of preparation set out in note 1 to the financial information and in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU.

It is our responsibility to form an opinion on the financial information and to report our opinion to you.

Basis of opinion

We conducted our work in accordance with the Standards for Investment Reporting issued by the Auditing Practices Board. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. It also included an assessment of the significant estimates and judgements made by those responsible for the preparation of the financial information and whether the accounting policies are appropriate to the entity's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial information is free from material misstatement whether caused by fraud or other irregularity or error.

Opinion

In our opinion, the financial information gives, for the purposes of the Admission Document dated 21 February 2006, a true and fair view of the state of affairs of the Company as at the dates stated in accordance with the basis of preparation set out in note 1 to the financial information and in accordance with International Financial Reporting Standards, as adopted by the EU.

Declaration

For the purposes of paragraph (a) of Schedule Two of the AIM Rules and paragraph (a) of Schedule Two of the IEX Rules we are responsible for this report as part of the Admission Document and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Admission Document in compliance with Schedule Two of the AIM Rules and Schedule Two of the IEX Rules.

Yours faithfully,

KPMG
Chartered Accountants
Dublin, Ireland

Income Statement

The Company was incorporated as AGI Therapeutics Limited on 16 December 2005 and converted to a public limited company on 2 February 2006.

The Company did not trade during the period from incorporation to 31 December 2005 and received no income and incurred no expenditure. Consequently during this period the Company made neither a profit nor a loss.

The Company had no recognised income or expenses nor any cash flows during this period and accordingly no statement of recognised income and expense or cashflow statement is presented for the period from incorporation to 31 December 2005. Apart from the initial share issue on incorporation, there were no further shares issued and consequently no statement of changes in equity is presented.

Balance Sheet

	Note	As at 31 December 2005 €
Assets		
Current assets		
Cash and cash equivalents		1
Total current assets		1
Total assets		1
Shareholders' equity and liabilities		
Shareholders' equity		
Issued capital	2	1
Shareholders' equity		1

1 Summary of significant accounting policies

Basis of preparation

The financial information presents the financial record of the Company for the period from incorporation on 16 December 2005 to 31 December 2005. The Company was incorporated as AGI Therapeutics Limited on 16 December 2005 and was converted to a public limited company on 2 February 2006.

The financial information for the period presented has been prepared for the purposes of this exercise in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU and their interpretations adopted by the International Accounting Standards Board ("IASB"). The financial information also complies with IFRS as issued by the IASB.

2 Issued capital

	31 December 2005 *€*
Authorised:	
100,000 Ordinary shares of €1 each	100,000
Issued, called up and fully paid:	
1 Ordinary share of €1 each	1

On incorporation of the Company on 16 December 2005 the authorised share capital of the Company was €100,000 divided into 100,000 ordinary shares of €1 each and subsequently one share of €1 was issued to the Company's sole shareholder for cash consideration of €1.

3 Post balance sheet events

Re-organisation of the Company

On 19 January 2006, the Company sub-divided its Ordinary share capital into 10,000,000 Ordinary shares of €0.01 each and the Company issued 1,663,499 Ordinary shares for cash at par.

The authorised share capital of the Company was increased on 20 January 2006 by the creation of 70,000,000 Ordinary shares of €0.01 each and 20,000,000 A Ordinary Preference shares of €0.01 each in the Company.

On 20 January 2006, the Company issued 13,749,900 Ordinary shares of €0.01 each and 18,269,125 A Ordinary Preference shares to acquire the entire interest in AGI Therapeutics Research Limited, which became its wholly owned subsidiary. The shares were issued to the shareholders of AGI Therapeutics Research Limited in the ratio of 125 shares in the Company for one share in AGI Therapeutics Research Limited. Subsequently the entire A Ordinary Preference share capital was converted into Ordinary shares at a ratio of one Ordinary share for every one A Ordinary Preference share.

KPMG
Chartered Accountants
1 Stokes Place
St. Stephen's Green
Dublin 2
Ireland

The Directors
AGI Therapeutics plc
Adelaide Chambers
Peter Street
Dublin 8
Ireland

21 February 2006

Dear Sirs

Accountant's Report on AGI Therapeutics Research Limited ("the Company"), formerly AGI Therapeutics Limited, for the three months ended 31 December 2003, year ended 31 December 2004, and for the nine months ended 30 September 2005.

We report on the financial information set out in Part VI in respect of the Company. This financial information has been prepared for inclusion in the Admission Document dated 21 February 2006 of AGI Therapeutics plc on the basis of the accounting policies set out in note 2 to the financial information. This report is required by paragraph (a) of Schedule Two of the AIM Rules and by paragraph (a) of Schedule Two of the IEX Rules and is given for the purpose of complying with those paragraphs and for no other purpose.

Responsibilities

The Directors of the Company are responsible for preparing the financial information on the basis of preparation set out in note 1 to the financial information and in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU.

It is our responsibility to form an opinion on the financial information and to report our opinion to you.

Basis of opinion

We conducted our work in accordance with the Standards for Investment Reporting issued by the Auditing Practices Board. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. It also included an assessment of the significant estimates and judgments made by those responsible for the preparation of the financial information and whether the accounting policies are appropriate to the entity's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial information is free from material misstatement whether caused by fraud or other irregularity or error.

Opinion

In our opinion, the financial information gives, for the purposes of the Admission Document dated 21 February 2006, a true and fair view of the state of affairs of the Company as at the dates stated in accordance with the basis of preparation set out in note 1 to the financial information and in accordance with International Financial Reporting Standards as adopted by the EU.

Declaration

For the purposes of paragraph (a) of Schedule Two of the AIM Rules and paragraph (a) of Schedule Two of the IEX Rules we are responsible for this report as part of the Admission Document and declare that

we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Admission Document in compliance with Schedule Two of the AIM Rules and Schedule Two of the IEX Rules.

Yours faithfully,

KPMG
Chartered Accountants
Dublin, Ireland

Income Statement

	Note	*3 months ended 31 December 2003* €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Revenue		—	—	—
Research and development expenses		—	(2,341,497)	(3,036,995)
Administrative expenses			(360,812)	(377,796)
Other operating expenses		—	(1,055)	(1,260)
Operating loss	3	—	(2,703,364)	(3,416,051)
Interest income	4	—	140,000	86,270
Interest expense	*5*	—	(558,069)	(528,748)
Loss before tax		—	(3,121,433)	(3,858,529)
Income tax	6	—	—	—
Loss for the period		—	(3,121,433)	(3,858,529)
Basic loss per ordinary share	7	—	(37.33)	(35.08)

Balance Sheet

	Note	*As at 31 December 2003* €	*As at 31 December 2004* €	*As at 30 September 2005* €
Assets				
Non-current assets				
Intangible assets	8	—	1,555,199	1,529,398
Equipment	9	—	3,692	2,811
Total non-current assets		—	1,558,891	1,532,209
Current assets				
Other current assets	10	100	99,526	86,004
Cash and cash equivalents		—	6,782,011	3,909,983
Total current assets		100	6,881,537	3,995,987
Total assets		100	8,440,428	5,528,196
Shareholders' equity and liabilities				
Shareholders' equity				
Issued capital	11	100	1,100	1,100
Share premium		—	4,167,126	4,167,126
Other reserves		—	9,678	20,566
Retained losses		—	(3,121,433)	(6,979,962)
Shareholders' equity		100	1,056,471	(2,791,170)
Non-current liabilities				
Convertible preference shares	12	—	7,237,943	7,766,691
Total non-current liabilities		—	7,237,943	7,766,691
Current liabilities				
Accounts payable		—	129,126	172,632
Accrued and other liabilities	14	—	16,888	380,043
Total current liabilities		—	146,014	552,675
Total shareholders' equity and liabilities		100	8,440,428	5,528,196

Statement of Changes in Equity

	Note	*Share capital* €	*Share premium* €	*Retained earnings* €	*Other reserves* €	*Total* €
At date of incorporation on 3 October 2003		—	—	—	—	—
Issue of A Ordinary shares		68	—	—	—	68
Issue of B Ordinary shares		24	—	—	—	24
Issue of D Ordinary shares		8	—	—	—	8
At 31 December 2003	11	**100**	**—**	**—**	**—**	**100**
On 18 March 2004 issue of Ordinary shares to acquire intellectual property from Athpharma Limited	8	900	1,580,100	—	—	1,581,000
On 10 May 2004 issue of Ordinary shares to new director	11	100	4,900	—	—	5,000
Equity component of A Ordinary Preference shares	11	—	2,648,477	—	—	2,648,477
Fair value of Ordinary shares issued to new director	11	—	—	—	9,678	9,678
Transaction costs arising on equity component of A Ordinary Preference shares		—	(66,351)	—	—	(66,351)
Net loss		—	—	(3,121,433)	—	(3,121,433)
At 31 December 2004		**1,100**	**4,167,126**	**(3,121,433)**	**9,678**	**1,056,471**
Fair value of Ordinary shares issued to new director		—	—	—	10,888	10,888
Net loss		—	—	(3,858,529)	—	(3,858,529)
At 30 September 2005		**1,100**	**4,167,126**	**(6,979,962)**	**20,566**	**(2,791,170)**

Cashflow Statement

	Note	*3 months ended 31 December 2003* €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Operating activities				
Cash generated from operations	15	—	(2,676,508)	(3,388,991)
Increase in accounts payable		—	129,126	43,506
Increase in accrued and other liabilities		—	16,888	363,155
(Increase)/decrease in other current assets		(100)	(70,426)	30,522
Fair value of shares issued to director over service period		—	9,678	10,888
Unpaid share capital		100	—	—
Net cash outflow from operating activities		—	(2,591,242)	(2,940,920)
Investing activities				
Interest received		—	111,000	69,270
Purchase of equipment		—	(4,747)	(378)
Net cash inflow from investing activities		—	106,253	68,892
Financing activities				
Net proceeds from the issue of ordinary shares	15	—	5,000	—
Net proceeds from issue of preference shares	15	—	9,262,000	—
Net cash inflow from financing activities		—	9,267,000	—
Net increase/(decrease) in cash and cash equivalents		—	6,782,011	(2,872,028)
Opening balance in cash and cash equivalents		—	—	6,782,011
Closing balance in cash and cash equivalents		—	6,782,011	3,909,983

Notes to the financial information

1 Basis of preparation

The financial information presents the financial record of the Company for the 3 months ended 31 December 2003, the year ended 31 December 2004 and for the nine month period ended 30 September 2005.

The Company was incorporated in Ireland on 3 October 2003, as AGI Therapeutics Limited. It changed its name to AGI Therapeutics Research Limited on 14 December 2005. The financial information includes the income statements, balance sheets and cash flows of the Company.

The Company is involved in the development of new improved drug therapies for the treatment of gastrointestinal diseases and disorders. The Company applies its KME development model to identify existing drugs or "known molecular entities" with established safety profiles which can be developed and clinically differentiated for gastrointestinal indications.

On 20 January 2006 and as described in further detail in note 21 "Post Balance Sheet Events" the shareholders in the Company exchanged their interest in the Company for an equivalent interest in AGI Therapeutics Limited, to be re-registered as AGI Therapeutics plc on 2 February 2006. On that date the Company became a wholly owned subsidiary of AGI Therapeutics Limited.

In preparing the financial information, we have adjusted the statutory financial statements of the Company as previously reported and audited by RSM Robson Rhodes, Chartered Accountants for the three months ended 31 December 2003 and for the year ended 31 December 2004. There were no adjustments to the financial statements for the three months ended 31 December 2003. These financial statements were prepared in accordance with accounting principles generally accepted in Ireland ("Irish GAAP"). A reconciliation of the financial information to previously reported Irish GAAP figures in the financial statements for the year ended 31 December 2004 is provided in notes 18 and 19 to the financial information.

The financial information for each of the periods presented has been prepared for the purposes of this exercise in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU and their interpretations adopted by the International Accounting Standards Board. A reconciliation of adjusted Irish GAAP figures to the IFRS financial information is provided in note 19. For the purpose of presenting the financial information, IAS32 "Financial Instruments" has been applied from incorporation to date.

2 Summary of significant accounting policies

(a) Basis of preparation

The financial information has been prepared in Euro ("€") in accordance with the accounting policies below which are based on IFRS in issue and adopted by the EU.

The preparation of financial statements requires the directors to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual outcomes could differ from those estimates.

(b) Revenue recognition

To date the Company has not earned any revenues. When the Company enters into revenue generating contracts, revenue will be recognised when earned and non-refundable and when there is no obligation with respect to the revenue, in accordance with the terms prescribed in the applicable contract.

(c) Leasing

Operating lease rentals are charged to the income statement on a straight line basis over the period of the lease.

(d) Research & development expenses

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in the income statement as an expense as incurred.

Expenditure on development activities, whereby research findings are applied to a plan or design for the production of new or substantially improved products and processes, is capitalised if the product or process is technically and commercially feasible and the Company has sufficient resources to complete development. The expenditure capitalised includes the cost of materials, direct labour and an appropriate proportion of overheads. Other development expenditure is recognised in the income statement as an expense as incurred. To date the Company has not incurred development costs that have met the criteria for recognition of an internally generated intangible asset and as such all development costs have been recognised as an expense in the income statement as incurred. The Company considers that regulatory and other uncertainty inherent in the development of its products preclude it from capitalising development costs.

(e) Income Tax

Income tax comprises current and deferred tax.

Current tax is the expected tax payable on the taxable income for the year using tax rates enacted or substantially enacted at the balance sheet date and any adjustments to tax payable in respect of previous years.

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases on assets and liabilities and their carrying amounts in the financial statements except to the extent that temporary differences arising on goodwill not deductible for tax purposes or the initial recognition of assets or liabilities that affect neither accounting or taxable profits. Deferred tax assets are recognised to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilised.

(f) Equipment

Equipment is stated at cost less accumulated depreciation. Depreciation is charged to the income statement on a straight line basis over an estimated useful life of 3 years for office and computer equipment.

(g) Intangible assets

Acquired in process research and development (IPR&D) and acquired patent and licence agreements are stated at cost or valuation, less impairment losses (see accounting policy (h)).

The acquired patent and licence agreements are being amortised over their useful lives on a straight line basis. Estimated useful life is the lower of legal duration and economic useful life and has been estimated as 17 years. The acquired IPR&D will be amortised on a straight line basis over its estimated useful life which will commence upon generation of economic benefits relating to the acquired IPR&D.

(h) Impairment of assets

Assets are reviewed at each balance sheet date to determine whether there is any indication that the carrying amount may not be recoverable. An impairment loss is recognised in the income statement whenever the carrying amount of an asset exceeds its recoverable amount. The recoverable amount of an asset is the greater of its fair value less cost to sell and value in use. For the purposes of assessing impairments, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units).

(i) Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short term highly liquid investments with original maturities of three months or less.

(j) Employee benefits

(a) Share based compensation

On 27 January 2006 AGI Therapeutics plc created an equity settled, share based compensation plan. The Company will account for the share based compensation plan in accordance with IFRS 2

"Share-based Payment." The fair value of the employee services received in exchange for the grant of options is recognised as an expense. The total amount to be expensed over the vesting period is determined using an appropriate valuation model by reference to the fair value of the options granted, excluding the impact of any non-market vesting conditions. Non-market vesting conditions are included in assumptions about the number of options that are expected to vest. At each balance sheet date, the Company will revise its estimates of the number of options that are expected to vest. It recognises the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity.

(b) Pension obligation

The Company does not currently operate a pension scheme. It has made contributions to a personal pension scheme held by one of the shareholders/directors. These contributions are recognised as an expense in the period in which they are paid.

(k) Preference share capital

Preference share capital is classified as equity if it is non-redeemable and any dividends are discretionary, or is redeemable but only at the Company's option. Dividends on preference share capital classified as equity are recognised as distributions from equity.

