



**FUTURA**  
MEDICAL PLC

INTRODUCTION TO  
THE ALTERNATIVE INVESTMENT MARKET  
BY WILLIAMS DE BROË PLC

**This document is important and requires your immediate attention. If you are in any doubt about the contents of this document and what action you should take you should consult a person authorised under the Financial Services and Markets Act 2000 who specialises in advising on the acquisition of shares and other securities.**

Application will be made for the whole of the Ordinary Share capital of Futura Medical plc in issue to be admitted to trading on the Alternative Investment Market of the London Stock Exchange plc (“AIM”). **AIM is a market designed primarily for emerging or smaller companies to which higher investment risks tend to be attached than to larger or more established companies. 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 consultation with his or her own independent financial adviser.**

The rules of AIM are less demanding than those of the Official List of the UK Listing Authority (the “Official List”). It is emphasised that no application is being made for admission of these securities to the Official List. Further, neither the UK Listing Authority nor the London Stock Exchange have approved the contents of this document. **The whole of the text of this document should be read. You should be aware that an investment in the Company involves a high degree of risk. Your attention is drawn to the Risk Factors set out in Part II of this document.**

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# Futura Medical plc

*(incorporated and registered in England and Wales under the Companies Act 1985 with number 4206001)*

## **Introduction to trading on the Alternative Investment Market of the London Stock Exchange by Williams de Broë Plc**

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### **SHARE CAPITAL ISSUED AND OUTSTANDING ON ADMISSION**

<i>Authorised Number of Ordinary Shares £ of 0.2p each</i>	<i>Issued and fully paid Number of Ordinary Shares £ of 0.2p each</i>
1,000,000 500,000,000	88,051 44,025,571

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The Directors of the Company, 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.

**This document is not being issued in connection with any issue or sale of Ordinary Shares and no reliance should be placed on this document or any part of it by any subscriber or purchaser of Ordinary Shares in relation to such subscription or purchase.**

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A copy of this document is available, free of charge, to the public at the offices of Williams de Broë Plc, 6 Broadgate, London EC2M 2RP from the date of this document until Admission and for one month thereafter.

The Ordinary Shares have not been, nor will be, registered under the United States Securities Act of 1933, as amended, or under the registered securities legislation of any state of the United States of America. No document in relation to Admission has been, or will be, lodged with, or registered by, the Australian Securities Commission, and no registration statement has been, or will be, filed with the Japanese Ministry of Finance, in relation to the Admission of the Ordinary Shares. Accordingly, subject to certain exceptions, the Ordinary Shares may not be directly or indirectly offered or sold within the United States of America, Australia or Japan or offered or sold to a person within the United States of America or a resident of Australia or Japan.

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## DIRECTORS, SECRETARY AND ADVISERS

<b>Directors</b>	Dr William Duncan Potter ( <i>Non-executive Chairman</i> ) James Henry Barder ( <i>Chief Executive Officer</i> ) Anthony Louis Clayden ( <i>Finance Director</i> ) David Bryn Davies ( <i>Product Development Director</i> ) Jonathan David Freeman ( <i>Non-executive Director</i> ) Andrew Slater ( <i>Non-executive Director</i> )  all of: Surrey Technology Centre 40 Occam Road Surrey Research Park Guildford Surrey GU2 7YG
<b>Company Secretary and Registered Office</b>	Anthony Louis Clayden Surrey Technology Centre 40 Occam Road Surrey Research Park Guildford Surrey GU2 7YG
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<b>Patent Attorneys</b>	Withers & Rogers 1 Redcliff Street Bristol BS1 6NP
<b>Registrars</b>	Capita Registrars The Registry Beckenham Kent BR3 4TU

## DEFINITIONS

The following definitions apply throughout this document unless the context requires otherwise:

“Act”	the Companies Act 1985
“Admission”	the admission to trading on AIM of the Ordinary Shares in issue and to be issued pursuant to the Subscription Agreement, becoming effective in accordance with the AIM Rules
“AIM”	the Alternative Investment Market of the London Stock Exchange
“AIM Rules”	the rules governing the operation of AIM
“Board”	the board of directors of the Company
“Combined Code”	the principles of good governance and code of best practice prepared by the Committee on Corporate Governance, chaired by Sir Ronald Hampel and published in June 1998, as amended from time to time
“Company”	Futura Medical plc
“CREST”	the system (as defined in the Uncertificated Securities Regulations 2001) in respect of which CRESTCo Limited is the operator
“CRESTCo”	CRESTCo Limited, the operator of CREST
“CREST Member”	a person who has been admitted by CRESTCo Limited as a system member (as defined in the AIM Rules)
“CREST Participant”	a person who is, in relation to CREST, a system participant (as defined in the AIM Rules)
“Directors”	the directors of the Company at the date of this document, whose names are set out on page 3 of this document
“EU”	the European Union
“Futura”	the Company and/or the Subsidiary, as the context requires
“the Group”	the Company and the Subsidiary
“Introduction”	the introduction and admission of the whole of the issued Ordinary share capital of the Company to AIM
“Introduction Agreement”	the agreement dated 14 July 2003 between Williams de Broë and the Company relating to the Introduction, as described in paragraph 8.1 of Part VI of this document
“IPO”	initial public offering
“Ordinary Shares”	ordinary shares of 0.2p each in the capital of the Company
“Patent Attorneys”	Withers & Rogers, the Company’s chartered Patent and Trade Mark attorneys in Bristol
“Shareholders”	holders of Ordinary Shares
“Share Option Schemes”	the Futura Medical plc EMI Approved Share Option Scheme 2002 and pre-IPO (Unapproved) Share Option Scheme 2002

“SSL” or “SSL International plc”	SSL International plc, including its wholly-owned subsidiary LRC Products Limited
“Subscription Agreement”	the conditional agreement dated 19 June 2003 between the Company and Long Fleet Systems Inc., details of which are set out in paragraph 8.5 of Part VI of this document
“Subsidiary”	Futura Medical Developments Limited
“UK”	United Kingdom of Great Britain and Northern Ireland
“US” or “United States”	United States of America, its territories and possessions, any state of the United States and the District of Columbia
“Warrants”	the warrants granted or to be granted over 1,000,000 Ordinary Shares in accordance with the terms and conditions of the Subscription Agreement, details of which are set out in paragraph 8.5 of Part VI of this document
“Williams de Broë	Williams de Broë Plc

## GLOSSARY OF TERMS

The following terms apply throughout this document unless the context requires otherwise:

“alprostadiil”	a hormonal drug (prostaglandin) injected into the penis to induce an erection
“angina”	pain (heaviness or tightness in the centre of the chest) caused when the arteries supplying the heart become so narrow that not enough oxygen-containing blood can reach the heart muscle
“bio-equivalence”	scientific basis on which generic and brand-name drugs are compared in terms of biological properties and biological activity
“cGMP”	cyclic guanosine monophosphate, a chemical messenger involved in cell signalling pathways
“chlamydia”	the term commonly used for chlamydia trachomatis, an organism that causes a variety of diseases including genital infections in men and women
“contra indicate”	a particular type of medication to be avoided if there is a certain pre-existing condition or the patient is on a medication where he/she is advised not to take the present medication in combination
“corpus cavernosa”	the two sponge-like cylinders in the penis that fill with blood to result in penile erection
“CSD500”	the Company’s medical device aimed at reducing condom slippage for men
“elastomer”	cross-linked, high polymer materials with elastic behaviour
“EMEA”	European Medicine Evaluation Agency, a European regulatory agency
“erectile dysfunction”	the inability to achieve or maintain an erection sufficient for satisfactory sexual intercourse
“erectogenic”	erection-inducing, or likely to cause an erection
“EROXON™”	the trademark (UK No 2,320,890 (Class 5)) for which the Company has applied, for the product also known as MED 2001
“European Medical Device Directives” or “Directives”	the first Directive (90/385/EEC) concerns active implantable medical devices and covers all powered medical devices implanted and left in the human body. The second Directive (93/42/EEC) covers most other medical devices – from bandages to diagnostic X-ray machines. The third Directive (98/79/EC) covers in vitro diagnostic medical devices (testing kits and equipment) used for examining specimens taken from the human body.
“FDA”	the Food and Drug Administration, the US regulatory body which governs the supply of medicines and medical devices
“FLD500”	the Company’s medical device aimed at reducing condom failure by increasing female lubrication and vasodilation
“GTN”	abbreviation for glyceryl trinitrate. A form of nitrate used in medicines for the treatment of angina (see nitrates)

“HIV”	human immuno-deficiency virus, associated with AIDS
“hypotension”	abnormally low blood pressure with associated symptoms and risks
“MCA”	the Medicines Control Agency, the UK regulatory body which governs the supply of medicines, now merged with MDA to become MHRA
“MDA”	the Medical Devices Agency, the UK regulatory body which governs the supply of medical devices, now merged with MCA to become MHRA
“MED2001”	the Company’s product for the treatment of male erectile dysfunction
“MHRA”	the Medical and Healthcare Products Regulatory Agency
“nitrates”	a class of medicines widely used in the treatment of angina
“nitrate tolerant patients”	patients who have been taking nitrates for some time and who have developed tolerance to the known side effects of GTN
“pharmacokinetic”	the study of the bodily absorption, distribution, metabolism and excretion of drugs
“Phase I”	Phase I trials are conducted in healthy volunteers to provide evidence of safety and determination of the maximum tolerated dose. The trials also examine the pharmacokinetic profile of the drug – the absorption, distribution, metabolism and excretion of the drug by the human body and its biological effects on humans
“Phase II”	Phase II trials are conducted in limited numbers of patients to assess short term safety and preliminary efficacy. Appropriate dose ranges and regimens for Phase III trials are also determined at this stage
“Phase III”	Phase III trials provide a comprehensive evaluation of safety and efficacy in large numbers of patients, the results of which complete the process prior to regulatory approval being granted
“PDE5”	abbreviation for Phosphodiesterase type 5 enzyme. PDE5 is found at highest concentrations in the smooth muscle of the corpus cavernosa. It is responsible for the breakdown of CGMP, a messenger molecule produced, <i>inter alia</i> , as a result of sexual stimulation. CGMP causes smooth relaxation resulting in inflow of blood into the corpus cavernosa which causes an erection
“PDE5 Inhibitors”	a collective term for the class of orally administered male erectile dysfunction treatments currently available; Viagra™, Cialis™ and Levitra™
“POM”	a prescription only medicine
“sexual dysfunction”	emotional or physical loss of ability, desire or interest to engage in sexual activity
“STI”	sexually transmitted infection
“topical”	used to describe drugs or medications that are applied directly to the surface of the part of the body being treated

“tumescence”	rigidity of the penis caused by engorgement with blood within the corpus cavernosa
“vasodilator”	a substance that increases blood vessel size and improves blood flow
“Viagra™”	a PDE5 Inhibitor that is used to treat impotence in men
“ZANIFIL™”	the Company’s trademarked name (UK No 2,300,097 (Class 5)) for the product also known as CSD500

## **MARKET STATISTICS**

Number of Ordinary Shares in issue (undiluted) on Admission	44,025,571
Number of Ordinary Shares subject to options granted under the Share Option Schemes	4,130,000
Number of Ordinary Shares subject to the Warrants	250,000
Maximum number of Ordinary Shares in issue (fully diluted) excluding shares subject to the Call Options and the Warrants to be issued in connection therewith	48,405,571

The above statistics assume that the Call Options granted under the Subscription Agreement will not be exercised.

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## **EXPECTED TIMETABLE OF PRINCIPAL EVENTS**

	2003
Admission effective and dealings commence in the Ordinary Shares	8.00 a.m. on 22 July
CREST member accounts credited with Ordinary Shares (where applicable)	22 July

## KEY INFORMATION

The following information is derived from, and should be read in conjunction with the full text of this document. In particular, investors should consider the statement of Risk Factors in Part II of this document. A glossary of terms used is set out on pages 6 to 8.

### **Futura's business**

The Group's business, which was founded in 1997, is the development of innovative pharmaceutical products and the Group has a portfolio of products at varying stages of development focused on the sexual well-being of healthy people and the treatment of sexual dysfunction in men and women.

### **The sexual health market**

The erectile dysfunction market has been revolutionised since the launch of Viagra™ in 1998. At the same time there has been a dramatic rise in the incidence of sexually transmitted infections. It is Futura's strategy to seek to capitalise on the market by the development and introduction of a number of products which enhance sexual well-being.

### **Futura's products are at varying stages of development**

- CSD500 is a gel incorporated within the teat of a latex condom to help healthy men to maintain an erection throughout intercourse, so reducing condom slippage. An exclusive agreement exists with SSL International plc (the makers of Durex™) to distribute the product, which is expected to be income generating by summer 2004.
- FLD500 will be a sister product of CSD500, primarily aimed at the female partner of male condom users to help women maintain lubrication during intercourse and thereby reducing the risk of condom failure.
- MED2001 is a rub on cream for the treatment of male erectile dysfunction and has recently completed Phase II trials in Mexico. The Directors intend to begin work shortly on the EU clinical programme to complete the dossier for an EU licence submission.

### **Operations**

It is the Directors' strategy to generate future revenues by granting licences to other pharmaceutical businesses, which will manufacture, market and distribute the Group's products.

### **Immediate objectives**

Futura's main objectives over the next twelve months will be to:

- collaborate with SSL to submit the EU regulatory dossier and the subsequent launch of CSD500 within the EU;
- conduct the FLD500 proof of concept studies;
- conduct the MED2001 Phase I studies to determine cardiovascular safety in angina patients and to determine the extent of product transference between sexual partners;
- finalise regulatory strategy for MED2001, and commence the EU clinical programme; and
- negotiate further distribution agreements.

### **Financial record**

Futura has not yet generated any revenue. To date approximately £7.0 million has been raised by the Company by way of equity capital including the sum of £1.7 million (before commissions and expenses) which will be raised on Admission under the Subscription Agreement. After completion of the Subscription Agreement and the costs of the AIM Admission, the Directors believe that Futura will have approximately £2.0 million cash available for the development of the business.

## PART I

### Information on the Group

#### Introduction

Futura develops innovative pharmaceutical products for sexual health and well-being. The Group is based at the Surrey Research Park in Guildford.

Futura Medical Developments Limited was founded in 1997 to develop a topical cream for the treatment of male erectile dysfunction and was acquired by a share for share exchange by Futural Medical plc in June 2001. In January 2002 Futura Medical plc completed its first fund raising of £3.3 million by way of a private placing at a price of 33 pence a share. A further fund raising, which was completed in October 2002, raised £617,500 at a price of 50 pence a share. Pursuant to the Subscription Agreement, the Company will raise a further £1.7 million (before commissions and expenses) in July 2003 by way of a private subscription for Ordinary Shares at 70 pence per share, conditional on Admission to AIM.

The Company has a portfolio of products under development focused on the sexual well-being of healthy people and the treatment of sexual dysfunction. These products are at varying stages of development. The most advanced product is expected to start generating revenues by summer 2004. Futura has signed an exclusive agreement for global distribution of this product with SSL International plc, (the makers of the Durex™ condom range). This agreement remains subject to certain conditions including satisfactory performance of the product and regulatory approval.

Futura currently has two products at an advanced stage of development: CSD500 and MED2001.

CSD500 is a latex condom which incorporates a gel to help healthy men to maintain an erection throughout intercourse, so reducing the risk of condom slippage. Currently within the final stages of development, the Directors expect that the EU dossier will be submitted by early 2004.

The second product, MED2001, is a rub-on cream for the treatment of male erectile dysfunction and has recently completed Phase II trials in Mexico. The Directors intend to begin work shortly on the EU clinical programme to complete the dossier for an EU licence submission.

The Directors believe that Futura is at an appropriate stage in its development to benefit from Admission to AIM. An AIM listing is expected to enhance the Company's profile, increase its ability to raise finance in the future and provide a means of incentivising its key staff. It is anticipated that the Company will require additional funds in order to progress the development of its products in the manner set out in this document.

#### The sexual health market

It is five years since the launch of Viagra™ by Pfizer Inc. Since then Viagra™ has revolutionised the market for erectile dysfunction with annual global sales of US\$ 1.7 billion in 2002 (up 14 per cent. on the previous year) and led to an enormous increase in public awareness of the problems of erectile dysfunction. It is thought that 50 per cent. of men aged 45 or over have some degree of erectile dysfunction. The British Journal of Urology expects the number of men with erectile dysfunction to more than double from its current level of 152 million worldwide to 322 million by 2025. The market continues to grow rapidly with, for example, the recent launch by GlaxoSmithKline plc and Bayer AG of Levitra™, an alternative treatment to Viagra™.

Condom use (branded and unbranded) is currently estimated at 13 billion units per annum globally with annual growth of 3.3 per cent. In the UK a government report from the Public Health Laboratory Service has shown that since 1996 new cases of syphilis have increased by 600 per cent., HIV by 300 per cent. and gonorrhoea and chlamydia by 200 per cent. As part of the Government's sexual health strategy to try and combat the increase in STIs, it has been recommended that sexual health education be included within the national curriculum. In addition, Dr Kevin Fenton, head of the HIV and STI division of the Health Protection Agency, has recommended that to tackle the increasing rise in STIs greater personal

responsibility for our own sexual health needs to be taken, which includes the use of condoms with all new and casual sexual partners.

### **Business Overview**

The Group develops innovative pharmaceutical products for sexual health and well being.

The Directors consider that the range of products being developed by Futura may have applications in the following areas:

- increasing the appeal, safety and use of latex condoms for both men and women;
- the treatment of erectile dysfunction amongst the general population;
- the treatment of erectile dysfunction amongst nitrate tolerant patients, for whom PDE5 inhibitors are contra-indicated;
- the treatment of premature ejaculation amongst the general population; and
- the treatment of female sexual dysfunction.

Futura currently has two products at an advanced stage of development: CSD500 and MED2001.

CSD500 is a latex condom which incorporates a gel to help healthy men to maintain an erection throughout intercourse, so reducing the risk of condom slippage. Currently within the final stages of development, the Directors expect that the EU dossier will be submitted by early 2004.

The second product, MED2001, is a rub-on cream for the treatment of male erectile dysfunction and has recently completed Phase II trials in Mexico. The Directors intend to begin work shortly on the EU clinical programme to complete the dossier for an EU licence submission.