Preference share capital is classified as a liability if it is redeemable on a specific date or at the option of the shareholders or if dividend payments are not discretionary. Dividends thereon are recognised in the income statement as an interest expense.

Convertible preference shares include a debt and equity element. For initial recognition purposes the fair value of the debt is determined by discounting the expected cash flows generated by the financial instrument using a market rate for a debt instrument that could be issued by the company over the same term. The difference between the proceeds raised and the fair value of the debt is deemed to be the equity element. The debt element is thereafter accounted for on an amortised cost basis and interest is accrued up to the redeemable amount of the instrument over its life. The costs of raising the convertible, preferred shares are split proportionally between the debt and equity components.

(l) Interest income

Interest income is recognised in the income statement as it accrues.

(m) Foreign currency

Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated into local currency at the rate of exchange ruling at the balance sheet date, and the resulting gains and losses are recognised in the income statement.

3 Operating loss

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
The operating loss is stated after charging:			
Directors' remuneration	—	284,137	282,736
Directors' fees	—	25,000	25,000
Key managements' remuneration (including directors) (note 17)	—	342,200	324,187
Auditors' remuneration	—	5,000	—
Amortisation of intangible assets	—	25,801	25,801
Depreciation of equipment	—	1,055	1,259
Operating lease rentals	—	11,438	9,550
Loss/(profit) on foreign currencies	—	30,096	(7,430)

Auditors' remuneration is the amount paid to the auditor in respect of the statutory audit for the year ended 31 December 2004.

4 Interest income

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Interest income	—	140,000	86,270

5 Interest expense

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Interest expense	—	558,069	528,748

The interest expense arises on the debt component of the convertible A Ordinary Preference shares.

The fair value of the debt component was determined on the issue date using a market interest rate for an equivalent non-convertible debt instrument. Interest is accrued on the basis of an effective interest rate method over the life of the instrument so that on redemption, the value of the instrument is equivalent to the redemption amount of the debt. The conversion and redemption rights for the A Ordinary Preference shares are detailed in note 12 to the financial information.

6 Income tax

No tax charge arose as the Company has generated losses in each of the periods since its incorporation. No deferred tax asset has been recognised on the tax losses forward as it is not sufficiently probable at this point in time that future taxable profits will be available against which the temporary differences can be utilised.

7 Earnings per share

Basic loss per ordinary share is computed by dividing the net loss attributable to the ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

	Net loss €	*Weighted average numbers of shares issued in period*	*Basic loss per Share €*
Period			
3 months ended 31 December 2003	—	25	—
Year ended 31 December 2004	(3,121,433)	83,602	(37.33)
9 months ended 30 September 2005	(3,858,529)	110,000	(35.08)

The convertible A Ordinary Preference Shares do not have a dilutive impact on the basic loss per share shown above.

8 Intangible assets

	Acquired patents and licences €	*In-process research and development €*	*Total €*
Cost or valuation			
At 31 December 2003	—	—	**—**
Additions in the year ended 31 December 2004	580,000	1,001,000	1,581,000
At 31 December 2004	**580,000**	**1,001,000**	**1,581,000**
Additions in the nine months ended 30 September 2005	—	—	—
At 30 September 2005	**580,000**	**1,001,000**	**1,581,000**
Accumulated amortisation			
At 31 December 2003	—	—	—
Charge for the year ended 31 December 2004	25,801	—	25,801
At 31 December 2004	**25,801**	**—**	**25,801**
Charge for the nine months ended 30 September 2005	25,801	—	25,801
At 30 September 2005	**51,602**	**—**	**51,602**
Net book value			
At 30 September 2005	**528,398**	**1,001,000**	**1,529,398**
At 31 December 2004	554,199	1,001,000	1,555,199
At 31 December 2003	—	—	—

In-process research and development and certain patent and licence agreements were purchased from Athpharma Limited on 18 March 2004. The consideration for the acquisition was the issue by the Company of 612 A ordinary shares, 216 B ordinary shares and 72 D ordinary shares to the then shareholders of Athpharma Limited in proportion to their existing investment in that Company. The value of the assets acquired was appraised by an independent valuation specialist and was determined to amount to €1,581,000, of which €580,000 was ascribed to the acquired patent and licence agreements and €1,001,000 was ascribed to in-process research and development.

9 Equipment

	Office and computer equipment €
Cost	
At 31 December 2003	**—**
Additions for the year ended 31 December 2004	4,747
At 31 December 2004	**4,747**
Additions for the nine months ended 30 September 2005	378
At 30 September 2005	**5,125**
Accumulated depreciation	
At 31 December 2003	—
Charge for the year ended 31 December 2004	1,055
At 31 December 2004	**1,055**
Charge for the nine months ended 30 September 2005	1,259
At 30 September 2005	**2,314**
Net book value/carrying amount	
At 30 September 2005	**2,811**
At 31 December 2004	3,692
At 31 December 2003	—

10 Other current assets

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Prepayments	—	53,915	20,659
Deposit interest retention tax recoverable	—	28,367	45,621
Value added tax recoverable	—	17,144	19,624
Unpaid share capital	100	100	100
	100	99,526	86,004

11 Issued and authorised capital

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Authorised:			
100,000,000 Ordinary Shares of €0.01 each	—	1,000,000	1,000,000
400,000 A Ordinary Shares of €1 each	400,000	—	—
100,000 B Ordinary Shares of €1 each	100,000	—	—
400,000 C Ordinary Shares of €1 each	400,000	—	—
100,000 D Ordinary shares of €1 each	100,000	—	—
500,000 A Ordinary Preference Shares of €0.01 each	—	5,000	5,000
	1,000,000	1,005,000	1,005,000
Issued, called up and fully paid			
100,000 Ordinary Shares of €0.01 each	—	1,000	1,000
Issued and upaid			
10,000 Ordinary Shares of €0.01 each	—	100	100
68 A Ordinary Shares of €1 each	68	—	—
24 B Ordinary Shares of €1 each	24	—	—
8 D Ordinary Shares of €1 each	8	—	—
	100	1,100	1,100

On incorporation of the Company on 3 October 2003 the authorised share capital of the Company was €1 million divided into 400,000 A Ordinary shares of €1 each, 100,000 B Ordinary shares of €1 each, 400,000 C Ordinary shares of €1 each and €100,000 D Ordinary shares of €1 each. Subsequent to incorporation 68 A Ordinary shares of €1 each, 24 B Ordinary shares of €1 each and 8 D Ordinary shares of €1 each were issued at par.

As prescribed by the Company's Articles of Association, the Ordinary shares confer on the holders the right to receive notice of and to attend and vote at all general meetings of the Company. The holders are entitled to one vote per share held.

On 18 March 2004 as consideration for the purchase of in-process research and development and certain patent and licence agreements from Athpharma Limited, shares in the Company were issued to the then shareholders of Athpharma Limited in proportion to their existing investment in the Company. 612 A Ordinary shares, 216 B Ordinary shares, 72 D Ordinary shares with a nominal value of €1 each were issued to the directors.

Subsequently the authorised share capital of the Company was altered to €1,005,000 divided into 100,000,000 Ordinary shares of €0.01 each and 500,000 A Ordinary Preference shares of €0.01 each. On that date, the current issued share capital of A, B and D Ordinary shares were re-classified and sub-divided as Ordinary shares of €0.01 each.

On 10 May 2004, 10,000 Ordinary Shares of €0.01 each were issued to a director of the Company for consideration of €5,000. The ownership of these shares vests with the purchaser over a 4 year service period. Share premium of €4,900 arose on this transaction. The fair value of these shares, amounting to €58,067, was based on the value ascribed to the shares issued to acquire the intellectual property, adjusted for the fact that this was a minority interest ranking below the redeemable preference shares. The difference between the fair value and the issue price is being charged to the income statement over the service period.

The A Ordinary Preference share capital is a compound financial instrument. It has both a debt component as the preference shares are redeemable at the option of the holders 4 years and 90 days after issue and an equity component given that the holders also have a right to convert the shares into Ordinary shares on a one for one basis. Accordingly the proceeds of issue of the A Ordinary Preference share capital has been split into its respective debt and equity components based on their relative fair values on the issue date. The fair value of the debt component was determined using a market interest rate for an equivalent non-convertible debt instrument and has been determined to be €6,851,523. The equity

component is the difference between the fair value of the debt component and the consideration received on issue of the A Ordinary Preference shares which amounted to €9,500,000. The total equity component amounted to €2,648,477.

12 Non-current liabilities

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Debt component of convertible A Ordinary Preference shares	—	6,851,523	7,237,943
Accrued interest	—	527,778	498,457
Transaction costs	—	(171,649)	—
Amortisation of transaction costs	—	30,291	30,291
	—	7,237,943	7,766,691

On 18 March 2004 the authorised share capital of the Company was altered to €1,005,000 divided into 100,000,000 Ordinary Shares of €0.01 each and 500,000 A Ordinary Preference shares of €0.01 each.

Subsequently ACT Venture Capital Fund No. 1 Limited Partnership, ACT Venture Capital Fund No. 2 Limited Partnership, ACT 2001 Capital Fund No. 2 A Limited Partnership and ACT 2001 Venture Capital GmbH & Co. K.G. ("ACT"), the Irish Bioscience Venture Capital Fund ("Seroba"), Delta Equity Fund II Limited Partnership ("Delta"), Merlin Nexus ILP ("Merlin") entered into a subscription and shareholders' agreement relating to an investment by ACT, Seroba, Delta and Merlin ("syndicate investors") to acquire an aggregate of 132,169 A Ordinary Preference shares of €0.01 each for €8,591,000. The existing shareholders of the Company subscribed for 13,984 A Ordinary Preference Shares of €0.01 each in proportion to their existing shareholdings in the Company, for consideration of €909,000.

The convertible A Ordinary Preference shares are shown net of transaction costs arising on the issue of the shares. Transaction costs allocated to the debt component of the A Ordinary Preference Shares amounted to €171,649 and are being amortised to the income statement over the term of the debt. Amortisation amounted to €30,291 for the period from the issue date through to 31 December 2004 and €30,291 for the nine months ended 30 September 2005 and is included as part of interest expense in the income statement.

As prescribed by the Company's Articles of Association, the A Ordinary Preference Shares confer on the holders the right to receive notice of and to attend and vote at all general meetings of the Company. The holders are entitled to one vote per share held and are entitled to receive dividends as declared by the Company.

On the occurrence of a liquidation, the holders of the A Ordinary Preference shares are entitled to receive, prior to and in preference to any distribution of the assets of the Company to the other shareholders, an amount equal to the A Preferred Share Subscription Price, or the nominal value plus premium subscribed for each A Ordinary Preference share together with cumulative interest at an annual rate of 3% per annum on the A Preferred Share Subscription Price less an amount equal to any dividends received by them from the Company. If on the occurrence of liquidation, the assets of the Company available for distribution to the shareholders are sufficient for payment to the A Ordinary Preference shareholders, then the remaining assets of the Company shall be applied among all shareholders pro rata according to the number of shares held by them.

Each holder of the A Ordinary Preference shares is entitled at any time by notice in writing to the Company to require that some or all of the A Ordinary Preference shares held by the holder be converted into Ordinary shares at a conversion rate of one Ordinary share for one A Ordinary Preference share.

The Company will, on the receipt of at least 90 days notice in writing from any A Ordinary Preference shareholder on or after the fourth anniversary of the adoption of the Articles of Association of the Company, and subject to the prior written consent of the holders of 70 per cent of A Ordinary Preference shares, redeem all of the A Ordinary Preference shares held by the shareholder.

The A Ordinary Preference share capital and share premium is a compound financial instrument having both a debt component as the preference shares are redeemable at the option of the holders 4 years and

90 days after issue, and an equity component as the holders also have a right to convert the shares into Ordinary shares. The Company's contractual obligation to make future payments to the shareholders of the A Ordinary Preference shares remains outstanding until it is extinguished through conversion or redemption.

The A Ordinary Preference share capital and share premium have been split into their respective debt and equity components on the basis of their relative fair values on the issue date. The fair value of the debt component was determined using a market interest rate for an equivalent non-convertible debt instrument and has been determined to be €6,851,523. The equity component was then determined by deducting the fair value of the debt component from the consideration received on issue of the A Ordinary Preference shares which amounted to €9,500,000. The total equity component amounted to €2,648,477.

Interest is accrued on the debt component of the A Ordinary Preference shares at the market rate of interest at the date of issue for an equivalent non-convertible debt instrument. This amounted to €527,778 for the year ended 31 December 2004 and €498,457 for the nine months ended 30 September 2005.

13 Fair value of financial assets and liabilities

No differences arose between the determined fair values of the financial assets and liabilities of the Company and their carrying amounts in the balance sheet at 31 December 2003, 31 December 2004 and 30 September 2005.

Cash and cash equivalents

The carrying amount of cash and cash equivalents is deemed to reflect its fair value.

Accounts payable

The carrying amount of accounts payable falling due for payment in less than one year is deemed to reflect its fair value.

Convertible preference shares

The fair value of the debt component of the A Ordinary Preference share capital was determined using a market interest rate for an equivalent non-convertible debt instrument. No material difference arose between the fair value of the debt component of the A Ordinary Preference share capital and its carrying amount in the balance sheet for each of the periods presented.

14 Accrued and other liabilities

	3 months ended 31 December 2003	*Year ended 31 December 2004*	*9 months ended 30 September 2005*
	€	*€*	*€*
Accrued and other liabilities	—	4,504	28,785
Accrued clinical research service costs	—	—	351,258
PAYE/PRSI	—	12,384	—
	—	16,888	380,043

15 Cashflow statement

Cashflows from operating activities

Cashflows from operating activities are those derived from the Company's primary activities. This is calculated by the indirect method, adjusting the Company's operating profit for any operating income and expenses that are not cash flows in order to derive the cash generated from operations.

Cash generated from operations

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Loss for period	—	(3,121,433)	(3,858,529)
Interest received	—	(140,000)	(86,270)
Interest expense	—	558,069	528,748
Operating Loss	—	(2,703,364)	(3,416,051)
Depreciation of equipment	—	1,055	1,259
Amortisation of intangible assets	—	25,801	25,801
Cash generated from operations	—	(2,676,508)	(3,388,991)

Cash received on issue of A Ordinary Preference shares

On 18 March 2004, 132,169 A Ordinary Preference shares of €0.01 each were issued to a syndicate of investors for a consideration of €8,591,000. On this date the existing shareholders of the Company subscribed for 13,984 A Ordinary Preference shares of €0.01 each for a cash consideration of €909,000. The total cash consideration received for the issue of A Ordinary Preference shares amounted to €9,500,000. Transaction costs arising from the issue of the A Ordinary Preference shares amounted to €238,000, which have been allocated on a proportional basis to the debt and equity components of the A Ordinary Preference shares.

Cash received on issue of ordinary shares

On 10 May 2004, 10,000 Ordinary shares of €0.01 each were issued to a new director of the Company for a cash consideration of €5,000.

16 Commitments

a) Operating leases

Operating lease commitments payable are analysed as follows:

	3 months ended 31 December 2003 €	*Year ended 31 December 2004* €	*9 months ended 30 September 2005* €
Operating leases which expire within one year	—	4,269	17,784

In April 2005 the Company entered into a lease agreement with a third party for the lease of an office. The agreement will terminate in September 2006.

b) Capital commitments

There were no capital commitments at 31 December 2003, 31 December 2004 or at 30 September 2005.