The Directors believe that the successful licensing of these products within the EU will facilitate the approval processes in other territories throughout the world.

The Directors intend to generate future revenues by granting licenses to other pharmaceutical businesses, which will manufacture, market and distribute the Group's products. Futura has already signed a global licensing and distribution agreement for CSD500 and a UK and Ireland distribution agreement for MED 2001, and is in negotiations with a number of parties for other territories in respect of MED2001.

Futura has taken steps to ensure that the intellectual property rights of its products are protected by applying for various patents and trademarks. In particular, Futura owns certain patents and has patent applications pending, trademark registrations and trademark applications pending as detailed below and in Part III.

### **Marketing and business strategy**

The Group's strategy is to outsource the major part of its operations and activities wherever possible and appropriate. Accordingly, where signed agreements are not already in force, Futura intends that further product development and sales activities will be the subject of joint venture and licensing agreements with appropriate third parties. The Directors believe that this approach will enable the Group's products to be more effectively and expeditiously developed and will help optimise subsequent sales and investor returns.

All product manufacture is subcontracted to accredited pharmaceutical manufacturers and laboratories. All clinical trials are similarly outsourced to accredited pharmaceutical contract research organisations which are chosen by reference to their suitability, expertise and costings for each relevant clinical study.

This strategy of outsourcing requires the Group to use expert and experienced personnel capable of making informed judgements about product development and marketing. In addition to expertise on the Board, the Group has established an independent Medical Advisory Board and uses other external consultants as required. Details of the members of these boards are given below.

## Regulatory approval process

### *Medical devices*

The term ‘medical device’ covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring, or treatment of illness or handicap. The range of products is very wide: it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames – many thousands of items used every day by healthcare providers and patients.

In the UK, as is the case in some other European countries, the Governmental Regulatory Agencies responsible for medicinal products (MCA) and medical devices (MDA) have recently combined to form the new Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA is now the UK Competent Authority under the European Medical Device Directives and has responsibility for:

- implementing the Directives and ensuring that products on the UK market are safe;
- ensuring that the UK regulations are enforced and the market monitored to check compliance;
- assessing applications from manufacturers for clinical investigations of new devices; and
- designating and monitoring the UK notified bodies who perform the regulatory assessments on behalf of manufacturers.

The MHRA provided the UK lead in developing and negotiating three Directives to regulate medical devices throughout the EU. The first Directive (90/385/EEC) concerns active implantable medical devices and covers all powered medical devices implanted and left in the human body. The second Directive (93/42/EEC) covers most other medical devices – from bandages to diagnostic X-ray machines. The third Directive (98/79/EC) covers *in vitro* diagnostic medical devices (testing kits and equipment) used for examining specimens taken from the human body. The UK implementing regulations build upon these Directives and lay down essential requirements for the performance and safety of medical devices sold or supplied in the UK. They also specify procedures for checking that products comply with the relevant legislation. Devices that meet the requirements carry the CE mark to denote conformity, which is bestowed by a Notified Body operating under the control of the MHRA in the UK.

The classification of medical devices, particularly those at the “drug/device interface” is precisely controlled under these Directives. In some circumstances the combination of a recognised medical device with an approved medicinal product will be regulated as a medicinal product, for example a disposable injection pen integral with an insulin containing cartridge. Conversely a remarkably similar device such as a re-usable insulin injection pen which uses replaceable insulin cartridges is regulated as a medical device whilst the pre-filled cartridges are regulated as a medicine.

The Directors believe that CSD500 and FLD500, details of which are set out below, will both be classified as medical devices within the EU. Other territories have their own regulatory processes and there can be no assurance that Futura’s products will be treated in the same manner in such territories.

### *Medicines*

Within the EU, medicinal products are regulated under a series of Directives which are more prescriptive than the Medical Device Directives discussed above. Once again, MHRA are the UK regulatory agency.

In order to obtain regulatory approval for a prescription medicine it is necessary to demonstrate its safety and efficacy. Each new medicine is therefore required to undergo extensive pre-clinical testing through Phase I, II and III clinical trials. The key steps of this process are outlined below:

Human clinical trials are carried out in three phases, each of which requires detailed submissions to be made to regulatory authorities:

- Phase I trials are conducted in healthy volunteers to provide evidence of safety and determination of the maximum tolerated dose. The trials also examine the pharmacokinetic profile of the drug – the absorption, distribution, metabolism and excretion of the drug by the human body and its biological effects on humans;

- Phase II trials are conducted in limited numbers of patients to assess short term safety and preliminary efficacy. Appropriate dose ranges and regimens for Phase III trials are also determined at this stage;
- Phase III trials provide a comprehensive evaluation of safety and efficacy in large numbers of patients, the results of which complete the process prior to regulatory approval being granted.

Once a pharmaceutical company believes it has compiled sufficient data from its research to demonstrate safety and efficacy, it then submits a product marketing authorisation application to the relevant regulatory authority. In the UK, this authority is the MHRA which is responsible for the licensing of drugs (e.g. MED2001). In a simple case, the MHRA will evaluate the data submitted to them in order to determine whether or not to grant a marketing authorisation approved for the UK.

In the wider EU market scenario there are two registration procedures; centralised or mutual recognition. The relevant procedure in this case is mutual recognition, in which a first approval is obtained for a Member State (“MS”) of the licensor’s choice (for example in the UK via MHRA). This MS therefore becomes the Reference Member State (“RMS”), which produces an assessment report for transmission to the Concerned Member States (“CMS”) in which the sponsor wishes to market the product. The CMS authorities are then requested to “mutually recognise” the positive assessment report from the RMS, on the basis of the label proposed by and agreed with the sponsor. In the EU this document is called the Summary of Product Characteristics. It is the intention of the Directors to use the mutual recognition procedure with the MHRA as the RMS.

The Directors believe that MED2001, details of which are set out below, will be licensed as a drug. Other territories have their own regulatory processes and there can be no assurance that Futura’s products will be treated in the same manner in such territories.

## **Futura’s products**

### ***CSD500 – CONDOM SAFETY DEVICE***

#### *Product positioning*

CSD500 will be a condom used by healthy men. This incorporates an erectogenic compound to help men maintain an erection during intercourse to reduce condom slippage. The gel is to be licensed under the trademarked brand name of ZANIFIL™.

#### *Product development*

A recent survey commissioned by the Group on healthy American male condom users supported the Directors’ belief that a significant percentage of healthy men can experience a loss of sensitivity when using a condom. This in turn can contribute to a partial loss of rigidity during intercourse, resulting in condom slippage.

It has been estimated that approximately two percent of condoms slip off during intercourse. It has been estimated that global condom usage (branded and unbranded) in 2003 will exceed 13 billion. This implies that incidences of “slippage” may occur up to 260 million times a year, with the resultant risk of both unwanted pregnancies and the transference of STIs.

The Group is developing CSD500, a medical device which is aimed at reducing condom slippage by improving the rigidity, tumescence and duration of an erection through the addition of a vasodilating gel localised within the teat of a condom. The Group intends to market this product as a Class III medical device in the EU and has already had discussions with a number of EU regulatory authorities in this regard.

The formulation for CSD500 consists of a low dose of GTN, together with an appropriate carrier, thickening agents and pH buffers in a single dose 250mg volume. GTN is a potent vasodilator and has been used for the treatment of angina for more than 40 years, where it has been determined to be a safe and effective drug for this indication with a known side effect profile.

The EU dossier is nearing completion. The Directors believe that all clinical, compatibility and toxicological trials have been concluded. Product stability testing is continuing, along with manufacturing scale-up prior to the submission to the appropriate notified body. In addition, a marketing study is being undertaken by SSL for product validation. The Directors expect the dossier for CSD500 to be submitted by early 2004 for an EU licence approval.

The Directors believe that the licence approval process in other non-EU territories will be facilitated once approval has been given within the EU.

Discussions have also been held with the FDA, who have indicated that CSD500 will be assigned to the Center for Drug Evaluation and Research (“CDER”) for review and regulation as a combination product. The Group will be collaborating closely with the FDA with a view to achieving regulatory approval for CSD500 within the US.

#### *Distribution and marketing*

Futura has received significant interest from the world’s leading condom distributors. The Directors believe that this is due to the unique selling points of CSD500 and the commercial advantages this could give in a competitive market with annual growth historically limited to around 3 per cent. Futura has signed a global distribution agreement with the world’s largest branded condom manufacturer and distributor, SSL International plc (makers of the Durex™ condom range) for the lifetime of the patents. Certain terms of the agreement are commercially sensitive and therefore must remain confidential between the two parties. The Directors expect that SSL will launch the CSD500 product as a premium priced product. The payments to Futura by SSL will be royalty based with certain minimum payments due each year. A summary of this agreement is detailed in paragraph 8.3 of Part VI.

A market survey in 2001 conducted by Entri Research (the “Entri Survey”) on behalf of Futura showed that 88 per cent. of existing condom users and 49 per cent. of non-condom users would be interested in purchasing CSD500. The results shown in this survey are particularly interesting as, if it proves to be a reliable indicator of the purchasing patterns of CSD500, it would give CSD500 a significant share of the existing market as well as the potential to generate significant growth in the condom market from non-condom users. The Directors believe that this potential demand can only be met by CSD500 and its distribution partner as the Directors are unaware of any product with similar claims in the market place.

The Directors believe that the combination of the unique selling points of CSD500, the strength of the Durex™ brand, the premium price of the product and its patent position makes CSD500 a commercially attractive proposition.

#### ***FLD500 – FEMALE LUBRICATION DEVICE***

A condom containing a compound embedded elastomer where the elastomer is expected to be licensed under the trademarked brand name of ZANIFIL™

#### *Product positioning*

FLD500 will be a sister product of CSD500 primarily aimed at the female partner of male condom users to help healthy women maintain lubrication during intercourse, thereby reducing the risk of condom failure.

#### *Product development*

FLD500 is intended to be used by healthy men for the mutual benefit of themselves and their partner. It is intended that the condom will incorporate a potent vasodilator compound embedded within an elastomer film on the external surface. During sexual penetration a pharmacological dose will be delivered to the clitoris and peri-clitoral regions. This will result in improved local blood flow which in turn should lead to increased vaginal lubrication. By reducing friction during intercourse, this should reduce the risk of condom slippage or breakage. As well as improving safety, this may facilitate an enhanced overall sexual experience for both partners although this has yet to be clinically tested.

The product is expected to be classified within the EU as a Class III medical device with an ancillary medicinal substance (as is CSD500).

Futura intend to adopt a similar regulatory strategy for FLD500 to that defined for CSD500 (i.e. a condom with an improved safety claim). All toxicological studies carried out on behalf of CSD500 were deliberately extended to cover the possibility of the development of FLD500. Therefore issues of local tolerance with heroic doses have already been addressed and the product was found to be well tolerated. The most suitable elastomer has been identified and Futura will shortly be commencing a Phase I proof of concept study of GTN cream directly applied to the vaginal and clitoral area.

#### *Distribution and Marketing*

The Entri Survey conducted for Futura in the UK showed that 38 per cent. of condoms are purchased by women. A further survey conducted amongst women on behalf of Futura by ACC International Limited showed there was a high level of appeal for FLD500, which was perceived to be a unique product providing a competitive advantage for better and safer sex.

Futura has granted an option for a global distribution licence to the world's largest branded condom manufacturer and distributor, SSL International plc (makers of the Durex™ condom range) which, if exercised, will be for the lifetime of the patents. A summary of this agreement is detailed in paragraph 8.3 of Part VI.

The Directors believe that, as with CSD500, the combination of the unique selling points of FLD500, the strong female appeal, the strength of the Durex™ brand, the premium price of the product and patent position makes FLD500 a commercially attractive proposition.

#### ***MED2001 – TREATMENT FOR MALE ERECTILE DYSFUNCTION***

To be sold under the trademarked brand name of EROXON™

#### *Product positioning*

MED2001 is a 'rub-on' cream applied directly to the penis for the treatment of male erectile dysfunction.

#### *Product development*

The formulation is likely to consist of a range of doses of GTN (typically 0.5 per cent. to 2 per cent. weight by volume), together with skin penetration enhancers, and will be supplied in unit dose tubes. GTN is a potent vasodilator and has been used for the treatment of angina and associated cardio-vascular defects for more than 40 years, where it has been determined to be a safe and effective drug with a known side effect profile.

MED2001 is applied as a cream to the glans area of the penis. The GTN is absorbed into the penile blood system and is converted to nitric oxide having the effect of relaxing muscles surrounding the corpus cavernosa and dilating the penile arteries. This allows the corpus cavernosa to engorge with blood and, following sexual stimulation, a natural erection occurs.

The generally reported side-effect profile in patients, which are dose-related, are typically cited as headaches, flushing (reddening of the face), dizziness and mild hypotension.

A pharmacokinetic study has been completed to show a rapid systemic uptake of GTN with a time to maximum systemic concentration (t-max) of between 15 and 30 minutes and with rapid elimination (a half-life of 82 minutes). Sperm count, motility and morphology were not significantly affected by GTN.

Phase I and II trials, as well as a condom compatibility study which demonstrates that latex condoms can be safely used with MED2001, have been completed within Europe and Mexico. In all trials conducted so far the Group has recommended that a condom be used to reduce the risk of transference of GTN to the partner. The Group intends shortly to conduct a Phase I study intended to demonstrate there is a minimal amount of GTN left on the glans of the penis, once an erection has been achieved. The Directors believe this could remove any need to use a condom to avoid transference of GTN between partners.

A randomised, multi-centre, double-blind, placebo-controlled, escalating-dose-ranging study has been recently completed in 67 patients within Mexico City. The results are currently being analysed.

The Group intends to meet the MHRA to reaffirm the EU regulatory pathway and strategy prior to the commencement of the EU clinical programme.

Futura is aware that there is a significant subset of erectile dysfunction sufferers who have stable angina, which is treated with nitrate medicines. Due to the mode of action of nitrate medicines these patients cannot take any of the PDE5 inhibitors. It is estimated that this subset of patients accounts for 5 to 10 per cent. of all erectile dysfunction sufferers. The Directors believe that patients with mild to moderate angina may represent a population with unmet clinical needs. Futura intends to carry out a Phase I study to examine the safety of MED2001 under controlled conditions of cardiac stress in this target patient population, pending the appropriate ethical and regulatory approvals. Subject to a satisfactory outcome from this study, Futura would seek to refine the EU clinical programme eligibility criteria to include a sub-group of patients with mild to moderate angina.

#### *Distribution and Marketing*

Futura signed a distribution agreement in August 2000 with Carter Wallace S.A. for MED2001 for a number of Central American countries including Mexico. Following the acquisition of Carter Wallace Limited by Armkel LLC, a strategic decision was made by them to withdraw from the distribution and marketing of POMs. Consequently, Carter Wallace Limited has terminated the distribution agreement with Futura and discussions are ongoing with a potential replacement distributor for Mexico and other Central American countries.

The Group has signed a UK & Ireland distribution agreement with Goldshield Pharmaceuticals Limited, who also have an option to extend to other European territories. Certain terms of the agreement are commercially sensitive and must therefore remain confidential between the two parties. A summary of this agreement is detailed in paragraph 8.4 of Part VI.

The Group has received a number of approaches from interested pharmaceutical distributors for other countries and discussions are actively ongoing.

The Directors believe there is a demand for a topical treatment which is less invasive than the current PDE5 Inhibitors, a mode of application more consistent with sexual foreplay and a fast onset of action. Moreover, MED2001 may represent a treatment for mild to moderate angina sufferers with erectile dysfunction, thus satisfying an unmet clinical need.

Details of the patents and trademarks are provided in Part III of this document.

#### **Intellectual Property**

Futura's core products are significantly enhanced commercially by the fact that Futura has applied for patent rights in those international territories the Directors consider appropriate for its products during their development. Granted patents are a form of monopoly protection which may be used to prevent people from copying the technology developed by others, and normally last for 20 years from the date of their filing.

Futura has patents granted and patent applications pending for a number of inventions. An independent report on Futura's patent rights is set out in Part III of this document. Though difficult to quantify, the Directors believe there is considerable commercial, and therefore financial, value in Futura's intellectual property portfolio. If a competitor wishes to use the products covered by any of Futura's patent applications once granted, they will require a licence from Futura.

Futura retains Withers & Rogers, a firm of chartered Patent and Trade Mark attorneys, to handle the filing, administration and prosecution of its patent portfolio.

Further details of Futura's intellectual property relating to its principal products are set out in the Patent Report in Part III of this document.

## Competition

### *CSD500 and FLD500*

There are a number of international condom manufacturers, of which SSL is the largest branded condom manufacturer. The Directors are unaware of direct competition from products with similar claims to either CSD500 or FLD500. In addition, the distribution agreement entered into with SSL prohibits SSL from marketing any alternative product with similar claims. A summary of the distribution agreement is detailed in paragraph 8.3 of Part VI of this document.

### *MED2001*

There are a number of current treatments for erectile dysfunction. In particular, the Directors are aware of the class of PDE5 inhibitor oral treatments such as Viagra™, Cialis™, and Levitra™. However the Directors believe these treatments cannot be taken by angina patients using nitrate medicines giving MED2001 a potential market niche. The Directors are also aware of two topical creams called Alprox-TD™ and Topiglan™. Both treatments contain the active Alprostadil and are being developed by Nexmed Inc and Macrochem Inc respectively. The Directors understand that both the Alprostadil products are currently in Phase III development for the US market alone. In contrast MED2001 is being targeted for licensing within the EU and other non-US territories.

## Financial record

The trading record of the Group for the three years ended 31 January 2003 (being that of Futura Medical Developments Limited for all three years and that of Futura Medical plc from its incorporation on 25 April 2001) which has been extracted without adjustment from the Accountants' Report set out in Part IV of this document and should be read in conjunction with the full text of this document, is summarised as follows:

	<i>Year ended 31 January</i>		
	<i>2001</i>	<i>2002</i>	<i>2003</i>
	<i>£</i>	<i>£</i>	<i>£</i>
Research and development costs	(206,557)	(682,902)	(810,754)
Administrative expenses	(185,032)	(660,416)	(485,322)
Operating loss	(391,589)	(1,343,318)	(1,296,076)
Loss on ordinary activities before taxation	(402,204)	(1,350,027)	(1,237,256)
Tax credit	29,998	100,000	152,175
Loss on ordinary activities after taxation	(372,206)	(1,250,027)	(1,085,081)
Cash balance as at 31 January	289,863	2,042,741	1,511,319

## Current trading and prospects

As well as continuing its existing research and development programme, the Group plans to identify opportunities for potential products to add to its portfolio with the main area of research and development continuing to be in the field of sexual health, in which Futura has considerable expertise.