17 Employees

The average number of persons employed by the Company (including executive directors) was as follows:

	3 months ended 31 December 2003	*Year ended 31 December 2004*	*9 months ended 30 September 2005*
	€	*€*	*€*
Average number of employees	—	5	5

Staff costs comprise:

	3 months ended 31 December 2003	*Year ended 31 December 2004*	*9 months ended 30 September 2005*
	€	*€*	*€*
Wages and salaries	—	272,098	254,251
Social welfare	—	25,531	27,711
Pension costs	—	44,571	42,225
	—	342,200	324,187

18 Reconciliation of financial information for the year ended 31 December 2004 to audited Irish GAAP financial statements

	Irish GAAP financial statements	*Costs arising on issue of A Ordinary Preference shares (a)*	*Fair value of shares issued to director (b)*	*Intangible asset amortisation (c)*	*Reclassification of R&D salaries and consultancy fees (d)*	*Adjusted Irish GAAP financial information*
	€	*€*	*€*	*€*	*€*	*€*
Income statement						
Revenue	—	—	—	—	—	—
Research & development expenses	(2,117,926)	—	—	(25,801)	(197,770)	(2,341,497)
Administrative expenses	(786,904)	238,000	(9,678)	—	197,770	(360,812)
Other operating expenses	(106,455)	—	—	105,400	—	(1,055)
Operating loss	(3,011,285)	238,000	(9,678)	79,599	—	(2,703,364)
Interest income	140,000	—	—	—	—	140,000
Loss before tax	(2,871,285)	238,000	(9,678)	79,599	—	(2,563,364)
Income tax	—	—	—	—	—	—
Loss for period	**(2,871,285)**	**238,000**	**(9,678)**	**79,599**	**—**	**(2,563,364)**
Balance sheet						
Assets						
Non-current assets						
Intangible assets	1,475,600	—	—	79,599	—	1,555,199
Equipment	3,692	—	—	—	—	3,692
Total non-current assets	1,479,292	—	—	79,599	—	1,558,891
Current assets						
Other current assets	99,526	—	—	—	—	99,526
Cash and cashequivalents	6,782,011	—	—	—	—	6,782,011
Total current assets	6,881,537	—	—	—	—	6,881,537
Total assets	**8,360,829**	**—**	**—**	**79,599**	**—**	**8,440,428**

18 Reconciliation of financial information for the year ended 31 December 2004 to audited Irish GAAP financial statements (continued)

	Irish GAAP financial statements €	*Costs arising on issue of A Ordinary Preference shares (a)* €	*Fair value of shares issued to director (b)* €	*Intangible asset amortisation (c)* €	*Reclassification of R&D salaries and consultancy fees (d)* €	*Adjusted Irish GAAP financial information* €
Shareholders' equity and liabilities						
Shareholders' equity						
Issued capital	2,562	—	—	—	—	2,562
Share premium	11,083,538	(238,000)	—	—	—	10,845,538
Other reserves	—	—	9,678	—	—	9,678
Retained losses	(2,871,285)	238,000	(9,678)	79,599	—	(2,563,364)
Total shareholders equity	**8,214,815**	**—**	**—**	**79,599**	**—**	**8,294,414**
Non-current liabilities						
Convertible redeemable Preference shares	—	—	—	—	—	—
Total non-current liabilities						
Current liabilities						
Accounts payable	129,126	—	—	—	—	129,126
Accrued and other Liabilities	16,888	—	—	—	—	16,888
Total current liabilities	146,014	—	—	—	—	146,014
Total shareholders' equity and liabilities	**8,360,829**	**—**	**—**	**79,599**	**—**	**8,440,428**

a) Transaction costs arising on issue of A Ordinary Preference were previously expensed. These costs were treated as a deduction from share premium in the adjusted Irish GAAP financial information.

b) The excess of the fair value of certain shares issued by the Company over the consideration received is expensed to the income statement over the service period during which the shares vest.

c) Reversal of amortisation on acquired IPR&D as amortisation of the intangible only commences upon generation of economic benefits relating to the acquired IPR&D

d) Reclassification of certain overheads, principally payroll costs included in administrative expenses that are more properly classified as research and development expenses.

19 Reconciliation of adjusted Irish GAAP financial information for the year ended 31 December 2004 to IFRS financial information

	Adjusted Irish GAAP financial information €	*Reclassification Of debt component of A ordinary preference share (e)* €	*Accrual of interest on Fair value of debt component of A ordinary preference shares (f)* €	*Allocation of costs arising on issued A ordinary preference shares between debt and equity components (g)* €	*Amortisation of transaction costs allocated to debt component of A ordinary preference shares (h)* €	*IFRS financial information* €
Income statement						
Revenue	—	—	—	—	—	—
Research & development expenses	(2,341,497)	—	—	—	—	(2,341,497)
Administrative expenses	(360,812)					(360,812)
Other operating expenses	(1,055)	—	—	—	—	(1,055)
Operating loss	(2,703,364)	—	—	—	—	(2,703,364)
Interest income	140,000	—		—	—	140,000
Interest expense	—	—	(527,778)	—	(30,291)	(558,069)
Loss before tax	**(2,563,364)**	**—**	**—**	**—**	**—**	**(3,121,433)**
Income tax	—	—	—	—	—	—
Loss for the period	**(2,563,364)**	**—**	**(527,778)**	**—**	**(30,291)**	**(3,121,433)**
Balance sheet						
Assets						
Non-current assets						
Intangible assets	1,555,199	—	—	—	—	1,555,199
Equipment	3,692	—	—	—	—	3,692
Total non-current assets	1,558,891	**—**	**—**	**—**	**—**	1,558,891
Current assets						
Other current assets	99,526	—	—	—	—	99,526
Cash and cash equivalents	6,782,011	—	—	—	—	6,782,011
Total current assets	6,881,537	—	—	—	—	6,881,537
Total assets	**8,440,428**	**—**	**—**	**—**	**—**	**8,440,428**

19 Reconciliation of adjusted Irish GAAP financial information for the year ended 31 December 2004 to IFRS financial information (continued)

	Adjusted Irish GAAP financial information €	*Reclassification of debt component of A ordinary preference shares (e)* €	*Accrual of interest on fair value of debt component of A ordinary preference shares (f)* €	*Allocation of transaction costs on issue of A ordinary preference shares between debt and equity components (g)* €	*Amortisation of transaction costs allocated to debt component of A ordinary preference shares (h)* €	*IFRS financial information* €
Shareholders' equity and liabilities						
Shareholders' equity						
Issued capital	2,562	(1,462)	—	—	—	1,100
Share premium	10,845,538	(6,850,061)	—	171,649	—	4,167,126
Other reserves	9,678	—	—	—	—	9,678
Retained losses	(2,563,364)	—	(527,778)	—	(30,291)	(3,121,433)
Shareholders equity	**8,294,414**	**(6,851,523)**	**(527,778)**	**171,649**	**(30,291)**	**1,056,471**
Non-current liabilities						
Convertible redeemable preference shares	—	6,851,523	527,778	(171,649)	30,291	7,237,943
Total non-current liabilities	**—**	**6,851,523**	**527,778**	**(171,649)**	**30,291**	**7,237,943**
Current liabilities						
Accounts payable	129,126	—	—	—	—	129,126
Accrued and other Liabilities	16,888	—	—	—	—	16,888
Total current liabilities	**146,014**	**—**	**—**	**—**	**—**	**146,014**
Total shareholders' equity and liabilities	**8,440,428**	**—**	**—**	**—**		**8,440,428**

(e) Reclassification of the fair value of the debt component of the A Ordinary Preference shares to non-current liabilities

(f) Accrual of interest on fair value of the debt component of the A Ordinary Preference shares based on its effective interest rate

(g) Transaction costs related to the debt element of the A Ordinary Preference shares are offset against the debt rather than share premium

(h) Transaction costs are amortised to the income statement over the term of the debt

20 Related party transactions

(a) Transactions with founding members and shareholders

On 18 March 2004, the Company acquired intellectual property rights ("acquired IP rights consisting of in-process research and development and certain patent and licence agreements from Athpharma Limited, a company owned and controlled by the directors of the Company. Shares were issued to the directors as consideration for the acquired IP rights at a valuation determined by an external valuer of €1,581,000. Share premium of €1,580,100 arose on the transaction.

During 2004 and 2005, four employees of the Company including 2 of its current directors were employed on a shared basis by the company and Athpharma Limited. Remuneration costs were shared between the Company and Athpharma Limited under a cost sharing arrangement based on time spent on each entity. This arrangement ceased to exist with effect from 1 January 2006 and the directors became full time employees of the Company.

Since its incorporation, the Company has occupied a premises previously owned by Athpharma Limited. The Company has entered into negotiations with the current owner to negotiate lease terms and accordingly no amounts have been paid with regard to the rental of this premises in the nine month period ended 30 September 2005.

In the nine months ended 30 September 2005, the Company paid €13,509 in consulting fees to Kellpharm, a company of which John Kelly, a shareholder of the Company, is also a shareholder.

(b) Transactions with other related parties

The Company entered into an agreement with BioClin Research Laboratories Ltd ("BioClin") on 25 April 2005. Under this agreement, BioClin provides Bioanalytical Sample Analysis to the Company at contracted rates. In the period ended 30 September 2005 €84,060 was paid to BioClin for these services. Mary Martin, a director of the Company is also a director of BioClin.

21 Post balance sheet events

Re-organisation of the Company

On 20 January 2006, the Company underwent a re-organisation by virtue of which the Company's shareholders in their entirety exchanged their shares in the Company for shares in AGI Therapeutics plc at a ratio of one share in the Company for 125 shares in AGI Therapeutics plc.

To achieve the re-organisation, all the shareholders of the Company entered into a share exchange agreement dated 20 January 2006 under which the shareholders of the Company agreed to exchange collectively a total of 146,153 A Ordinary Preference shares and 110,000 A Ordinary shares in exchange for the allotment and issue of 18,269,125 A Ordinary Preference shares of €0.01 each and 13,749,900 Ordinary shares of €0.01 each in the capital of AGI Therapeutics plc.

PART VII — ADDITIONAL INFORMATION

(1) RESPONSIBILITY STATEMENT

The Directors, whose names appear on page 3 of this document, accept responsibility for the information contained in this document. To the best of the knowledge and belief of the Directors (who have taken all reasonable care to ensure that such is the case) the information contained in this document is in accordance with the facts and does not omit anything likely to affect the import of such information.

Bridgehead accepts responsibility for the information contained in Part III of this document. To the best of the knowledge of Bridgehead (which has taken all reasonable care to ensure that such is the case), the information contained in Part III of this document is in accordance with the facts and makes no omission likely to affect the import of such information.

Finnegan accepts responsibility for the information contained in Part IV of this document. To the best of the knowledge of Finnegan (which has taken all reasonable care to ensure that such is the case), the information contained in Part IV of this document is in accordance with the facts and makes no omission likely to affect the import of such information.

(2) INCORPORATION AND STATUS OF THE COMPANY

The Company was incorporated in Ireland under the Irish Companies Acts as a private limited company on 16 December 2005 with registered number 412638. On 2 February 2006 the Company was converted into a public limited company.

The address of the Company's registered office is at Adelaide Chambers, Peter Street, Dublin 8, Ireland. The telephone number of the Company is (01) 449 3250 or, if dialling from outside Ireland, +353 (1) 449 3250. The Company has one subsidiary which will be fully consolidated in the financial statements of the Company, details of which are as follows:

Name	*Country of Incorporation*	*Date of Incorporation*	*Percentage ownership*
AGI Therapeutics Research Limited	Ireland	3 October 2003	100%

The name of the Company's sole subsidiary, AGI Therapeutics Research Limited, was changed from AGI Therapeutics Limited on 14 December 2005 as part of the Company's preparation for Admission. The Company acquired the entire issued share capital of AGI Therapeutics Research Limited on 20 January 2006 pursuant to the Share Exchange Agreement described in section 12.5 of this Part VII.

(3) SHARE CAPITAL

On incorporation, the authorised share capital of the Company was €100,000 divided into 100,000 ordinary shares of €1.00 each, of which one such ordinary share was issued, fully paid, to John Devane.

(a) The following changes have occurred in the authorised share capital of the Company since 16 December 2005, the date of its incorporation:

  (i) on 19 January 2006, the authorised share capital of the Company was subdivided into 10,000,000 Ordinary Shares;

  (ii) the authorised share capital of the Company was increased on 20 January 2006 by the creation of 70,000,000 Ordinary Shares and 20,000,000 A Preferred Shares; and

  (iii) the 20,000,000 authorised A Preferred Shares were converted into 20,000,000 authorised Ordinary Shares at a ratio of one Ordinary Share for every one A Preferred Share pursuant to a resolution of the members of the Company passed on 20 February 2006 and conditional only on Admission.

(b) The following changes have occurred in the issued share capital of the Company since 16 December 2005, the date of its incorporation:

  (i) on 19 January 2006, the one ordinary share of €1.00 in issue was sub-divided into 100 Ordinary Shares, and the Company issued 1,663,499 Ordinary Shares for cash, at par, as part of the Company's preparation for Admission;

(ii) on 20 January 2006, 13,749,900 Ordinary Shares and 18,269,125 A Preferred Shares were issued, allotted and, credited as fully paid to the shareholders of AGI Therapeutics Research Limited pursuant to the Share Exchange Agreement described in section 12.5 of this Part VII; and

(iii) the 18,269,125 A Preferred Shares were converted into 18,269,125 Ordinary Shares pursuant to a resolution of the members of the Company passed on 20 February 2006 and conditional only on Admission.

(c) The authorised and issued share capital (assuming conversion of the A Preferred Shares) of AGI Therapeutics plc as at the close of business on 20 February 2006 (being the latest practicable date prior to the publication of this document) and as it will be immediately following Admission is as follows:

	Authorised Number	*Amount*	*Issued and Fully Paid Number*	*Amount*
At date of this document				
Ordinary Shares	100,000,000	€1,000,000	33,682,624	€336,826.24
After Admission				
Ordinary Shares	100,000,000	€1,000,000	67,412,783	€674,127.83

(d) The Enlarged Issued Share Capital is in registered form and will be capable of being held in certificated or uncertificated form in CREST. Application has been made to the London Stock Exchange and the Irish Stock Exchange for the Enlarged Share Capital to be admitted to trading on AIM and IEX. It is expected that Admission will become effective and dealings will commence on 27 February 2006.

(e) By a shareholder resolution passed on 20 February 2006 and conditional on Admission, the Directors were generally and unconditionally authorised pursuant to Section 20 of the 1983 Act, to allot relevant securities (as defined in section 20(10) of the 1983 Act) up to an aggregate nominal amount of €597,491 such authority to expire five years after the date of the passing of the resolution save that the Company may before such expiry make an offer or agreement or grant any right which would or might require relevant securities to be allotted after such expiry and the directors may allot relevant securities in pursuance of such offer or agreement or rights as if the power conferred by such resolution had not expired.

(f) By a shareholder resolution passed on 20 February 2006 and conditional on Admission, the Directors were empowered to allot equity securities (as defined in section 23 (12) of the 1983 Act) for cash pursuant to the authority referred to at paragraph 3 (e) above as if section 23 (1) of the 1983 Act did not apply such power being limited to:

(i) the allotment of the Placing Shares;

(ii) the allotment of equity securities in connection with an offer of securities, open for acceptance for a period fixed by the Directors by way of rights to holders of Ordinary Shares and such other equity securities of the Company as the Directors may determine on the register on a fixed record date in proportion to their respective holdings of such securities or in accordance with the rights attached thereto (but subject to such exclusions or other arrangements as the Directors may deem necessary or expedient to deal with fractional entitlements that would otherwise arise or with legal or practical problems under the laws of, or the requirements of, any recognised regulatory body or any stock exchange in any territory or otherwise howsoever) and

(iii) the grant of options over and/or the allotment of up to 3,548,042 Ordinary Shares in connection with the Share Option Scheme;

(iv) the allotment (other than pursuant to sub-paragraphs (i) (ii) and (iii) above) of equity securities up to an aggregate nominal amount of €70,691

(g) Save as disclosed in this document no share or loan capital of the Company or its subsidiaries has been issued in the two years preceding the publication of this document or is being prepared to be issued for cash or other consideration and no commissions, discounts, brokerages or other special terms have been granted by the Company or any of its subsidiaries in connection with any such issue or sale.