Futura's main objectives over the next twelve months will be to:

- collaborate with SSL to submit the EU regulatory dossier and subsequent launch of CSD500 within the EU;
- conduct the FLD500 proof of concept studies;
- conduct the MED2001 Phase 1 studies to determine cardiovascular safety in angina patients and to determine the extent of product transference between sexual partners;
- finalise regulatory strategy for MED2001 and commence further clinical programmes; and
- negotiate further distribution agreements.

## **Directors**

On Admission, the Board will comprise six directors as follows:

### *Dr William Potter, non-executive Chairman (aged 56)*

Dr Potter joined London International Group plc in 1985 and became the R&D director in 1988. He joined the Board of London International Group plc in 1993 as the group scientific affairs director until the company merged with Seton Scholl in June 1999 when he set up his own consultant organisation. Prior to this, Dr Potter was a research chemist and manager at Smith & Nephew plc. Dr Potter has managed numerous successful research and development programmes on a wide range of medical devices, many of which involved the introduction of new materials and polymer coatings. He also has extensive experience of world-wide regulatory procedures, particularly in Europe and the USA and intellectual property issues including licence negotiations and patent litigation. Dr Potter serves on and chairs a number of national, European and international standards committees for healthcare products. Dr Potter joined the Board in June 2001.

### *James Barder, Chief Executive (aged 43)*

Mr Barder joined the Company as Chief Executive in June 2001. Since 1977, Mr Barder has predominantly worked in the field of insurance and finance with a number of firms including Lyon de Falbe International, JSB International, a firm he founded himself, Seascope Reinsurance Brokers and Lochain Patrick Insurance Brokers which he co-owned. In 1989 he set up a joint venture reinsurance firm with Seascope Reinsurance Brokers called Seascope Special Risks Limited. This firm was acquired by Aon Corporation in 1994 and renamed Aon Re Special Risks Limited. In 1995 he set up and was managing director of a new investment banking division within Aon Corporation called Aon Capital Markets Limited prior to his resignation in June 2001. He has been a director of the Group since 1998. Mr Barder recently joined the board of the Loss Recovery Group Ltd as a non-executive director.

### *Anthony Clayden, Finance Director and Company Secretary (aged 36)*

Mr Clayden qualified as a chartered accountant in 1994 whilst at BDO Stoy Hayward. In 1994 he joined KPMG where he worked managing shareholder restructuring, disposals and fundraisings for technology and services businesses. In 1997 he moved to PricewaterhouseCoopers as Corporate Finance Manager focusing mainly on technology businesses. There he advised on a range of corporate finance matters, including company sales, and acquisition advice for privately owned, FTSE 100 and multi-national companies. In 1999, he joined advantage @ the edge Ltd becoming company secretary and head of finance, and oversaw operational, strategic and financial matters during a period of rapid growth for that company. In 2000, he undertook a head of finance role with Redstor Limited involving seeking offers of finance from a variety of sources, including venture capital, leasing and banking. He joined the Company as Finance Director and Company Secretary in October 2001.

### *David Davies, Product Development Director (aged 41)*

For the past 20 years Mr Davies has worked in the field of pharmaceutical and healthcare product development. Twelve of these years were spent working within pharmaceutical companies and eight working for global contract clinical research organisations. Mr Davies began his career in 1982, conducting micro biological research at Porton Down and was later engaged in pre-clinical research at Glaxo Group Research, investigating novel anti-bacterial compounds for development as pharmaceutical candidates. His clinical experience began with Wellcome Research Ltd for a 4 year period in the management of international clinical trials of novel anti-viral products throughout Europe and South-East Asia. Subsequently, he held a similar role with Zambon Limited working on anti-infective and cardiovascular products. He led pan-European clinical projects as International Clinical Project Manager at PPD Pharmaco Ltd, before becoming Director of their Project Development Office in 1996. In 1998 Mr Davies became Director of Project Management at Clintrials Research Ltd where he oversaw the delivery of 140 clinical projects. He has an MBA from the Open University and is the Treasurer of the Pharmaceutical Contract Management Group. Mr Davies has been a director of the Company since September 2001.

*Jonathan Freeman, Non-executive Director (aged 38)*

Mr Freeman started his career in the property refurbishment sector, becoming a director of a privately owned company in London. He has a degree in business studies from Stirling University and an MBA from Warwick University, gained in 1993. Since 1993, Mr Freeman has worked in the field of corporate finance in the EU, including 4 years working on the creation and launch of the pan-European stockmarket, EASDAQ, which has since been taken over by NASDAQ. In 1997 Mr Freeman joined the corporate finance department of Beeson Gregory and was appointed a director in 1998. Mr Freeman has acted as the lead advisor in all aspects of corporate finance for privately owned companies and those on both AIM and the Official List. In 2002 he joined Gambit Corporate Finance as a partner, where he has continued to provide corporate finance advisory services. He joined the Board in July 2003.

*Andrew Slater, Non-executive Director (aged 55)*

Mr Slater has over 20 years of international healthcare marketing experience. He joined London International Group plc ("LIG") in 1982, initially as Marketing Controller for family planning products. Subsequently he headed the successful US introduction of the group's Biogel surgeons' gloves, and from 1994 through to the merger with Seton Scholl in 1999 was Managing Director of Germany, the UK, and then of LIG's Northern European operation. Following the creation of the newly merged company, SSL International plc, Mr Slater was appointed to the Main Board, becoming Managing Director of the Americas and then most recently Managing Director of Europe, prior to SSL's decision to dispose of their medical division. He joined the board of Futura in July 2003.

### **Medical Advisory Board**

The Medical Advisory Board was established as an informal consultancy body to assist the Company with professional expert advice in respect of its product development. The members of the board are:

Professor Pierre Costa	Professeur des Université Practicien Hospitalier Urologie, Hospital Gaston Doumerque, Nimes, France
Dr Sharon McCullough	Consultant medical director for Zygian Limited
Dr William Potter	Non-executive chairman of Futura Medical plc and director of Stapleford Scientific Services Limited
Dr David Ralph	Consultant Urologist, University College Hospital
Ann Tailor	Director of UK and European impotence associations

### **Subscription Agreement**

The Company has entered into an agreement with Long Fleet Systems Inc. ("Long Fleet"), pursuant to which Long Fleet has agreed, conditional *inter alia* on Admission, to procure subscribers for 2,428,571 new Ordinary Shares at a price of 70p a share on Admission to raise £1.7 million (before expenses). Under the agreement, Long Fleet has also granted three call options to the Company, exercisable following Admission, pursuant to which the Company will be entitled to call upon Long Fleet to raise a total of a further £2.4 million at a price equal to a ten per cent. discount to the average mid-market quotations of the Company's shares for the five dealing days prior to exercise. Certain commissions are payable by the Company on Admission and following the exercise of any of the call options to Long Fleet. A summary of the Subscription Agreement and these commissions is set out in paragraph 8.5 of Part VI of this document.

### **Share option schemes**

On 25 February 2002 the Company established an EMI Share Option Scheme ("the Approved Scheme") which complies with the Inland Revenue requirements and a pre-IPO Share Option Scheme ("the Unapproved Scheme"). The EMI scheme was established in order to assist in the recruitment, retention and incentivisation of high quality employees and executive directors. The pre-IPO scheme was established to similarly incentivise staff and others who have contributed to the development of the Company. A summary of the terms of these schemes is set out in paragraph 7 of Part VI of this document. To date, options have

been granted over a total of 4,130,000 Ordinary Shares, representing 9.4 per cent. of the issued share capital. This total includes 410,000 options which have been granted, conditional on Admission. Further options may be issued following Admission, however it is the intention of the Board that the total number of options outstanding will not exceed 10 per cent. of the Company's issued share capital.

### **Warrants**

Under the Subscription Agreement, the Company has agreed, conditional *inter alia* on Admission, to issue warrants to Long Fleet to subscribe for 250,000 new Ordinary Shares at a price of 63p a share at any time within twelve months following the date of grant. Upon exercise of each of the three call options granted to the Company under the Subscription Agreement, the Company has agreed to issue following each exercise further warrants to Long Fleet to subscribe for 250,000 new Ordinary Shares exercisable at a subscription price equal to the exercise price of the call options at any time within 12 months of the date of grant. Up to 1,000,000 Ordinary Shares may therefore be subject to the Warrants.

### **Lock-in arrangements**

In accordance with the AIM Rules, James Barder and David Davies, being the only Directors who hold shares in the Company, have undertaken, save in certain limited circumstances, not to dispose of any of their respective interests in such Ordinary Shares at any time prior to the first anniversary of Admission. Additionally, Medinvest Holdings Limited has entered into the lock-in arrangements in respect of their shareholding. In total, 4,721,679 Ordinary Shares representing 10.73 per cent. of the issued Ordinary Share capital at the date of Admission are subject to lock-ins. Further details of the lock-in agreements are set out in paragraphs 8.1 and 8.2 of Part VI of this document.

### **Corporate governance**

Whilst taking into account the size and nature of the Company, the Board recognises the importance of good corporate governance. As the Company grows, the Directors intend that the Company should develop policies and procedures which reflect the Principles of Good Governance and Code of Best Practice, as published by the Committee on Corporate Governance (the "Combined Code") and which are appropriate for a company of its size. The Board will take such measures, so far as is practicable, to comply with the Combined Code.

On Admission the Board will comprise the non-executive Chairman, three executive directors and two further non-executive Directors. The Board will meet regularly to review key operational issues and the strategic development of the Group. The Directors are responsible for establishing adequate internal controls to minimise the risk of financial loss or material misstatement. The controls established have been designed to meet the particular needs of the Company having regard to the nature of its business.

The Directors have also established an Audit committee and a Remuneration committee. The Audit committee meets at least once per annum and is responsible for ensuring the integrity of the financial information reported to Shareholders and the systems of internal controls. This committee, which is chaired by Dr Potter and also consists of Jonathan Freeman (both Non-executive Directors), provides an opportunity for reporting by the auditors. The Remuneration committee will meet at least once per annum to determine the terms of employment and total remuneration of the executive Directors, including the granting of share options. The objective of this committee is to attract, retain and motivate executives capable of delivering the Group's objectives. The Remuneration committee is chaired by Dr Potter and consists of the other Non-executive Directors of the Company.

### **Taxation**

#### *Enterprise Investment Scheme, Corporate Venturing Scheme and Venture Capital Trust status*

The Company has received advance clearance in respect of its Enterprise Investment Scheme ("EIS"), Corporate Venturing Scheme ("CVS") and Venture Capital Trust ("VCT") status. The Company is able to issue new Ordinary Shares to EIS, CVS and VCT investors under the provisions of those schemes. Following the issue of the new Ordinary Shares, the Company will be able to make a formal application to the Inland

Revenue for its EIS, CVS and VCT status to be confirmed and then issue appropriate certificates to qualifying investors.

### **Dividend policy**

The Company has not paid dividends in the past and anticipates that earnings, if any, will not be distributed for the foreseeable future to shareholders as dividends but will be retained for the development of its business. The declaration and payment by the Company of any future dividends, and the amount thereof, will depend upon the success of the Group's operations, financial condition, cash requirements, future prospects, profits available for distribution and other factors deemed by the Directors to be relevant at the time.

### **Working capital**

The Directors are of the opinion that, having made due and careful enquiry, the working capital available to the Group will be sufficient for its present requirements, that is, for at least the twelve months from Admission.

### **Settlement and dealing**

Application will be made to the London Stock Exchange for the Admission of the entire issued share capital of Futura to trading on AIM. It is expected that Admission will take place, and that dealings will commence, on 22 July 2003.

### **CREST**

CREST is a computerised paperless share transfer and settlement system, which allows shares and other securities, to be held in electronic rather than paper form. The Company has applied for its shares to be admitted to CREST with effect from Admission.

CREST is a voluntary system and shareholders who wish to retain certificates will be able to do so. Any shareholder wishing to hold their stock through CREST can dematerialise from a certificated holding to a CREST holding by lodging their share certificate and a CREST transfer form with their stockbroker or other CREST member.

### **Further information**

Your attention is drawn to the additional information in Parts II to VI of this document.

## **PART II**

### **RISK FACTORS**

Prospective investors should be aware that an investment in the Company involves a high degree of risk. Investors are accordingly advised to consult an investment adviser authorised under the Financial Services and Markets Act 2000 who specialises in the acquisition of shares and other securities before making their decision to invest in Futura. In addition to the other information contained in this document, the following risk factors affecting the Group should be considered carefully in evaluating whether to make an investment in the Company.

It should be noted that this list is not necessarily exhaustive and that other risk factors may apply. In particular, the Group's performance may be affected by changes in the market and/or economic conditions and in legal, regulatory and tax requirements.

#### **Stage of development of the Company's product portfolio**

The Group has not yet successfully marketed any of its potential products, and there can be no assurance that any of the Group's product candidates will be successfully marketed. The Company may encounter delays and incur additional development costs and expenses, over and above those currently expected by the Directors, in order to receive necessary regulatory approvals of its products. There can be no assurance that any of the Group's products, except to the extent they have already done so, will successfully complete clinical trials or that they will meet the regulatory and production requirements necessary for commercial distribution. Adverse or inconclusive results from testing or trials of these candidates may substantially delay, or halt entirely, any further development of the products. If regulatory approvals are obtained, the products and their manufacture will remain subject to continual review and there can be no assurance that such approval will not be withdrawn or restricted at any time.

The regulatory authorities in one or more jurisdictions may require that clinical trials not yet planned are undertaken on all products before marketing approval is given. The Group's products may not successfully complete such clinical trials and marketing approval may not be given or may only be given subject to restrictions and limitations which may mean that such products are not commercially viable.

#### **Product testing and regulatory approval**

Companies operating in the field of pharmaceuticals are subject to strict controls on the manufacture, labelling, supply and marketing of pharmaceutical products. The Group's products will be subject to such regulation.

There can be no guarantee that any of the Group's products will be able to obtain or maintain the necessary regulatory approvals in any or all of the territories in respect of which applications for such approvals are made. Where regulatory approvals are obtained, there can be no guarantee that the conditions attached to such approvals will not be considered too onerous by the Company in order to market its products effectively.

In all countries the Group or its distributors will be required to obtain and maintain regulatory approval ("marketing authorisation") for its products from the relevant regulator to enable such products to be marketed in that country. The grant of a marketing authorisation for a medical product or medical device requires the evaluation of clinical data relating to efficacy, safety, and, under current regulations, bioequivalence of a product. The manufacturing facilities for medicinal products are also subject to regulatory approval and the application of good manufacturing practices is subject to tight regulatory review. There can be no assurance that any of the Group's products, except to the extent they have already done so, will successfully complete the clinical trial process or that the necessary regulatory approvals to manufacture and market the Group's products will ultimately be obtained or maintained.

Different regulatory authorities in different countries may impose their own specific requirements (by, for instance, restricting the product's indicated uses) and may refuse to grant, or may require additional data

before granting, an authorisation, even though the same product may have been approved by another country. If an authorisation is obtained, the product and its manufacture are subject to continual review and there can be no assurance that such approval will not be withdrawn or restricted. Changes in applicable legislation or regulatory policies, or the discovery of problems with the product, production process, site or manufacturer may result in the imposition of restrictions on the product's sale or manufacture, including the withdrawal of the product from the market, or may otherwise have an adverse effect on the Group's business. Many countries including the members of the EU and the US, have very high standards of technical appraisal and, accordingly, the clinical trial process is, in most cases, very lengthy. The time taken to obtain such approval in particular countries varies, but may take several years from the date of application.

There can be no assurance that regulatory regimes in major markets will not change so that the Group's products are required to undergo clinical trials in addition to those planned prior to receiving regulatory approval.

Failure to comply with applicable regulatory requirements can, among other things, result in fines, injunctions, civil penalties, total or partial suspension of regulatory approvals, refusal to approve pending applications, recalls, seizures of product, operating and production restrictions and criminal prosecutions.

### **Product liability and insurance**

The Group's business exposes it to potential product liability risks which are inherent in research and preclinical study, clinical trials, manufacturing, marketing and the use of human therapeutic products. In addition, it may be necessary for the Group to secure certain levels of insurance as a condition to the conduct of clinical trials, where these are required. There can be no assurance that future necessary coverage will be available to the Group at an acceptable cost, if at all, or that, in the event of a claim, the level of insurance carried by the Group now or in the future will be adequate or that a liability or other claim would not materially and adversely affect the business.

### **Patents and proprietary rights**

The commercial success of Futura and its ability to compete effectively with other companies depends, amongst other things, on its ability and/or the ability of its licensees to obtain and maintain patent protection and to exploit its pharmaceutical products. Accordingly, attention is drawn to the Patent Report in Part III of this document. The lack of any such patents may have a material adverse effect on Futura's ability to develop its business.

However, there can be no assurance that:

- competitors have not developed or will not develop better techniques or processes or otherwise gain access to Futura's products;
- patents will be issued with respect to applications now pending or which may be applied for in the future;
- patents granted to Futura will be sufficiently broad in their scope to provide protection for Futura's intellectual property rights against third parties;
- the validity or scope of any patents which have been, or may in the future be, granted to Futura or that claims in relation to the patents will not be asserted by other parties.

The commercial success of Futura also depends upon Futura not infringing patents granted to third parties who may have filed applications or who have obtained or may obtain patents relating to business processes which might inhibit Futura's ability to develop and exploit its own business. If this is the case, Futura may have to obtain alternative technology or reach commercial terms on the exploitation of other parties' intellectual property rights. There can be no assurance that Futura will be able to obtain alternative technology or, if any licences are required, Futura will be able to obtain any such licence on commercially favourable terms, if at all. This may have a material adverse effect on Futura.

To the extent that Futura's products are protected by intellectual property rights and that Futura is alleged to infringe third party intellectual property rights, then litigation may be necessary and could result in substantial costs to, and diversion of efforts by Futura, with no guarantee of success. Futura will seek to have procedures in place to minimise the incidence of such circumstances.