(h) Save as disclosed in this document, no share or loan capital of the Company or its subsidiaries has been quoted or is proposed to be quoted fully or partly-paid up either in cash or otherwise than in cash.

(i) As at the date of this document the Company had not granted any options over Ordinary Shares to the Directors, employees or consultants of the Company in accordance with the rules of the Share Option Scheme.

(4) DIRECTORS' SHAREHOLDINGS

As at 20 February 2006 (the latest practicable date prior to the publication of this document), the interests of the Directors (including any connected person of a Director within the meaning of Section 26 of the 1990 Act) in the Existing Issued Share Capital, the existence of which is known to, or could with reasonable diligence be ascertained by, the Directors whether or not held through another party which is notifiable, as required to be disclosed pursuant to sections 53 or 64 of the Companies Act 1990 or which are required pursuant to section 59 of that Act to be entered in the register referred to therein, or are interests of a connected person of a Director which would, if the connected person were a Director, be required to be disclosed and the existence of which is known to or could with reasonable diligence be ascertained by that Director were as follows:

	Ordinary Shares[1] at date of this document	*Percentage of Existing Issued Share Capital %*	*Ordinary Shares following Admission*	*Percentage of Enlarged Issued Share Capital %*
John Devane	9,688,750	28.8	10,085,576	15.0
John O'Sullivan[2]	7,286,753	21.6	8,131,836	12.1
Peter Sandys[3]	3,643,376	10.8	4,065,918	6.0
Frank Kenny[4]	3,643,376	10.8	4,065,918	6.0
Patrick Ashe	1,498,020	4.5	1,597,226	2.4
Mary Martin	1,314,283	3.9	1,413,489	2.1
Ronan Lambe	—	—	396,825	0.6

1 Assumes conversion of the A Preferred Shares.

2 As Board nominee of ACT. John O'Sullivan is an investment director of ACT Venture Capital Limited and a partner in certain of the funds managed by it, including the funds holding shares in the Company in the name of ACT Nominees 2001 Limited.

3 As Board nominee of Seroba. Peter Sandys is a director and shareholder of Seroba BioVentures Limited

4 As Board nominee of Delta. Frank Kenny is the managing director of Delta Management Partners II Limited, the general partner of Delta.

(5) DIRECTORS' OTHER INTERESTS

(a) The Directorships and partnerships currently held by the Directors, in addition to that in the Company and any of its subsidiaries, and directorships and partnerships previously held within the five years prior to publication of this document, are as follows:

Name of Director	*Current Directorships and Partnerships*	*Previous Directorships and Partnerships*
Ronan Lambe	ICON plc	—
John Devane	J. Dev Limited	Athpharma Limited MV Pharma Limited Ebbisham Limited
Mary Martin	Bioclin Research Laboratories Monksland Industrial Estate Limited National Institute for Bioprocessing Research and Training Limited	
Patrick Ashe	Dov Pharmaceutical Inc	Nascime Limited
John O'Sullivan	Adaptra Limited Ultrasonic Scientific Limited Silicon and Software Systems Limited	Intense Photonics Limited

Name of Director	*Current Directorships and Partnerships*	*Previous Directorships and Partnerships*
Peter Sandys	ABN AMRO Emerging Europe Private Equity Fund PLC ABN AMRO Global Liquidity Funds plc Antonveneta ABN AMRO Investment Funds Limited Brandes Investment Funds plc Charles Schwab Asset Management (Ireland) Limited Charles Schwab Worldwide Funds plc i-cap Private Equity Fund plc Janus Trust Manager Limited Janus World Funds plc Rogge Funds plc Star MM Funds Limited Seroba BioVentures Limited Seroba Nominee Limited Alimentary Health Limited	Seroba Holdings Limited Imetrex Technologies Limited Eurologic Systems Group Limited Ossidian Technologies Limited Brunswick Russian Equity Fund Limited Evo1 Incorporated
Frank Kenny	Qumas Limited Galway Technology Centre limited Beacon Vale Limited Delta Technology Partners Limited Delta Nominees (DEF) Limited Delta Management Partners II Limited Quetta II Limited Quetta Scotland Limited Kelvinside Group Limited Neoss Limited Xancom Limited Durrow Enterprises Limited Delta Partners Limited Clephane Limited Delta Management Partners Limited Advanced Surgical Concepts Limited Atropos Limited Delta Nominees (DEFII) Limited Delta Nominees (BIEF) Limited Dublin Molecular Medicine Centre Neurocure Limited Quetta Limited Ridgefieldroad Partners	Quality Care Limited County Media Limited O'Leary Pharmacy (Lucan) Limited Westboro Software Limited Tullerstone Limited The Irish Venture Capital Association Limited Fontis Software Group Limited Radio Cork Limited Radio County Sound Limited Leaf Brook Limited Shawnee Limited Emporia Limited Itscomm Limited Radio County Sound (Production) Limited Quetta III Limited Dray Limited Kenfra Limited Kelvinside Holdings Limited Beta Management Partners LP Beta — FCIA LP

(b) Mr Sandys is a director of and has an indirect interest in Alimentary Health Limited, a company which is focused on using probiotics to discover new therapeutics for gastrointestinal and infectious diseases. Seroba BioVentures Limited, as the General Partner and manager of The Irish BioScience Venture Capital Fund has an interest in Alimentary Health Limited.

(c) Mr Kenny was a director of J.B. Management Limited which was dissolved following a creditors winding up in 1991. No adverse findings were made against Mr Kenny.

(d) Save as disclosed in paragraph 5(c) of Part VII of this document, none of the Directors identified above has:

(i) any unspent conviction in relation to indictable offences; or

(ii) had any bankruptcy order made against him or entered into any individual voluntary arrangement; or

(iii) been a director of any company placed in receivership, compulsory liquidation, creditors

voluntary liquidation, administration, or which has entered into any company voluntary arrangement or any composition or arrangement with its creditors generally or any class of its creditors of any company where such person was a director at the time of or within the 12 months preceding such events; or

(iv) been a partner of any partnership which has been put into compulsory liquidation, administration or entered into partnership voluntary arrangements at the time of or within the 12 months preceding such events; or

(v) been involved in receivership of any of his assets or of a partnership of which he was a partner at the time of or within 12 months preceding such events; or

(vi) been publicly criticised by statutory or regulatory authorities (including recognised professional bodies) nor has such Director ever been disqualified by a court from acting as a director of a company or from acting in the management or conduct of the affairs of any company.

(6) DIRECTORS' SERVICE AGREEMENTS AND LETTERS OF APPOINTMENT

6.1 *Dr John Devane*

Dr Devane has been employed by AGI Therapeutics Research Limited since 18 March 2004. He does not have a fixed term employment contract. His employment can be terminated by either party giving six months notice or AGI Therapeutics Research Limited may terminate by making a payment in lieu of notice. Dr Devane's remuneration is €160,000 per annum and is subject to review annually by the remuneration committee.

Under his service agreement, Dr Devane is permitted to:

(a) be available at the reasonable request of Athpharma to assist and advise Athpharma in relation to any of the existing obligations of Athpharma to third parties and proceedings, arbitrations and matters that Athpharma may be party to arising from those obligations;

(b) render all assistance to Elan Corporation plc (or any of its subsidiaries, affiliates, parent company or associated companies) as may be reasonably requested such as dealing with queries, or assisting in any investigation, arbitration or court proceedings arising from the activities conducted by Dr Devane during his employment with Elan in accordance with the terms of Dr Devane's termination letter with Elan Corporation plc dated 23 August 2002;

(c) act as a member of the advisory board of Midlands Business Innovation Centre;

(d) hold shares (not exceeding in any case 5 per cent of the total issued share capital) in companies listed on a stock exchange for investment purposes; and

(e) be a director and shareholder in J. Dev Limited and to be involved with J. Dev Limited insofar as it is engaged in the commercialisation or exploitation of Nic Mec or the KME trademark (to include, without limitation to the generality of the foregoing filing, maintenance and prosecution of the Nic Mec patents and the KME trademark and other property rights) as well as enforcing or defending any registered or unregistered rights associated with either Nic Mec or KME.

IP wholly and directly created by Dr Devane in the course of such activities is excluded from the IP protection provisions in Dr Devane's service agreement.

Whilst Dr Devane's service agreement is with AGI Therapeutics Research Limited, the duties and obligations of Dr Devane under his service agreement are also due and owing to the Company and may be enforced by the Company.

6.2 *Dr Mary Martin*

Dr Martin has been employed by AGI Therapeutics Research Limited since 15 March 2004. She does not have a fixed term employment contract. Her employment can be terminated by either party by giving to the other six months notice or AGI Therapeutics Research Limited may terminate by making a payment in lieu of notice. Dr Martin's remuneration is €140,000 per annum and is subject to review annually by the remuneration committee.

Under the terms of her service agreement, Dr Martin is permitted to:

(a) discharge her duties and obligations as a non-executive director and chairperson of the Board of BioClin Research Laboratories Limited;

(b) discharge her duties and obligations as a member of the judging panel of the Ernst & Young Entrepreneur of the Year competition;

(c) discharge her duties as a board member of the National Institute for BioProcessing, research and training;

(d) hold shares (not exceeding in any case 5 per cent of the total issued share capital) in companies listed on a stock exchange for investment purposes; and

(e) to discharge her duties as a member of the Enterprise Ireland Industrial Research & Commercialisation Committee.

IP wholly and directly created by Dr Martin in the course of such activities is excluded from the IP protection provisions in Dr Martin's service agreement.

Whilst Dr Martin's service agreement is with AGI Therapeutics Research Limited, the duties and obligations of Dr Martin under her service agreement are also due and owing to the Company and may be enforced by the Company.

6.3 *Patrick Ashe*

Mr Ashe has been employed by AGI Therapeutics Research Limited since 18 March 2004. He does not have a fixed term employment contract. His employment can be terminated by either party giving to the other six months notice or AGI Therapeutics Research Limited may terminate by making a payment in lieu of notice. Mr Ashe's remuneration is €140,000 per annum and is subject to review annually by the remuneration committee.

Under his service agreement, Mr Ashe is permitted to:

(a) be available at the reasonable request of Athpharma to assist and advise Athpharma in relation to any of the existing obligations of Athpharma to third parties and proceedings, arbitrations and matters that Athpharma may be party to arising from those obligations;

(b) discharge his duties and obligations as a director of Dov Pharmaceuticals Inc;

(c) discharge his duties and obligations as a member of the Business Advisory Committee of Seroba BioVentures Limited;

(d) hold shares (not exceeding in any case 5 per cent of the total issued share capital) in companies listed on a stock exchange for investment purposes; and

(e) be a director and shareholder in J.Dev Limited and to be involved with J. Dev Limited insofar as it is engaged in the commercialisation or exploitation of Nic Mec or the KME trademark (to include, without limitation to the generality of the foregoing filing, maintenance and prosecution of the Nic Mec patents and the KME trademark and other property rights) as well as enforcing or defending any registered or unregistered rights associated with either Nic Mec or KME.

IP wholly and directly created by Mr Ashe in the course of such activities is excluded from the IP protection provisions in Mr Ashe's service agreement.

Whilst Mr Ashe's service agreement is with AGI Therapeutics Research Limited, the duties and obligations of Mr Ashe under his service agreement are also due and owing to the Company and may be enforced by the Company.

6.4 *Dr Ronan Lambe*

Dr Ronan Lambe was appointed non-executive director and Chairman designate of the Company on 17 January 2006. Under his letter of appointment the appointment continues until determined by either the Company or Dr Lambe on three months' written notice. Dr Lambe receives a fee of €50,000 per annum.

6.5 *John O'Sullivan*

John O'Sullivan was appointed non-executive director of the Company on 19 January 2006. Under his letter of appointment, the appointment continues until determined by either the Company or Mr O'Sullivan on three months' written notice. Fees of €17,000 per annum are payable to ACT in respect of Mr O'Sullivan's appointment.

6.6 *Peter Sandys*

Peter Sandys was appointed non-executive director of the Company on 17 January 2006. Under his letter of appointment, the appointment continues until determined by either the Company or Mr Sandys on three months' written notice. Fees of €17,000 per annum are payable to Seroba in respect of Mr Sandys' appointment.

6.7 *Frank Kenny*

Frank Kenny was appointed non-executive director of the Company on 17 January 2006. Under his letter of appointment, the appointment continues until determined by either the Company or Mr Kenny on three months' written notice. Fees of €17,000 per annum are payable to Delta in respect of Mr Kenny's appointment.

Each of John O'Sullivan, Peter Sandys and Frank Kenny have also been non-executive directors of AGI Therapeutics Research Limited since 18 March 2004.

Save as set out in this section 6, there are no service agreements existing between any of the Directors and any member of the Group.

(7) DIRECTORS' INTERESTS IN CONTRACTS

(a) J. Dev Limited (company number 333790) is a company controlled by John Devane. J. Dev Limited is the legal and beneficial owner of the trade mark KME. AGI Therapeutics Research Limited entered into an agreement with J. Dev Limited, in the form of a non exclusive, non-royalty bearing license, to use KME in relation to gastrointestinal therapeutic drug products and associated GI clinical indications and uses for a one off payment of €500. John Devane also has the right to acquire the product Nic Mec from Elan Pharma International Limited which he intends completing through J. Dev Limited. It is the Group's intention, following Admission, and following the completion by J. Dev Limited of the acquisition of Nic Mec, that it will enter into a non exclusive, non-royalty bearing license for an expected one off payment of €500 with J. Dev Limited to use certain Nic Mec intellectual property and related information, insofar as it may apply to the use of mecamylamine (AGI-004) for gastrointestinal clinical indications.

Patrick Ashe has an option to acquire 25 per cent of Nic Mec, which would most probably be in the form of a 25 per cent share in J.Dev Limited for an aggregate exercise price of €50,000. The option is capable of being exercised at any time during the period of 180 days following 29 July 2005, or such other period as the parties might agree, and the parties have agreed to extend the option for 90 days after J. Dev Limited completes the acquisition of Nic Mec from Elan Pharma International Limited.

(b) Mary Martin is a director and non-executive chairperson of BioClin Research Laboratories Limited ("BioClin"). AGI has entered into 2 project agreements with BioClin:

BioClin/AGI Project Agreements dated 25 April 2005 and 18 August 2005

On 25 April 2005, a project agreement was entered into between BioClin and AGI. Under this agreement, BioClin provided bioanalytical sample analysis of 4-ASA and its metabolite. The total amount payable to BioClin in the 9 month period to 30 September 2005 was €84,060.

On 18 August 2005, a second project agreement was entered into between BioClin and AGI. Under this agreement, BioClin provides bioanalytical sample analysis of Omeprazole and its metabolite. The work envisaged in this contract is expected to commence during Q1/Q2, 2006 and to complete during Q2/Q3, 2006.

(c) Ronan Lambe was appointed non-executive chairman of the Company on 17 January 2006 and is a director of ICON plc ("ICON"). AGI Therapeutics Research Limited has entered into 1 master agreement and 2 project agreements with ICON:

ICON/AGI Agreements dated 13 August 2004, September 2004 and 6 September 2004

AGI Therapeutics Research Limited entered into a master services agreement with ICON on 13 August 2004 under which, when agreed between the parties, ICON will provide services to AGI

Therapeutics Research Limited relating to the management and conduct of clinical drug studies. Whenever AGI Therapeutics Research Limited wishes for ICON to work on a particular project, both parties will execute a project contract (similar in form to a pro forma contract attached to the master agreement), which together with the master agreement, constitute the entire agreement between them.