Additionally, obligations imposed on third parties by Futura to maintain its confidential information and know-how may be breached or otherwise become known in a manner which provides Futura with no recourse.

### **Manufacturing risk**

The Group's proposed products will need to be manufactured in commercial quantities, in compliance with regulatory requirements and at acceptable cost. The Group will be wholly dependent on subcontractors or licencees for the manufacture of its products. There can be no guarantee that the Group will succeed in establishing and maintaining the necessary contractual relationships with manufacturers or that its manufacturers will succeed in manufacturing the Group's products in accordance with requirements; manufacturers may be affected adversely by matters not related to the Group and its business.

### **Marketing risk**

Even if the Group's products are successfully developed and approved by the appropriate regulatory agencies, they may not enjoy commercial acceptance or success, which would adversely affect the Group's business and results of operations. Several factors could limit the Group's successful commercialisation of products, including:

- possible limited market acceptance among patients, physicians, medical centres and third party purchasers;
- the Group's inability to outsource the marketing of the product on acceptable terms or the inability of the person to whom marketing is outsourced to market the produce effectively;
- the Group's inability to supply a sufficient amount of product to meet market demand;
- the number and relative efficacy of competitive products that may subsequently enter the market; and
- the Company is reliant on third parties for the distribution and marketing of its products.

### **Distribution risk**

The Group will rely on commercial distributors to market and distribute its products. There can be no guarantee that the Group will succeed in establishing and maintaining the necessary contractual relationships with its commercial distributors or that such distributors will succeed in the marketing and distribution of the Group's products in accordance with requirements or expectations; distributors may be affected adversely by matters not related to the Group and its business.

### **Risks associated with international sales**

The Group, through its distributors, intends to license its products for sale in many parts of the world. As a result the Group's business could be affected by fluctuations in currency exchange rates. The Group may generate a significant percentage of its revenues, and a lower percentage of its operating expenses, in currencies other than pounds sterling. Therefore, the Group's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between pounds sterling and such other currencies.

### **Competition/competing products**

The Group's current and future potential competitors include, amongst others, major multinational medical instrument and healthcare companies with substantially greater resources than those of the Group. There is no assurance that competitors will not succeed in developing systems and products that are more effective

or economic than any of those developed by the Group with its distribution partners or which would render the Group's products obsolete or otherwise non-competitive.

### **Retention of key employees**

The Group is heavily reliant upon the skills of its management team and consultants and the loss of any of these key individuals could reduce the Group's ability to achieve its planned development objectives. The Company has endeavoured to ensure that the principal members of its management team are incentivised, but the retention of such staff cannot be guaranteed. In addition, the Group's success will be critical to recruiting and retaining appropriately qualified personnel to perform future research and development work. There can be no assurance that the Group will be able to recruit such personnel when it requires them.

### **History of operating losses and accumulated deficit**

The Subsidiary has experienced operating losses in each year since its inception and, as at 31 January 2003, had an accumulated deficit of approximately £3.3 million. The Group may incur further substantial operating losses over the next few years as its research and development activities continue. The revenue and profit goals of the Group depend on a number of factors outside the Group's control and there can be no assurance that the Group will ever achieve significant revenues or profitability.

### **Fluctuation of operating results**

The operating results of the Group may fluctuate significantly as a result of a variety of factors, many of which are outside the Group's control. Period-to-period comparisons of the Group's operating results may not be meaningful and investors should not rely on them as indications of the Group's future performance. The Group's operating results may fall below the expectations of securities analysts and investors. In that event, the trading price of the Ordinary Shares would almost certainly fall.

### **No assurance of profitability**

The Group has incurred and continues to incur substantial operating expenses in the research and development of its products and technologies, as well as in marketing of those products and technologies to potential customers. The Group hopes to achieve rapid growth in sales of the Group's products but there can be no guarantee that these sales levels can be achieved, or that they can be achieved within any particular time frame. There can be no assurance that in the future the Group will be profitable on a half-yearly or annual basis and, if profitable, whether the Group can sustain profitability, or that its operating losses will not increase.

### **Future capital needs**

The Group intends to continue to invest in research and development of its existing products and technologies and in new products and technologies, as well as in sales and marketing activities. The Group's future liquidity and capital requirements will depend upon numerous factors, including the costs and timing of expansion of research and development efforts and the success of these research and development efforts; the costs and timing of sales and marketing activities; the extent to which the Group's technologies and products gain market acceptance; competing technological and marketing developments; the costs involved in maintaining and enforcing patent claims and other intellectual property rights; the level and timing of revenues; available borrowings under line of credit arrangements; strategic acquisition opportunities and other factors. The Group may in the future apply for government and other grants in connection with the development of its products and there can be no guarantee that any such grant will be given or will not be withdrawn. The failure of the Group to secure additional funding when needed could have a material adverse effect on the Group's business, financial condition and results of operations. In addition, there can be no assurance that if the Group is able to raise additional funds when needed, such funds will be available on terms favourable to the Company.

**AIM Risks**

The share prices of publicly quoted companies can be volatile. The price of shares is dependent upon a number of factors, some of which are general or market or sector specific, others which are specific and others which are specific to the Group.

The Ordinary Shares will not be listed on the Official List of the UK Listing Authority and although the Ordinary Shares will be traded on AIM, this should not be taken as implying that there will always be a liquid market in the Ordinary Shares. In addition, the market for Ordinary Shares in smaller public companies is less liquid than for larger public companies. Therefore an investment in the Ordinary Shares may be difficult to realise and the share price may be subject to greater fluctuations than might otherwise be the case.

The Ordinary Shares will be quoted on AIM rather than the Official List. An investment in shares quoted on AIM may carry a higher risk than an investment in shares quoted on the Official List. AIM has been in existence since June 1995 but its future success and liquidity in the market for the Company's securities cannot be guaranteed. Investors should be aware that the value of the Ordinary Shares may be volatile and may go down as well as up and investors may therefore not recover their original investment.

The market price of the Ordinary Shares may not reflect the underlying value of the Group's net assets.

## PART III

### PATENT REPORT

WITHERS & ROGERS

1 Redcliff Street, Bristol BS1 6NP

EUROPEAN & CHARTERED PATENT  
ATTORNEYS  
TRADE MARK ATTORNEYS

The Directors  
Futura Medical Plc  
Surrey Technology Centre  
40 Occam Road  
The Surrey Research Park  
Guildford  
Surrey  
GU2 7YG

The Directors  
Williams de Broë Plc  
6 Broadgate  
London EC2M 2RP

14 July 2003

Dear Sirs,

#### **Futura Medical Plc – Intellectual Property Report**

##### **1. Introduction**

Futura Medical Developments Limited (“Futura”) is involved in the development of pharmaceutical compositions for topical application or for application to condoms, for alleviating male and female sexual dysfunction. Patent applications have been filed and are pending or have been granted for a number of inventions.

Futura is aware of the importance of intellectual property rights and particularly patent protection and has taken steps to protect its inventions in appropriate countries throughout the world.

##### **2. Scope of the Report**

This report describes the patent rights owned by Futura. We are not aware of any third party patents or patent applications which may represent an infringement risk to Futura. The report includes a brief description of the inventions which form the subject matter of the patent rights with brief details of their technical background. The report also details the filing history and current prosecution status together with, to the extent practicable, a report on the breadth and strength of the claims set out in the patents or patent applications.

##### **3. Our Retainer**

Withers & Rogers is a firm of Patent and Trade Mark Attorneys and is responsible for the filing and prosecution of patent and trade mark applications throughout the world. Patent applications at the UK or European Patent Offices are filed direct by Withers & Rogers; instructions are sent to patent attorneys in other countries for the filing of applications outside Europe.

We have acted for Futura since 1997, following an initial approach from Mr Colin Kemp, at that time a Director of Futura Medical Limited. The writer, Ivor Harrison, is a Partner of Withers & Rogers and has overall responsibility for the intellectual property work carried out by Withers & Rogers on behalf of Futura. We have been instructed to prepare this report in connection with the proposed admission of Futura's shares to the Alternative Investment Market.

#### **4. Intellectual Property Rights**

##### *Overview*

Patents protect inventions and are registered monopoly rights, granted by national or regional (such as the European) patent offices if the invention satisfies particular requirements, primarily novelty and inventive step (non-obviousness) and capability for industrial use. The extent of monopoly protection is defined by one or more claims which form part of the patent specification.

Patents give the patent owner the right to prevent others from carrying out the invention as claimed in the patent. The right, once granted, may be kept in force for a limited period (normally 20 years from the date of application for the patent) by payment of renewal fees. The right may be reserved for the exclusive use of the patent proprietor or may be licensed or assigned to another part on agreed terms. The right is generally enforceable by court proceedings.

Patents are territorial in nature and it is often the case that an invention is the subject of patent applications, and eventually granted patents, in a number of territories.

##### *UK Patent Protection*

A UK national patent may be obtained by filing a patent application at the British Patent Office, following which the application will be subject to a novelty search and then to a procedure known as substantive examination. This procedure involves an exchange of correspondence between an examiner in the Patent Office and the applicant (through his patent attorney) in which the applicant has an opportunity to respond to any objections to grant which the examiner may raise. A UK patent may typically be granted after perhaps three or four years from its original filing date, assuming that the examiner is satisfied that the application meets the statutory requirements for patentability. However, the patent application will generally be published before grant, as well as being re-published on grant, the publication of the pre-grant application providing a provisional right of retrospective compensation in any post-grant infringement proceedings.