On 10 September 2004, a project contract was entered into concerning AGI–001:S-Pindolol; AGI–003:R-Verapamil; AGI–004:Mecamylamine; and AGI–006:R-Baclofen. Under this agreement, ICON is to conduct clinical research, CRF design, data management, biostatistics, pharmacovigilance, medical writing, central laboratory and IVRS e-diary services for AGI. The total amount payable to ICON in the 9 month period to 30 September 2005 was €2,480,313.

On 6 September 2004, AGI Therapeutics Research Limited and ICON entered into a project contract exhibit A proposal and estimate — IMPD consultancy. Further to the clinical trials to be carried out in relation to Pindolol, Verapamil and Baclofen, AGI Therapeutics Research Limited agrees to pay for the application of EUDRACT numbers and the submission of IMPDs for the projects in relation to the above product candidates. This proposal only covers the scientific review and input to facilitate the assembly of an IMPD. The total fee is not to exceed €15,000. This project has been completed.

(d) Save as disclosed in this document, no Directors were involved in any unusual or significant transactions with the Company in the current or immediately preceding financial year. In addition, save as disclosed in this document, no such transaction from an earlier financial year remains outstanding or unperformed.

(e) There is no arrangement whereby any Director has waived or agreed to waive any future emoluments nor has there been any waiver of emoluments during the financial year immediately preceding the date of this document.

(f) There are no outstanding loans or guarantees provided by the Company or the Group to the benefit of any of the Directors.

(8) SIGNIFICANT SHAREHOLDERS

(a) So far as the Directors are aware, the names of the persons other than the Directors who, directly or indirectly, are interested in 3 per cent or more of the Existing Issued Share Capital are, as follows:

	Ordinary Shares[1] at date of this document	*Percentage of Existing Issued Share Capital %*	*Ordinary Shares following Admission*	*Percentage of Enlarged Issued Share Capital %*
ACT	7,286,753	21.63	8,131,836	12.1
Seroba	3,643,376	10.82	4,065,918	6.0
Delta	3,643,376	10.82	4,065,918	6.0
Merlin	3,312,369	9.83	3,606,329	5.3
Paul Stark	1,498,020	4.45	1,498,020	2.2
Jackie Butler	1,498,020	4.45	1,498,020	2.2

1 Assumes conversion of the A Preferred Shares.

(b) Save as disclosed above, the Group is not aware of and has not received any notification from any person confirming that such person is interested, directly or indirectly, in 3 per cent or more of the nominal share capital of the Company, nor is it aware of any person who directly or indirectly, jointly or separately, exercises or could exercise control over the Group.

(c) No shareholders have different voting rights to other shareholders.

(9) SHARE OPTION SCHEME

The Share Option Scheme was established by a resolution of the Board passed on 27 January 2006 ("Adoption Date") and conditional on Admission, for the purpose of incentivising executive directors, employees, consultants and contractors of the Group. It is not a scheme approved by the Irish Revenue Commissioners. The following are the principal terms of the Share Option Scheme.

Plan Limits

The maximum aggregate number of Ordinary Shares in respect of which options may be granted must not exceed 5 per cent of the number of Ordinary Shares in issue immediately following the admission to trading on AIM and IEX. The Board may grant options at any time within 10 years of the Adoption Date.

Eligibility

Employees and executive directors together with consultants and contractors of the Company and any associated companies are eligible to participate in the Share Option Scheme. Participants are nominated by the Remuneration Committee at its discretion.

Administration

The Scheme will be administered by a duly constituted committee of the board (Remuneration Committee).

Consideration

No consideration is payable by a participant on the grant of an Option.

Exercise Condition/Vesting

The exercise of Options may be made subject to exercise conditions (including vesting over time) determined by the Remuneration Committee at the date of grant of the Option.

Option Price

The option price will not be less than the higher of (a) the nominal value of the Ordinary Shares which are the subject of the Option; and (b) the closing market price of the Ordinary Shares on the last trading day immediately prior to the date of grant of the Option.

Exercise of Options

Subject to the rules of the Scheme, a vested Option shall be capable of being exercised at any time before the expiry of ten years after the date of grant of the Option.

On cessation of employment

The Remuneration Committee has discretion to accelerate the vesting of Options in the event of death or ill-health. In the event of the death or mental incapacity of a participant, the personal representative or committee, as the case may be, of such participant shall be entitled for a period of 12 months to exercise all rights in respect of vested Options and on the expiry of such period, any Options not exercised will lapse.

Where a participant ceases to be an employee or executive director of the Company or any of its associated companies due to a breach of his employment or service contract, fraud or dishonesty, all unexercised options (whether vested or not) shall expire on the date of cessation.

If a participant ceases to be an employee or executive director of the Company or any of its associated companies because (i) the company employing him has ceased to be a member of the Group or (ii) because the business or part of the business to which his employment or office relates has ceased to be owned by the Group, the vesting of any Options held by him will accelerate and he may within the period of 90 days (or such longer period as the Remuneration Committee will permit) after the date of such cessation, exercise all Options held by him and on the expiry of such period any Options not exercised will lapse.

If a participant ceases to be an employee or executive director of the Company or any of its associated companies because of redundancy, retirement or any reason other than specified in the preceding paragraphs, the participant may within the period of 90 days (or such longer period as the Remuneration Committee may agree) from the date of such cessation exercise all vested Options held by him and upon the expiry of such period any Options not exercised will lapse. The Board has the discretion to accelerate the vesting of Options in such circumstances.

On a liquidation, reconstruction or amalgamation, participants may exercise Options (whether vested or not) subject to any conditions which the Remuneration Committee might attach.

Change of Control

In the event any person or group of persons acting in concert acquire Control (as defined in Section 11 of the Taxes Consolidation Act, 1997) of the Company as a result of purchasing and/or subscribing for shares in the Company (an "Acquisition"), the vesting of all Options shall accelerate. The Company will promptly give notice of the acceleration to all participants, requesting that Options be exercised within a period then specified subject to any conditions in the rules and in the notice of acceleration. If an Option is not so exercised within the specified period, it will lapse on the expiry of the period.

If an offer for an Acquisition is made, the Board may determine that the vesting of Options accelerates immediately or at any other time up to completion of the Acquisition, or upon such conditions being met as the Board may specify; but in any event the vesting of Options will accelerate on completion of the Acquisition if not done before.

The Company may grant Options under the Scheme in substitution for Options held by employees of another corporation who become employees of the Company or other group company as a result of a merger or consolidation of the employing corporation with the Company or other group company, or as a result of the acquisition by the Company or any other group company of property or stock of the employing corporation. The Board may direct that substitute options be granted on such terms and conditions as the Board considers appropriate in the circumstances.

If the Company becomes a wholly-owned subsidiary of a holding company which is owned in substantially the same proportions by the members of the Company, the Board may resolve with the agreement of the board of the holding company that Options granted under the Scheme will be treated as if they were Options over shares in the holding company, but so:

(i) the new option will is exercisable in the same manner as the existing option;

(ii) the total market value of the new shares will, be equal to the total market value of the shares comprised in the existing option;

(iii) the option price will be the same;

(iv) the new shares will, have the same rights as the existing shares; and

(v) the new option will be deemed to have been granted as at the grant date of the original option.

Amendments to the Share Option Scheme

The Board may amend the Share Option Scheme as they consider appropriate. However, no alteration may be made which would adversely affect subsisting rights of participants without the approval of a majority of participants. In addition, the Scheme Limit cannot be increased or the rules altered to the advantage of participants without Shareholder approval.

General

Any Ordinary Shares issued under the Share Option Scheme will rank equally with Ordinary Shares already in issue on the date of allotment except in respect of rights arising by reference to a prior record date; Options will be adjusted following any variation in the share capital of the Company in line with such variation; options are non-assignable.

(10) DISCLOSURE OF INTERESTS IN ORDINARY SHARES

The Acts make provision regarding the disclosure of interests in shares. The Irish Companies Act 1990 requires, *inter alia*, that any person, which would include a person not resident in Ireland, who has an interest in shares of a public limited company which carry full voting rights is required to notify his interest to the company, if the total number of such shares in which he has an interest equals or exceeds a certain percentage (currently 5 per cent) of all such shares. Where that person ceases to hold that percentage or there is a change in the percentage level of his shareholding, he is also obliged to notify the company. The obligation to notify must be performed within the period of 5 business days from the date upon which the obligation arises.

The notification to the relevant company must be in writing and must specify the share capital to which it relates; the number of shares comprised in that share capital in which the person making the notification knows he was interested immediately after the time when the obligation arose, or in a case where the person no longer has a notifiable interest in shares comprised in the share capital, state that he no longer has an interest; identify the notifier and give his address and except where the notice is stating that the notifier no longer has a notifiable interest in the shares, give details of the registered holder of the shares and the number of shares held by such holder.

The AIM Rules and the IEX Rules require an AIM and IEX company to issue a notification without delay of any relevant changes, being changes to the legal or beneficial interest, whether direct or indirect, to the holding of a significant shareholder, a shareholder being 3 per cent and 5 per cent or more of any class of an AIM or IEX security respectively, which increase or decrease such holding through any single percentage.

(11) SUMMARY OF THE MEMORANDUM AND ARTICLES OF ASSOCIATION

(a) Memorandum of Association

The Memorandum of Association of the Company provides that its principal objects are, as set out in clause 3.1 of its Memorandum "to carry on the business of a holding and investment company in the pharmaceutical sector and to invest the capital and other funds of the Company in the shares, stocks, bonds, bills and other securities of any corporate body, government, state, municipal or local authority or entity of any kind and wherever located".

The objects of the Company also allow it to "carry on any other business except the issuing of policies of insurance which may seem to the Company capable of being conveniently carried on in connection with the above, or calculated directly or indirectly to enhance the value of or render profitable any of the Company's property or rights."

(b) Articles of Association

(1) Issue of Shares

Subject generally to the Acts and any resolution of the members, all unissued shares for the time being of the Company are at the disposal of the Board.

The Board may grant options to persons in the service or employment of the Company or any subsidiary and the Board may issue warrants to subscribe (by whatever name they are called) to any person to whom the Company has granted the right to subscribe for shares in the Company.

Subject to compliance with the Acts, the Board may issue redeemable shares, which on redemption may be cancelled or held as treasury shares.

(2) Variation of Rights

Subject to the Acts, if at any time the share capital is divided into different classes of shares, the rights attached to any class, may be varied or abrogated, whether or not the Company is being wound up, with the consent in writing of the holders of three quarters in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class (but not otherwise).

(3) Transfers of Shares

The Board may, in their absolute discretion and without giving any reason, refuse to register a transfer of any share which is not fully paid up provided that such restriction shall not prevent dealing in such share on a market of the London Stock Exchange or the Irish Stock Exchange on an open and proper basis, or on which the Company has a lien. The Board may also refuse to register a transfer of shares unless the instrument of transfer is stamped, accompanied by evidence of the transferor's right to transfer the share, relates to not more than one class of shares, and is in favour of not more than four transferees. Where a Restriction Notice has been served and the shares to which it relates represent not less than 0.25 per cent of the class of shares concerned, the Board may in certain circumstances refuse to register a transfer of any of the shares in question or a renunciation of any allotment of new shares or debentures made in respect thereof.

Shares may be transferred by instrument in writing in any usual common form or any other form which the Directors may approve. The Articles do not preclude shares from being held or transferred in accordance with the Companies Act 1990 (Uncertificated Securities) Regulations 1996 (as amended).

(4) General Meetings

The Company shall hold a general meeting in each year as its annual general meeting in addition to any other meeting in that year, and shall specify the meeting as such in the notices calling it. All general meetings other than annual general meetings shall be called extraordinary general meetings.

Subject to the provisions of the Acts allowing for meetings to be called at shorter notice, the AGM and any meeting at which a special resolution is proposed shall be called by at least 21 clear days' notice and all other extraordinary meetings shall be called by at least 14 clear days' notice.

The Directors may convene general meetings. General meetings may also be convened on the requisition of members in accordance with the Acts. General meetings may be adjourned and may be convened or adjourned to more than one place. The quorum for general meetings shall be three persons present in person or by proxy.

Subject to any restriction imposed on any shares, notices of any general meeting of the Company shall be given to each member, director and the auditors.

(5) Voting Rights

Votes may be given personally or by proxy and need not all be cast in the same way.

Subject to any special rights or restrictions as to voting for the time being attached to any class or classes of shares, on a show of hands every member present in person and every proxy shall have one vote so however that no individual shall on a show of hands have more than one vote and on a poll every member who is present in person or by proxy shall have one vote for each share of which he is the holder.

(6) Restrictions on Voting Rights

Unless the Board decides otherwise, no member will be entitled to vote at a general or class meeting in respect of any share unless all sums then payable in respect of such share have been paid.

If at any time the Directors shall determine a holder(s) has failed to pay any call or instalment at the time appointed for payment thereof or, if the holder(s) has failed to comply with the requirements relating to disclosure of beneficial ownership contained in section 81 of the 1990 Act to the satisfaction of the Board, the Board may serve a notice (a "Restriction Notice") to such effect on the holder(s). On the expiry of 14 days from the service of a Restriction Notice no holder(s) of the share(s) specified therein shall be entitled to attend, speak or vote, either personally or by proxy, at any general meeting, for so long as the Restriction Notice remains in force.

(7) Directors

A. Rotation of Directors

Each director must retire no later than the third AGM following his appointment or re-appointment. At every annual general meeting of the Company one third of the Directors or, if their number is not three or a multiple of three, then the number nearest but greater than one third shall retire from office. The directors to retire in every year shall be those who have been longest in office since their last election but as between persons appointed on the same day, those to retire shall (unless they otherwise agree among themselves) be determined by lot. A retiring director shall be eligible for re-election.

B. Remuneration of Directors

The ordinary remuneration of the directors who do not hold executive office for their services (excluding amounts payable under any other provision of the Articles) shall not exceed in aggregate €250,000 per annum or such higher amount as the members may by ordinary resolution decide and subject to that the Board shall determine fees payable. Additional remuneration may be paid for work undertaken outside the scope of ordinary duties.

The Directors may be paid all expenses properly incurred by them in attending board or committee meetings, or general or class meetings or otherwise in connection with the discharge of their duties.

C. Executive Directors

The Board may from time to time appoint one or more of their number to the office of Chief Executive or other executive office (including that of Chairman) on such terms and for such period as they think fit and, subject to the terms of any contract between him and the Company, may at any time revoke any such appointment and a director to such office shall receive such remuneration the Board may determine.

D. Qualifying Shares

There is no share qualification for a Director.

E. Proceedings of Directors

Subject as set out in the Articles, the Board may regulate their meetings as they think fit. The quorum for meetings shall be fixed by the Board and unless otherwise fixed shall be three. Questions arising at any meeting shall be decided by a majority of votes and if there is an equality of votes, the Chairman of the meeting shall have a casting vote. A notice of a Board meeting shall be deemed to be given, if given personally, by word of mouth, or sent in writing to the last kinown address given by him (including for electronic communication).

F. Disclosure of Interests and Voting Rights

Save as set out below, a Director shall not vote on any matter in which he directly or indirectly alone or together with any person connected to him has an interest which to his knowledge is a material interest (otherwise than by virtue of his interests in shares or debentures or other securities of or otherwise in or through the Company), or a duty which conflicts with the interests of the Company. A Director shall not be counted in the quorum at a meeting in relation to any resolution from which he is not entitled to vote.

A Director shall (in the absence of some other conflicting material interest or duty than is indicated below) be entitled to vote (and be counted in the quorum) in respect of any resolution concerning any of the following matters, namely:

(i) the giving of any security, guarantee or indemnity to him in respect of money lent or obligations incurred by him or any other person at the request of or for the benefit of the Company or any of its subsidiaries;

(ii) the giving of any security, guarantee or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which he has assumed responsibility under a guarantee or indemnity or by the giving of security;

(iii) any proposal re any offer for shares or debentures or other securities of or by the Company or any of its subsidiaries in which offer he is or may participate as a holder of shares, debentures, or other securities, or in which he is to be interested as a participant in underwriting it;

(iv) any proposal concerning any other company in which he is interested provided that he and any persons connected with him do not to his knowledge hold an interest in shares (as that term is used in Part IV, Chapter 2 of the 1990 Act) representing one per cent or more of the issued shares of any class of such company or of the voting rights of such company (or of a third company through which his interest is derived);

(v) any proposal relating to a superannuation fund or retirement benefits scheme under which he may benefit and is subject to revenue approval for taxation purposes and which does not award him any privilege or benefit not generally awarded to the employees to whom such fund or scheme relates;

(vi) any proposal relating to any scheme for enabling employees (including full time executive directors) of the Company and/or any subsidiary thereof to acquire shares in the Company or any arrangement for the benefit of employees of the Company or any of its subsidiaries under which the director benefits or may benefit and which does not award the director any privilege or benefit not generally awarded to the employees to whom such scheme or arrangement relates;

(vii) any proposal concerning insurance which the Company proposes to maintain or purchase for the benefit of the directors or for the benefit of persons including the directors.

G. Borrowing Powers

The Board may exercise all the powers of the Company to borrow or raise money, to guarantee, to indemnify, to mortgage or charge its undertaking, property, assets (present and future) and uncalled capital or any part thereof subject to Part III of the 1983 Act, and to issue debentures, debenture stock and other securities whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party without any limitation as to amount.

H. Dividends

Subject to the Acts the Company may by ordinary resolution declare dividends in accordance with the respective rights of the members but no dividends shall exceed the amount recommended by the Board. The Board also has the power to pay interim dividends. Where a Restriction Notice has been served and the shares to which it relates represent not less than 0.25 per cent of the class of shares concerned, the Directors shall be entitled to withhold payment of any dividend or other amount payable in respect thereof. Such dividends or other amounts shall accrue and become payable on cancellation of the Restriction Notice.

(8) Alteration in Share Capital

The Company by ordinary resolution may increase its share capital; consolidate and divide all or any of its share capital in shares of a larger amount; subject to the provisions of the Companies Acts sub-divide its shares or any of them into shares of a smaller amount; and cancel any shares which have not been taken or agreed to be taken and reduce the amount of its authorised share capital by the amount of shares so cancelled.

(9) Untraced Shareholders

The Company may at the best price reasonably obtainable sell the shares of a member or the shares to which a person is entitled by virtue of transmission on death, bankruptcy or otherwise by operation of law, if:

(a) during the period of twelve years prior to the date of advertisements (referred to below) at least three dividends in respect of such shares have been declared and all dividend warrants and cheques which have been sent, if any, have remained uncashed;

(b) the Company has at the expiry of the twelve year period, placed advertisements in a national daily paper and a paper circulating in the area of the last known address of such member; and

(c) during the period of twelve years and the period of three months following the publication of the advertisements the Company has received no indication either of the whereabouts or of the existence of such member or person.

To give effect to such a sale the Directors may authorise some person to execute an instrument of transfer and such instrument of transfer shall be as effective as if it had been executed by the holder of or person entitled to hold the shares. The net proceeds of the sale will belong to the Company which will be obliged to account to the former member or other person entitled as aforesaid for an amount equal to such proceeds and such former member or other person shall be entered into the books of the Company as a creditor for such amount. No interest shall be payable in respect of the same and the Company shall not be required to account for any money earned on the net proceeds which may be employed in the business of the Company or invested in such investments as the Board from time to time thinks fit.

(10) Winding Up — Distribution in specie

If the Company is being wound up, the liquidator may with the sanction of a special resolution of the Company divide amongst the members in specie the whole or any part of the assets of the Company.

(11) Directors' Indemnity

Subject to the provisions of the Companies Acts, every director, other officer or auditor of the Company shall be indemnified out of the assets of the Company against all costs, charges, losses,

expenses, and liabilities incurred by him in discharge of his duties or the exercise of his powers or otherwise in relation thereto. To the extent permitted by law, the directors may arrange insurance cover at the cost of the Company in respect of any liability, loss or expenditure incurred by any director, officer or the auditors in relation to anything done or alleged to be done or omitted to be done as director, officer or auditors.

(12) MATERIAL CONTRACTS

The following contracts, not being contracts entered into in the ordinary course of business, have been entered into by the Company or another member of the Group (i) within the two years immediately preceding the date of this document and are, or may be, material; or (ii) at any time and contain provisions under which any member of the Group has an obligation or entitlement which is material to the Group at the date of this document:

12.1 Placing Agreement

The Company, the Executive Directors and Davy have entered into a placing agreement dated 21 February 2006 (the "Placing Agreement") pursuant to which Davy has agreed to use all reasonable endeavours to procure subscribers for up to 33,730,159 Ordinary Shares to be issued by the Company at a price of €1.26 (Stg£0.865). The Company and the Executive Directors have given customary warranties and indemnities to Davy subject to limitations as to the time in which claims may be brought and the amount that can be recovered. If Admission has not occurred by 8.00 am on 27 February 2006 (or such later time and or date as the Company and Davy may agree being no later than 15 March 2006) the placing agreement will cease to have any further force or effect. In addition Davy can terminate the placing agreement prior to completion of the Placing in certain circumstances, principally where any warranties are found to be untrue or inaccurate and also in the event of a material adverse change in the financial position of prospects of the Group or in national or international financial, market, economic or political conditions.

12.2 Lock-in and Orderly Market Agreements

John Devane, Mary Martin, Patrick Ashe, Jackie Butler, Paul Stark, John Kelly, and the Syndicate Investors (together the "Lock-up Parties") have entered into a lock-in and orderly market agreements with Davy and the Company, dated 17 February 2006. Pursuant to this agreement the Lock-up Parties have undertaken, subject to certain limited exceptions, including a sale in the event of an offer for all the Ordinary Shares in the Company, not to sell, transfer, grant any option over or otherwise dispose of the legal, beneficial or any interest that they have in any Ordinary Shares or other securities in the Company or rights attaching from any such Ordinary Shares or other securities or attached to any such Ordinary Shares or other securities in the Company for a period of twelve months following Admission (the "Lock-up Period"), without the prior written consent of Davy.

Orderly market arrangements apply for twelve months after the expiry of the Lock-up Period. Pursuant to this agreement the Lock-up Parties are, where they decide to sell Ordinary Shares, obliged to sell Ordinary Shares through Davy (or the Company's then broker) for the purpose of preserving an orderly market in the Ordinary Shares of the Company.

12.3 Nominated Adviser, IEX Adviser and Broker Agreement

The Company and Davy have entered into a Nominated Adviser, IEX Adviser and Broker Agreement (the "Nomad Agreement") dated 20 February 2006 pursuant to which, and conditional upon Admission, the Company has appointed Davy to act as Nominated Adviser, IEX Adviser and Broker to the Company as required by the AIM and IEX Rules. Under the Nomad Agreement, Davy has agreed, *inter alia*, to provide such independent advice and guidance to the Directors as they may require to ensure compliance by the Company on a continuing basis with the AIM and IEX Rules. The Company has agreed to pay Davy a fee of €30,000 per annum for its services as Nominated Adviser, IEX Adviser and Broker under this agreement. The Nomad Agreement contains certain undertakings and indemnities given by the Company in respect of, *inter alia*, compliance with all applicable laws and regulations. The Nomad Agreement continues for an initial period of 12 months from Admission (unless terminated for reason prior to such date in accordance with the terms of the Nomad Agreement) and thereafter until terminated in accordance with the terms of the Nomad Agreement.

12.4 Sale Rights Agreement

In consideration for the surrender of certain rights which had been conferred upon them by their then shareholding in the Group, the Company has entered into an agreement dated 20 February 2006 (the "Sale Rights Agreement") with the Syndicate Investors, the members of the Executive Management Team (other than Mary Martin) and John Kelly, in their capacities as Shareholders, under which those shareholders will each have the right, on certain terms and subject to certain conditions, to include for sale Ordinary Shares held by them in any private placement of new Ordinary Shares for cash proposed to be made by the Company at any time in the two years following the first anniversary of Admission. The Sale Rights Agreement will terminate on the third anniversary of Admission. It will also terminate when the Syndicate Investors, the members of the Executive Management Team (other than Mary Martin) and John Kelly have together thereby realised a total of €10,022,370 from the sale of Ordinary Shares or, if earlier, when they no longer have any continuing interest in Ordinary Shares. Individually and subject to certain exceptions, the right will lapse if, in the event of a private placement by the Company, he, she or it, as the case may be, decides not to exercise the right to include Ordinary Shares in the placement. In addition, the right to include Ordinary Shares in any particular placement will not apply if the Company's nominated broker reasonably considers and so advises that its exercise would, having regard to market circumstances, prejudice the success of the proposed fundraising.

12.5 Share Exchange Agreement

On 20 January 2006 the Company entered into a share exchange agreement with all the shareholders in AGI Therapeutics Research Limited (the "Share Exchange Agreement"). Under the terms of the Share Exchange Agreement the Company acquired the entire issued share capital of AGI Therapeutics Research Limited in exchange for the issue of 125 ordinary shares of €0.01 each in the Company for each ordinary share in AGI Therapeutics Research Limited and 125 A preferred shares of €0.01 each in the Company for each A preferred ordinary share in AGI Therapeutics Research Limited.

12.6 AGI Shareholders' Agreement (as amended and restated)

By a series of agreements (being a subscription agreement dated 18 March 2004, a deed of adherence dated 10 May 2004, which were replaced by an amended and restated shareholders agreement dated 20 January 2006) the rights and obligations of the shareholders in the Company and the conduct and management of the Company were regulated, including the requirement of certain shareholder consents and provisions regulating the ownership of intellectual property outside of the GI field. The amended and restated agreement will terminate automatically upon Admission.

12.7 Athpharma/AGI Business Transfer Agreement

On 18 March 2004, Athpharma and AGI Therapeutics Research Limited entered into an agreement to acquire certain of Athpharma's assets (namely its patent portfolio relating to gastrointestinal products, including pindolol (AGI-001), verapamil (AGI-003), mecamylamine (AGI-004), baclofen (AGI-006), omeprazole (AGI-010) and 4-ASA (AGI-022), together being the "Patents") in consideration of the issue of shares in AGI Therapeutics Research Limited to the then shareholders in Athpharma, valued at US$1.581 million (the "Athpharma/AGI Business Transfer Agreement"). The Athpharma/AGI Business Transfer Agreement includes customary warranties limited to the value of the consideration. The Executive Management Team (other than Mary Martin) in their personal capacity agreed to counter-indemnify Athpharma in respect of any warranty claim by AGI Therapeutics Research Limited under this agreement. The business transferred included certain agreements which Athpharma had in place with third parties in relation to the utilisation and commercialisation of the Patents which require payment of patent royalties, other sums to such third parties on the completion of project milestones and in the case of one of the agreements regarding verapamil, a payment on subsequent assignment of 10% of any monetary lump sum consideration received on any subsequent assignment.

12.8 Athpharma Termination Agreement

Athpharma was a company controlled by John Devane. The remaining shares in Athpharma were owned by Patrick Ashe, Jackie Butler, John Kelly and Paul Stark. Each of John Devane, Jackie Butler and Paul Stark have resigned as directors of Athpharma. All of John Devane, Patrick Ashe, Jackie Butler, John Kelly and Paul Stark sold their respective shareholdings in Athpharma pursuant to a share sale agreement dated 19 May 2005.

The Syndicate Investors, John Devane, Patrick Ashe, Jackie Butler, Paul Stark, Kellpharm Limited and Athpharma entered into a termination agreement dated 23 December 2005 to sever the relationship between Athpharma and the other parties to this agreement following the share sale on 19 May 2005 (the "Termination Agreement"). The principal terms of the Termination Agreement were as follows:

(a) John Devane, Patrick Ashe, Jackie Butler and Paul Stark terminated their part-time employment with Athpharma with effect from 31 December 2005 provided that they will be available upon Athpharma's reasonable request, to assist and advise Athpharma in relation to Athpharma's obligations to third parties, subject to the provisions of their AGI service contracts;

(b) Kellpharm Limited (being a company controlled by John Kelly) terminated its consultancy agreement with Athpharma with effect from 31 December 2005 provided that John Kelly shall be available upon Athpharma's reasonable request, to assist and advise Athpharma in relation to Athpharma's obligations to third parties;

(c) the options granted to the Syndicate Investors pursuant to side letters between the Syndicate Investors, John Kelly, John Devane, Patrick Ashe, Jackie Butler, Paul Stark, the Syndicate Investors, Athpharma, AGI Therapeutics Research Limited and J Dev Limited concerning certain products sold by Athpharma to Biovail Inc and the commercialisation of certain statins products dated 18 March 2004 were terminated; and

(d) Athpharma was granted a right of first refusal in connection with the Patents and related know how (see 12.7 above) for purposes outside the treatment of gastrointestinal diseases and disorders whereby AGI must first ascertain whether or not Athpharma is interested in acquiring such IP rights on similar commercial terms, and in such circumstances AGI Therapeutics Research Limited must negotiate in good faith with Athpharma to finalise such an agreement.

(13) TAXATION

(i) General

The following summary, which is intended as a general guide only, outlines certain aspects of legislation and Revenue practice in Ireland and the United Kingdom regarding the ownership and disposition of Ordinary Shares. It relates only to the position of Shareholders who are resident or ordinarily resident in Ireland or the United Kingdom for tax purposes and who hold Ordinary Shares as capital assets and not for the purpose of a trade. This summary does not address the position of certain classes of Shareholders such as dealers in securities, to whom special rules apply. This summary is not exhaustive and Shareholders are advised to consult their own tax advisers as to the taxation consequences of their purchase, ownership and disposition of Ordinary Shares. The summary is based on current Irish and United Kingdom tax legislation and on the current Double Taxation Agreement between Ireland and the United Kingdom. Shareholders should be aware that future legislative, administrative and judicial changes could affect the taxation consequences described below.

(ii) Taxation of the Company

The Company is an Irish incorporated company and is managed and controlled in Ireland and accordingly it is resident in the Republic of Ireland for tax purposes.

(iii) Withholding Tax

Withholding tax at the standard rate of income tax (currently 20 per cent) applies to dividend payments and other profit distributions by an Irish resident company. The following categories of Shareholders can receive dividends free of dividend withholding tax provided they supply relevant declarations or certificates:

— an Irish resident company;

— an Irish pension fund or Irish charity approved by the Irish Revenue Commissioners;

— an individual who is neither resident nor ordinarily resident in Ireland and is resident in another EU Member State or in a treaty country;

— a company, or a 75 per cent subsidiary of a company, the principal class of share of which is substantially and regularly traded on a recognised stock exchange located in an EU Member State (other than Ireland), or in a country with which Ireland has a double tax treaty or another approved stock exchange;

— a company resident in a treaty country or another EU Member State that is not controlled by Irish residents;

— a company resident in another EU Member State and holding at least 5 per cent of the share capital of the paying company;

— companies wholly owned directly or indirectly by two or more companies the principal class of shares of each of which is substantially and regularly traded on a recognised stock exchange in a treaty country, another EU Member State or another approved stock exchange;

— Dividends paid to a UK company that does not fall within the above exemptions, will be subject to withholding tax. The Ireland/UK Tax Treaty reduces this withholding tax to:

(a) 5 per cent of the gross amount of the dividends if the beneficial owner is a company which controls directly or indirectly 10 per cent or more of the voting power in the company paying the dividends;

(b) in all other cases 15 per cent of the gross amount of the dividends. This summary does not address the position for intermediaries and qualifying intermediaries, as defined in the Finance Act 1999.

(iv) Taxation of Dividends

(a) Taxation of Irish Resident Shareholders

Irish resident Shareholders who are individuals will be subject to income tax and levies on the aggregate of the net dividend received and the withholding tax deducted. The withholding tax deducted will be available for offset against the individual's income tax liability. A Shareholder may claim to have the withholding tax refunded to him to the extent it exceeds his income tax liability. An Irish resident Shareholder, which is a company, will not be subject to Irish corporation tax on dividends received from the Company and tax will not be withheld at source by the Company provided the appropriate declaration is made. A company, which is a close company, as defined under Irish legislation, may be subject to a corporation tax surcharge on such dividend income to the extent that it is not distributed.

Shareholders who are Irish approved pension funds or Irish approved charities are generally exempt from tax on their dividend income and will not have tax withheld at source by the paying Company from dividends received provided the appropriate declaration is made.

(b) Taxation of United Kingdom Resident Shareholders

Dividends paid to a United Kingdom resident Shareholder will not be subject to Irish withholding tax on the understanding that the Shareholder satisfies the necessary legislative conditions described above.

UK Resident Companies

A United Kingdom resident Shareholder that is a company which either directly or indirectly controls, or is a subsidiary of a company which either directly or indirectly controls, less than 10 per cent of the voting power of the Company, will be subject to corporation tax in the United Kingdom on dividends received. If Irish tax is withheld on the dividend because the company does not fall within legislative conditions described above then the company will be subject to United Kingdom corporation tax on the gross amount (i.e. net dividend received plus withholding tax) and a deduction can be claimed against the UK tax liability for the Irish withholding tax suffered.

A United Kingdom resident Shareholder that is a company which either directly or indirectly controls, or is a subsidiary of a company which either directly or indirectly controls, 10 per cent or more of the voting power of the Company will be liable to United Kingdom corporation tax on the aggregate of the dividend (plus any withholding tax suffered) and the underlying Irish corporation tax. The underlying Irish corporation tax (and any Irish withholding tax suffered) will be available for set off against the United Kingdom corporation tax liability on the aggregate amount of the dividend taxed.

A United Kingdom resident Shareholder that is not subject to tax in the United Kingdom by reason of the United Kingdom law affording relief to charities and certain superannuation schemes or to

insurance companies in respect of their pension business may not be subject to tax in the United Kingdom on a dividend from the Company.

UK Resident Individuals

In respect of dividends on Ordinary Shares, individual shareholders who are resident in the UK for tax purposes and are only liable to tax at the lower or basic rates are taxed at 10 per cent on UK and foreign dividends. In the case of UK dividends they are also entitled to a tax credit at the rate of one ninth of the cash dividend or 10 per cent of the aggregate of the cash dividend and the associated tax credit. Dividend income will be treated as the top slice of an individual's income.

Dividends received from the Company will be treated as foreign dividends from an Irish company therefore the only tax credit available will be of any withholding tax deducted and which is not subsequently repaid to the taxpayer.

Consequently shareholders receiving dividends will be liable to income tax on the aggregate of the dividend and the withholding tax credit at, in the case of starting and basic rate taxpayers, the Schedule F ordinary rate of 10 per cent in 2005-2006 or, in the case of higher rate taxpayers, the Schedule F upper rate 32.5 per cent (in 2005-2006). The tax credit will be offset against their total income tax liability.

(c) Other

Non-UK resident shareholders and shareholders subject to tax in a jurisdiction other than the UK should consult an appropriate professional adviser concerning their liabilities to tax on dividends received.

(v) Capital Gains Tax

(a) Ireland

The Company's Ordinary Shares constitute chargeable assets for Irish capital gains tax purposes and, accordingly, Shareholders who are resident or ordinarily resident in Ireland, depending on their circumstances, may be liable to Irish tax on capital gains on a disposal of Ordinary Shares. The Irish capital gains tax rate is currently 20 per cent. Shareholders of the company who are neither resident nor ordinarily resident in Ireland are not subject to Irish tax on capital gains arising on the disposal of these Ordinary Shares.

(b) United Kingdom

The Company's Ordinary Shares constitute chargeable capital assets for UK tax purposes and, accordingly, Shareholders who are resident or ordinarily resident in the UK, depending on their circumstances, may be liable to UK tax on capital gains on a disposal of Ordinary Shares.

UK Resident Companies

UK resident companies within the charge to corporation tax on chargeable gains will be subject to corporation tax on the proceeds received less the sum of the base cost of their Ordinary Shares plus indexation allowance and incidental selling expenses.

UK Resident Individuals

In the case of individuals who are either resident or ordinarily resident in the UK, taper relief may be available to reduce the taxable gain. The amount of the reduction will depend on the length of time the shares have been held and whether the Ordinary Shares are regarded as business or non-business assets for taper relief purposes. The Inland Revenue accept that shares listed on the AIM are treated as "unlisted" for the purposes of UK capital gains tax taper relief and consequently the Ordinary Shares may qualify as a business asset for taper relief purposes. Taper relief availability will depend upon an individual's circumstances.

Subject to other capital gains arising in the tax year, individuals will be entitled to an annual capital gains exemption which for the tax year 2005-2006 amounts to stg£8,500. Individuals should note that the annual capital gains exemption is an annual exemption available in respect of the total chargeable gains of an individual for the relevant tax year. This exemption may not be transferred between spouses.

For individuals, gains exceeding their annual capital gains tax exemption are liable to tax at 10 per cent, 20 per cent or 40 per cent, depending on their taxable income.

Individual shareholders of the Company who are neither resident nor ordinarily resident in the UK and who hold the Ordinary Shares as part of the assets of a trade carried on through a permanent establishment in the UK may be subject to UK capital gains tax arising on the disposal of these Ordinary Shares where these shares are regarded as assets situated within the UK.

(vi) Stamp Duty

(a) Irish Stamp Duty

Irish stamp duty will be charged at the rate of 1% of the amount or value of the consideration on any conveyance or transfer on sale or voluntary disposition of Ordinary Shares. In relation to a conveyance or transfer on sale or voluntary disposition of Ordinary Shares under the CREST System, Irish stamp duty at the rate of 1% will be payable on the amount or value of the consideration.

(b) UK Stamp Duty

(i) the allotment and issue of Ordinary Shares by the Company pursuant to the Placing does not give rise to a charge to stamp duty;

(ii) a charge to stamp duty will arise only on the transfer of the Ordinary Shares where there is a matter or thing to be done in the UK or where the document of transfer is executed in the UK. Where the transfer is within the charge to stamp duty the rate of tax is 0.5% of the actual consideration paid (rounded up to the nearest multiple of £5). Where a stamp duty liability arises, this is payable by 30 days after the date on which the stampable transfer is executed. Interest and penalties are normally charged if stamp duty is paid after the due date;

(iii) there is normally no additional stamp duty where Ordinary Shares are taken out of CREST (otherwise than pursuant to a transfer on sale) or where Ordinary Shares are deposited in CREST for conversion into uncertificated form (otherwise than pursuant to a transfer on sale or in contemplation of such sale).

(iv) where stamp duty has already been paid in Ireland in respect of the transfer, then no further stamp duty is payable in the UK.

(c) UK Stamp Duty Reserve Tax

Settlement of Ordinary Shares within CREST is not subject to SDRT.

(vii) Irish Capital Acquisitions Tax

Capital acquisitions tax (CAT) covers both gift tax and inheritance tax. A CAT liability arises where the disponer or beneficiary is resident or ordinarily resident (unless not domiciled, in which case must be resident for 5 consecutive years immediately preceding the year of assessment and resident/ordinarily resident in that year) in Ireland or where the subject matter of the gift or inheritance is Irish property. Registered shares are located in the country of the register. Accordingly the Ordinary Shares are located in Ireland and a CAT liability may arise on a gift or inheritance of Ordinary Shares, notwithstanding that the gift or inheritance is between two non Irish resident and non ordinarily Irish resident individuals.

(viii) UK Inheritance Tax

UK domiciled individuals are chargeable to UK Inheritance Tax in respect of property situated anywhere in the world. Non-UK domiciled individuals are chargeable only to UK Inheritance Tax in respect of property situated in the UK.

UK Inheritance Tax legislation contains no specific rules for determining where property is situated and therefore the normal situs rules apply. As regards registered shares, they are generally situated where they are registered unless they are transferable in more than one jurisdiction and in such cases they are situated in the country in which they are likely to be dealt with in the normal course of affairs.

Where property is regarded as situated within the UK for UK Inheritance Tax purposes, a gift of such property by, or on the death of, an individual holder of such property may (subject to certain exemptions and reliefs, in particular Business Property Relief) give rise to a liability to UK inheritance tax. For inheritance tax purposes, a transfer of assets at less than full market value may be treated as a gift and particular rules apply where the donor reserves or retains some interest or benefit in the property being transferred. A gift of assets is potentially exempt from UK Inheritance Tax and falls out of an individual's estate provided the donor lives for 7 years.

Where the shares are treated as Irish assets they may be liable to Irish Capital Acquisitions Tax as well as UK Inheritance Tax. However where an individual is subject to Irish Capital Acquisitions Tax as well as UK Inheritance Tax a double taxation agreement is available between the UK and Ireland to provide relief from double taxation.

(ix) Venture Capital Trust legislation and Enterprise Investment Scheme

Individual investors should note that no relief from either UK Income Tax or UK Capital Gains Tax under the provisions of the Venture Capital Trust Scheme or the Enterprise Investment Scheme is expected to be available on subscription for shares in the Company.

If you are in any doubt as to your tax position, or are subject to tax in a jurisdiction other than Ireland or the UK, you should consult your professional adviser.

(14) WORKING CAPITAL

The Directors are of the opinion that, having made due and careful enquiry, the working capital available to the Company will be sufficient for its present requirements, that is for at least twelve months from the date of Admission.

(15) LITIGATION

There are no legal or arbitration proceedings (including any proceedings which are pending or threatened by or against the Company or its subsidiaries of which the Company is aware), which may have or have had during the twelve months preceding the date of this document, a significant effect on the financial position of the Company and its subsidiaries taken as a whole.

(16) MANDATORY BIDS, SQUEEZE-OUT AND BUY-OUT RULES

(a) Mandatory bid

The Irish Takeover Rules will apply to the Company. Under the Irish Takeover Rules, if an acquisition of Ordinary Shares were to increase the aggregate holding of the acquirer and its concert parties to Ordinary Shares carrying 30 per cent or more of the voting rights in the Company, the acquirer and, depending on the circumstances, its concert parties, would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding shares at a price not less than the highest price paid for Company Shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by any acquisition of shares by a person holding (together with its concert parties) shares carrying between 30 per cent and 50 per cent of the voting rights in the Company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05%.

(b) Squeeze-out

Under the Act, if an offeror were to acquire 80 per cent of the Ordinary Shares in issue within four months of making its offer, it could then compulsorily acquire the remaining 20 per cent. It would do so by sending a notice to outstanding shareholders telling them that it would compulsorily acquire their shares and then, unless the High Court of Ireland determined otherwise one month later, it would execute a transfer of the outstanding shares in its favour and pay the consideration to the Company, which would hold the consideration on trust for outstanding shareholders. Where the offeror already owns more than 20 per cent of the Company at the time that the offeror makes an offer for the balance of the shares, then the compulsory acquisition rights only apply if the offeror acquires at least 80 per cent of the remaining shares which also represent at least 75 per cent in number of the holders of the accepting shareholders.

(c) Buy-out

The Act also gives minority shareholders in the Company a right to be bought out in certain circumstances by an offeror who has made a takeover offer. If a takeover offer related to all the Ordinary Shares in the

Company and at any time before the end of the period within which the offer could be accepted, the offeror held or had agreed to acquire not less than 80 per cent of the Company Shares, any holder of shares to which the offer related who had not accepted the offer could by a written communication to the offeror require it to acquire those shares. The offeror would be required to give any shareholder notice of his right to be bought out within one month of that right arising.

(17) CONSENTS

(a) KPMG, who are a member of the Institute of Chartered Accountants in Ireland, has given and has not withdrawn its written consent to the issue of this document with the inclusion herein of its reports and of the references to its name in the form and context in which it appears and has authorised the contents of Parts V and VI of this document for the purposes of Section 79(3) of the Financial Services and Markets Act 2000 and the Financial Services and Markets Act (Official Listing of Securities) Regulations 2001.

(b) Bridgehead, has given and has not withdrawn its written consent to the inclusion in this document of its report which is set out in Part III of this document and references thereto in the form and context in which they are included. Bridgehead accepts responsibility for the information contained in the Bridgehead Report set out in Part III of this document and to the best knowledge and belief of Bridgehead having taken reasonable care to ensure that such is the case, the information contained in such report is in accordance with the facts and does not omit anything likely to affect the import of such information.

(c) Finnegan, has given and has not withdrawn its written consent to the inclusion in this document of its report which is set out in Part IV of this document and references thereto in the form and context in which they are included. Finnegan accepts responsibility for the information contained in the Finnegan Report set out in Part IV of this document and to the best knowledge and belief of Finnegan having taken reasonable care to ensure that such is the case, the information contained in such report is in accordance with the facts and does not omit anything likely to affect the import of such information.

(d) RSM Robson Rhodes, who are a member of the Institute of Chartered Accountants in Ireland, has given and has not withdrawn its written consent to the issue of this document with the inclusion herein of the references to its name in the form and context in which it appears.

(e) Davy, which is regulated by the Financial Regulator, has given and has not withdrawn its written consent to the issue of this document with the inclusion herein of the references to its name in the form and context in which it appears.

(18) SIGNIFICANT CHANGES

(a) Save as disclosed in this document, there has been no significant change in the trading or financial position of AGI Therapeutics plc since 31 December 2005, the date to which the Accountants' Report on AGI Therapeutics plc in Part V of this document was prepared.

(b) Save as disclosed in this document, there has been no significant change in the trading or financial position of AGI Therapeutics Research Limited since 30 September 2005, the date to which the Accountants' Report on AGI Therapeutics Research Limited in Part VI of this document was prepared.

(19) GENERAL

(a) The financial information set out in the Accountants' Reports in Parts V and VI and otherwise in this document does not constitute statutory accounts within the meaning of section 149 of the Act. Statutory accounts of AGI Therapeutics Research Limited (formerly AGI Therapeutics Limited) for the period from incorporation on 3 October 2003 to 31 December, 2003 and for the year ended 31 December 2004, on which their auditors, RSM Robson Rhodes, who are members of the Institute of Chartered Accountants in Ireland, made reports which were unqualified, have been delivered to the Registrar of Companies in Dublin. AGI Therapeutics plc (formerly AGI Therapeutics Limited) was incorporated on 16 December 2005 and no such accounts have been delivered to the Registrar of Companies in Dublin.

(b) The accounting reference date for the Company and its subsidiaries is 31 December. The Company has adopted International Financial Reporting Standards ("IFRS") and its financial statements for the year ended 31 December, 2006 will be presented in accordance with IFRS.

(c) The Placing Price of €1.26 per Ordinary Share represents a premium of €1.25 per Ordinary Share over the nominal value of an Ordinary Share.

(d) The expenses of or incidental to Admission and the Placing contemplated in this document are estimated to amount to approximately €2.7 million (excluding VAT) and are payable by AGI.

(e) The aggregate remuneration paid or payable by any member of the Group (including benefits in kind) to the Directors during the year ended 31 December 2005 was €374,205. The aggregate estimated remuneration paid or payable to the Directors by any member of the Group for the current financial year under the arrangements in force or proposed at the date of this document is expected to amount to approximately €669,284.

(f) Save as disclosed in this document, here are no significant investments by the Group under active consideration.

(g) The Company has no convertible debt securities, exchangeable debt securities or debt securities with warrants in issue.

(h) There are no arrangements in place under which future dividends are waived or agreed to be waived.

(i) As of 20 February 2006 (being the latest practicable date prior to the publication of this document), the Group employed 2 personnel and 2 consultants, excluding the Directors.

(j) Save as disclosed in this document, the Directors are not aware of any exceptional factors which have influenced the Company's activities.

(k) Save as disclosed in this document, the Directors believe that there are no patents, other intellectual property rights, licences or particular contracts which are of fundamental importance to the Group's business.

(l) Save as disclosed in this document, no person (excluding the Company's professional advisers to the extent disclosed elsewhere in this document and trade suppliers) in the 12 months preceding the Company's application for Admission received, directly or indirectly, from the Company or has entered into any contractual arrangements to receive, directly or indirectly, from the Company on or after Admission any of the following:

  (i) fees totalling either £10,000, €14,000 or more;

  (ii) securities in the Company with a value of either £10,000, €14,000 or more; or

  (iii) any other benefit with a value of either £10,000, €14,000 or more at the date of Admission.

(m) No new Ordinary Shares are being made available, in whole or in part, to the public in conjunction with the application for Admission.

(n) As at the date of this document, the Company remains the holding company of AGI Therapeutics Research Limited and has not acquired any other subsidiaries.

(o) The liability of the members of the Company is limited to the amount (if any) unpaid on the shares held by them in the capital of the Company.

(p) There is no fixed date on which any Shareholders' entitlements to dividends arises and there are no arrangements in place under which future dividends are to be waived or agreed to be waived.

(20) AVAILABILITY OF THIS DOCUMENT

Copies of this document will be available to the public, free of charge, at the offices of Davy, Davy House, 49 Dawson Street, Dublin 2, Ireland and at the offices of Field Fisher Waterhouse, 35 Vine Street, London, EC3N 2AA, United Kingdom from the date of this document until at least one month after Admission.

Dated: 21 February 2006

DEFINITIONS

In this document the following expressions have the following meanings, unless the context otherwise requires or unless it is otherwise specifically provided:

"A Preferred Shares"	A preferred ordinary shares of €0.01 each in the share capital of the Company, all of which, were converted to Ordinary Shares on 20 February 2006, conditional only on Admission;
"ACT"	ACT 2001 Venture Capital Fund No. 1 Limited Partnership, ACT 2001 Venture Capital Fund No. 2 Limited Partnership, ACT 2001 Venture Capital Fund No. 2A Limited Partnership and ACT 2001 Venture Capital GmbH & Co. KG acting through their manager ACT Venture Capital Limited and whose shares in AGI are held in the name of ACT Nominees 2001 Limited;
"Act"	the Companies Act 1963 of Ireland;
"Acts" or the "Irish Companies Acts"	Companies Acts 1963 to 2005 of Ireland;
"Admission"	the admission of the Enlarged Issued Share Capital to trading on AIM and IEX, becoming effective in accordance with the AIM Rules and IEX Rules respectively, currently expected to occur on 27 February 2006;
"Admission Document" or "Document"	this document;
"AGI" or the "Group"	AGI Therapeutics plc and its Subsidiary;
"AIM" or "AIM Market"	the market of that name operated by the London Stock Exchange;
"AIM Rules"	the rules for AIM companies and their nominated advisors issued by the London Stock Exchange in relation to AIM traded securities;
"Athpharma"	Athpharma Limited;
"Athpharma/AGI Business Transfer Agreement"	the agreement dated 18 March 2004 between Athpharma and AGI Therapeutics Research Limited for the sale and transfer of certain of Athpharma's assets to AGI Therapeutics Research Limited;
"Articles"	the articles of association of the Company, as amended from time to time;
"BioClin"	BioClin Research Laboratories Limited;
"Biovail"	Biovail Corporation;
"Board" or "the Directors"	the board of directors of the Company at the date of this document, whose names are set out on page 3 of this document;

"Bridgehead"	Bridgehead International Limited;
"Bridgehead Report"	the experts' report contained in Part III of this document;
"Combined Code"	The Combined Code on Corporate Governance issued by the Financial Reporting Council;
"Company"	AGI Therapeutics plc;
"CREST"	the computerised settlement system to facilitate paperless settlement of trades and the holding of shares in uncertificated form, operated by CRESTCo Limited;
"CREST Regulations"	the Companies Act 1990 (Uncertificated Securities) Regulations 1996 (S.I. 68 of 1996) of Ireland;
"Davy"	J&E Davy, trading as Davy including its affiliate Davy Corporate Finance Limited and any other affiliates, or any of its subsidiary undertakings;
"Delta"	Delta Equity Fund II Limited Partnership acting through its general partner Delta Management Partners II Limited and whose shares in AGI are held by Delta Nominees (DEF II) Limited;
"Élan"	Élan Corporation plc and its subsidiaries;
"Enlarged Issued Share Capital" or "Enlarged Share Capital"	the Existing Issued Share Capital together with the Placing Shares, being in aggregate 67,412,783 Ordinary Shares;
"Existing Issued Share Capital" or "Existing Share Capital"	33,682,624 Ordinary Shares being the number of fully paid Ordinary Shares in issue as at 20 February 2006 (being the latest practicable date prior to the publication of this document and assuming conversion of the A Preferred Shares);
"Executive Directors"	John Devane, Mary Martin and Patrick Ashe (together);
"Executive Management Team" or "Management Executives"	John Devane, Mary Martin, Patrick Ashe, Jackie Butler and Paul Stark;
"Financial Regulator"	the Irish Financial Services Regulatory Authority;
"Finnegan"	Finnegan, Henderson, Farabow, Garrett & Dunner LLP;
"Finnegan Report"	the patent agent's report contained in Part IV of this document;
"Generally Accepted Accounting Principles"	an accepted set of rules, conventions, standards and procedures for reporting financial information, as established by the Financial Accounting Standards Board;

"IEX"	the market of that name operated by the Irish Stock Exchange;
"IEX Rules"	the rules for IEX companies and their nominated advisers issued by the Irish Stock Exchange in relation to IEX traded securities;
"IFRS"	International Financial Reporting Standards;
"Ireland"	the island of Ireland excluding Northern Ireland, and the word "Irish" shall be construed accordingly;
"Irish Stock Exchange"	The Irish Stock Exchange Limited;
"Irish Takeover Rules"	the Irish Takeover Panel Act 1997, Takeover Rules 2001 and 2002 (as amended) or any of them as the context may require;
"London Stock Exchange"	London Stock Exchange plc;
"Merlin"	Merlin Nexus Fund I, L.P.;
"Official Lists"	each of the official lists of securities maintained by the UK Listing Authority and the Irish Stock Exchange;
"Option(s)"	Option(s) over Ordinary Share(s) issued in accordance with the Share Option Scheme;
"Ordinary Share(s)"	ordinary share(s) of €0.01 each in the capital of the Company;
"PD Regulations"	the Prospectus (Directive 2003/71/EC) Regulations 2005 of Ireland;
"Placing"	the conditional placing by Davy of 33,730,159 Ordinary Shares described in this document;
"Placing Agreement"	the conditional agreement between AGI, Davy and the Executive Directors providing for the Placing dated 21 February 2006, described in section 12 of Part VII of this document;
"Placing Price"	the price €1.26 (Stg£0.865) per Placing Share;
"Placing Shares"	the 33,730,159 new Ordinary Shares to be allotted and issued by the Company pursuant to the Placing;
"Registrars"	Computershare Investor Services (Ireland) Limited;
"Seroba"	The Irish BioScience Venture Capital Fund Limited Partnership acting through its general partner Seroba BioVentures Limited;
"Share Exchange Agreement"	the agreement dated 20 January 2006, whereby the Company acquired the entire issued share capital of AGI Therapeutics Research Limited;

"Shareholders"	shareholders of AGI Therapeutics plc;
"Share Option Scheme" or the "Scheme"	the Company's share option scheme to be adopted conditional upon Admission, further details of which can be found in section 9 of Part VII of this document;
"Subsidiary"	shall be construed in accordance with the Act;
"Syndicate Investors"	ACT, Seroba, Delta and Merlin;
"Termination Agreement"	the agreement dated 23 December 2005 between the Syndicate Investors, AGI Therapeutics Research Limited, John Devane, Patrick Ashe, Jackie Butler, Paul Stark, Kellpharm Limited and Athpharma to sever certain remaining links between Athpharma and AGI Therapeutics Research Limited;
"the 1963 Act"	the Companies Act 1963;
"the 1983 Act"	the Companies (Amendment) Act 1983;
"the 1990 Act"	the Companies Act 1990;
"UK" or "United Kingdom"	the United Kingdom of Great Britain and Northern Ireland;
"UKLA" or "UK Listing Authority"	the Financial Services Authority, acting in its capacity as the competent authority for the purposes of Part IV of the Financial Services and Markets Act, 2000; and
"US" or "United States"	the United States of America, its territories and possessions, any state of the United States of America, the District of Columbia and all other areas subject to the jurisdiction of the United States of America.

Notes:

(i) Unless otherwise stated in this document, all reference to statutes or other forms of legislation shall refer to statutes of legislation of Ireland. Any reference to any provision of any legislation shall include any amendment, modification, re-enactment or extension thereof.

(ii) The symbols ''€'' and ''c'' refer to euro and euro cent respectively, the lawful currency of Ireland pursuant to the provisions of the Economic & Monetary Unit Act, 1998. The symbols ''£'' and ''p'' refer to British pounds and pence respectively. The symbols ''US$'' or'' $'' refer to United States dollars. The rate of exchange used for the purposes of this document is €1;Stg£0.6867, being the mid-market rate of exchange as at 20 February 2006, the latest practicable date prior to the date of publication of this document.

(iii) Words importing the singular shall include the plural and vice versa and words importing the masculine gender shall include the feminine or neuter gender.

GLOSSARY OF TECHNICAL TERMS

The following terms apply throughout this document, unless the context otherwise requires:

Abdominal	Pertaining to the abdomen; the area between the chest and hips on the front side of the body;
Aetiology	The investigation of the cause, origin or development of a disorder or disease;
Aminosalicylates	A class of antiflammatory agent;
Approved	The granting by the appropriate health regulatory authority of its approval to commence marketing of a therapeutic drug product;
CHRONAB	formulations of PPI developed under US patent application no. 10/932,098;
Chronic	A persistent and lasting condition;
Clinical programme	Relates to the compilation of tasks undertaken to design, execute, manage and conclude either a Phase I, II or III clinical trial made to investigate the effects of a drug, medical treatment, or device on a group of subjects;
Clinical indication	A condition which makes a particular treatment or procedure advisable;
c-IBS	Constipation-predominant irritable bowel syndrome;
Controlled release	A drug delivery method that dispenses a substance into the body gradually;
CRO	Clinical research organisation;
Disorder	A condition in which there is a disturbance of normal functioning;
d-IBS	Diarrhoea-predominant irritable bowel syndrome;
Dose escalation	The gradual increase of drug dosages in a clinical trial to determine the amount that delivers the best balance of high efficacy and acceptable side effects;
Double-blind	A research procedure used in a clinical trial in which neither researchers nor patients know who is receiving the experimental drug or treatment and who is receiving a placebo;
Drug delivery	The delivery of a drug to the site of action;
Efficacy	The effectiveness or ability of a drug to control or cure a disorder or disease;
FD	Functional dyspepsia;
FDA	Food and Drug Administration;
Ganglion	A cluster of nerve cells;

GERD	Gastroesophageal reflux disease;
GI	Gastrointestinal;
GCP	Good clinical practice;
GLP	Good laboratory practice;
GMP	Good manufacturing practice;
H2 antagonist drug	Drug used to block the action of histamine on parietal cells in the stomach, decreasing acid production by these cells;
H.pylori	A bacterium that infects the mucus lining of the human stomach;
IBS	Irritable bowel syndrome;
ICH	International conference on harmonisation;
Immunotherapeutic	Treatments that promote or support the body's immune system response to a disease;
IMPD(s)	Investigational Medicinal Product Dossier(s);
Incidence	A measure of the proportion of people in a population affected with a particular disease at a given time;
In-license	The acquisition of rights and obligations from a third party, which can involve co-marketing and/or co-development by both parties;
In vitro	Within a glass, observable in a test tube, in an artificial environment;
In-market sales	Sales made in an existing defined market (to end-users, being defined as patients);
IP	Intellectual property;
Isomer	A variation in the arrangement of atoms in two or more otherwise similar chemical compounds;
KME	Known molecular entity, a methodology used 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;
Mixed IBS or m-IBS	A condition that alternates between diarrhoea-predominant and constipation-predominant irritable bowel syndrome;
NAB	Nocturnal Acid Breakthrough;
New Chemical Entity or NCE	A new drug compound;
New Drug Application or NDA	An application submitted to the FDA for a license to market a drug for a specified clinical indication after clinical trials have been completed;

Nic Mec	A combination product for smoking cessation containing nicotine and mecamylamine;
Off label	Refers to the use of a drug for a clinical indication for which it is not approved;
Orphan Drug	A status granted to unpatentable medications developed for rare diseases;
Out-licence	The transfer of rights and obligations to a third party which can involve co-marketing and/or co-development by both parties;
Parallel-group	A clinical trial that compares two contemporaneous groups of patients, one of which receives the treatment of interest and one of which is a control group;
Patent agent	A person who acts on behalf of an applicant for the purposes of drafting a patent application and then taking that patent application through the various stages needed to grant the patent;
Patent Cooperation Treaty or PCT	A multilateral treaty that eliminates some of the duplication involved when obtaining patent protection for the same invention in several countries;
pH	The measure of the activity of hydrogen ions in a solution and therefore its acidity or alkalinity;
Pharmacokinetic	The study of absorption, distribution, metabolism and excretion of a drug;
Pharmacology	The properties and reactions of drugs especially with relation to their therapeutic value and medical toxicology;
Phase I	Refers typically to the initial introduction of an investigational new drug into humans in order to determine the metabolism and pharmacologic actions and side effects of the drug in humans, as well as its side effects. Phase I also refers to the study in human patients or normal human volunteer subjects of the pharmacokinetics of a drug. The Group's product candidates, being based on known and approved drugs, are not typically required to be tested in the typical range of Phase I trials required for NCE drugs;
Phase II	Refers to controlled clinical trials conducted to evaluate the effectiveness of a therapeutic drug for a particular indication or indications in human patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug;
Phase III	Refers to expanded controlled and uncontrolled clinical trials which are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for product labelling and use;
Placebo	An inactive pill, liquid, or powder that is used in clinical trials which has no therapeutic value;

Pre-clinical	Comprehensive in vitro and animal testing of the drug candidate to establish its target specificity, toxicity in various doses and pharmacokinetics;
Prevalence	A measure of the proportion of people in a population that would be affected with a particular disease;
Proton pump inhibitor/PPI	A group of drug that is used to reduce the amount of gastric acid produced and thereby treat GERD and ulcers;
Putative	Accepted as true on inconclusive grounds;
Q	A three month period in a calendar year, of which there are four, January to March (Q1), April to June (Q2), July to August (Q3) and September to December (Q4);
Racemic	A mixture of equal amounts of left and right hand isomers of a molecule;
Randomised	A study in which participants are randomly (ie, by chance) assigned to one of two or more treatment arms of a clinical trial;
R&D	Research and development;
Statin drugs	A group of drugs that reduce the amount of cholesterol and certain fatty substances in the blood by inhibiting a key enzyme that helps produce cholesterol;
Stereo-isomers	Isomers that contain the exact same numbers and kinds of atoms, which are bonded to each other in the very same order;
Synthesis	The formation of a compound from simpler compounds or elements;
Therapeutic	referring to the cure or management of a disorder or disease;
Transdermal patch	A medicated adhesive pad placed on the skin for absorption of a time released dose of medication into the bloodstream; and
UC	Ulcerative colitis.

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