A British patent application may also serve as a so-called priority application for national applications to be filed in other countries and also for various types of supra-national patent applications, of which the most important are European patent applications and PCT (International) patent applications. Applications in or for other countries outside the UK must be filed within twelve months of the UK application in order to claim priority and it is the "priority date" which is the relevant date for assessing the novelty and inventive step criteria for patentability.

##### *European Patent Protection*

A European patent application is filed at the European Patent Office which also carries out both a novelty search and substantive examination of the application. The application can be filed in the English language and designates those countries in which it may be desired, after grant, to have patent protection. It may take three to six years, or (exceptionally) even longer, before a European patent is granted. Once this happens, the patent can then be validated in some or all of the European countries which were designated in the original application. Validation generally involves preparation and filing, at the respective national Patent Offices, of a translation of the text of the granted patent in the appropriate national language. The European patent then becomes, in effect, a "bundle" of national patents, each of which has to be kept in force by the payment of annual renewal fees to the Patent Office of the country concerned.

##### *International Patent Protection*

A PCT application is often filed when it is desired that the invention be protected in at least several territories including territories outside Europe. The application may designate a large number of territories, including

Europe, USA and Japan. A PCT application can again be filed in English and may be regarded as purchasing an option on patent protection in the designated countries, the option being realised on a selective basis by the filing of applications in appropriate national/regional patent offices usually 30 or 31 months from the original British priority date. A PCT patent application is subject to a novelty search and, optionally, a first stage examination procedure (International Preliminary Examination), both carried out by the European Patent Office.

Following the filing of individual regional or national applications, those applications are subject to search and examination procedures as required by national or regional patent law, taking into account the international search report, before patents can be granted in the respective countries.

Where an invention has two or more different aspects to it, it may be necessary, or at least desirable, to obtain two or more corresponding patents. However, where the different aspects nevertheless involve the same inventive concept, claims to the respective aspects can in most cases remain in the same application and eventually in the same granted patent.

## 5. Details of Futura's Patents and Patent Applications

We have been informed by the Directors of Futura that all its patent rights relating to its products are listed below and that they know of no other facts or matters relating to validity other than those set out in this report.

The patent applications in respect of the listed inventions are currently being prosecuted by us and we confirm that these patent applications are subsisting and have the status indicated below. No adverse interest by any third party has been recorded or asserted against any of the patent applications or any patents yet granted thereon.

The overall patent position is believed to be strong. For one of the inventions, patents have been granted by at least one of the key examining patent offices (USA, Europe, Japan, UK) and the position of pending applications is, for the remainder of the inventions, believed to be favourable, although not all applications filed have yet been subject to novelty searches. Further details are given below in connection with each individual invention.

Other than those matters confirmed in this report, we are not aware of any matter that Futura should take into account in respect of the transaction referred to in our letter of instruction.

## 6. Invention 1: MED 2001

### 6.1 Description of Invention

A cream for topical application to the penis to alleviate male erectile dysfunction, the cream containing glyceryl trinitrate and lanolin as well as other formulation ingredients.

### 6.2 Filing History and Current Position

COUNTRY	APPLICATION NUMBER	STATUS
International	PCT/GB99/00288	Now national application
European	99902686.7	Granted; in force in Germany, France, Austria, Belgium, Switzerland/Liechtenstein, Cyprus, Denmark, Spain, Finland, United Kingdom, Greece, Ireland, Italy, the Netherlands, Portugal, Sweden, Monaco, Luxembourg
Australia	22898/99	Granted (22 August 2001); Patent 747085
Brazil	PI9908358-2	Pending
Canada	2319202	Pending
China	99803716.8	Pending

Hong Kong	01103149.3	Granted (6 September 2001); Hong Kong Standard Patent Number HK 1033647
Israel	137,561	Pending
India	IN/PCT/2000/00234	Pending
Japan	P2000-529239	Published on 22 January 2002 under Publication Number P2002-501893A; pending
Korea	2000-7008344	Published on 15 May 2001 under Publication Number 2001-40488; pending
Mexico	4998	Published in September 2001 under Publication Number PA/a/2000/004998; pending
New Zealand	506580	Notice of Acceptance issued
Pakistan	719/2000	Sealing fee paid awaiting Notice of Grant
Saudi Arabia	00210637	Pending
United States of America	09/601,106	Pending

### 6.3 *Ownership and Title*

The inventor is Colin Kemp and the invention is owned by Futura by virtue of s.39 of the Patents Act 1977. The US application is in the name of Colin Kemp but has been assigned to Futura.

### 6.4 *Patentability*

The European application has been granted and validated in the various contracting states and corresponding applications have been granted in Australia and Hong Kong. The remainder of the applications are still pending, although the applications in New Zealand and Pakistan have been accepted for grant purposes and the Certificates of Grant are awaited. The invention therefore has a good presumption of patentability. There is extensive prior art concerning the use of the active ingredient (glyceryl trinitrate) as a vasodilator for treatment of angina and it has also been proposed for treatment of erectile dysfunction but, nevertheless, the MED 2001 composition appears to be clear of the prior art and it is anticipated that granted patents will also be obtained in the other countries.

### 6.5 *Validity and Enforceability*

The monopoly protection is generally restricted to the use of glyceryl trinitrate as the sole active ingredient, the composition also containing lanolin as an essential component. Prior art does exist relating to the use of glyceryl trinitrate as an active co-ingredient and it follows that the patents could not be asserted against another party using glyceryl trinitrate in combination with another active ingredient, although there would be some prospect for success if the co-ingredient were added in such small amounts or otherwise was present in a way which had no material effect on the performance of the glyceryl trinitrate itself.

## 7 **Invention 2: CSD 500**

### 7.1 *Description of Invention*

A condom carrying on its interior surface an erectogenic compound or composition, localised at the head end region.

### 7.2 *Filing History and Current Position*

<i>COUNTRY</i>	<i>APPLICATION NUMBER</i>	<i>STATUS</i>
International	PCT/GB02/01486	National phase applications due 30 September 2003

The International patent application claims priority from four separate UK applications, the earliest priority date being 30th March 2001. The due date for filing national/regional phase applications is 30th September 2003.

### 7.3 *Ownership and Title*

The inventor is Colin Kemp and the invention is owned by Futura by virtue of s.39 of the Patents Act 1977. The inventor has signed appropriate assignment documents for national applications (not yet filed) in various countries, including the USA.

### 7.4 *Patentability*

It is anticipated that a favourable International preliminary examination report will be established which, while not being binding on any national or regional patent office following the filing of corresponding national or regional applications, will nevertheless contain a positive indication concerning the prospects for patentability in such countries.

### 7.5 *Validity and Enforceability*

Prior art exists which relates to erectogenic compositions being generally applied to condoms but we are not aware of any prior proposal to prevent the compound from migration from the head end nor, for purpose, to render it immiscible with the lubricant of the condom. To the extent, therefore, any patents granted on national applications pursuant to the PCT application should have a strong presumption of validity and enforceability.

## **8 Invention 3: FLD 500**

### 8.1 *Description and Invention*

A condom having an erectogenic compound or composition applied to the exterior surface, in order to alleviate female sexual dysfunction.

### 8.2 *Filing History and current Position*

<i>COUNTRY</i>	<i>APPLICATION NUMBER</i>	<i>STATUS</i>
International	PCT/GB03/001586	Filed 14 April 2003 – national phase applications due 16 October 2004
Malaysia	–awaited–	Pending
Thailand	081678	Pending
Taiwan	–awaited–	Pending

The International and national applications claim priority from a UK application filed on 16 April 2002. Publication of the International application will take place in October 2003.

### 8.3 *Ownership and Title*

The inventor is James Barder and the invention is owned by Futura by virtue of s.39 of the Patents Act 1977.

### 8.4 *Patentability; Validity and Enforceability*

The International application will now be subject to a novelty search in the European Patent Office but, pending receipt of the search report, we are not aware of any relevant prior art.

Yours faithfully

**Withers & Rogers**

## PART IV

### FINANCIAL INFORMATION RELATING TO FUTURA



**BDO Stoy Hayward**  
Chartered Accountants

Kings Wharf  
20-30 Kings Road  
Reading  
RG1 3EX

The Directors  
Futura Medical Plc  
Surrey Technology Centre  
40 Occam Road  
The Surrey Research Park  
Guildford  
GU2 7YG

The Directors  
Williams de Broë Plc  
6 Broadgate  
London  
EC2M 2RP

14 July 2003

Dear Sirs

#### **Futura Medical Plc (the “Company”)**

##### **Introduction**

We report on the financial information set out below. This financial information has been prepared for inclusion in the admission document dated 14 July 2003 of the Company (“the Admission Document”).

The Company was incorporated as Futura (Holdings) plc on 25 April 2001.

On 6 June 2001, the Company acquired, in exchange for shares, credited as fully paid, the entire issued share capital of Futura Medical Limited.

On 11 July 2001, Futura Medical Limited changed its name to Futura Medical Developments Limited (“FMD”) and Futura (Holdings) plc changed its name to Futura Medical plc. The Company and FMD are referred to in this report as “the Group”.

The Company is a holding company only and all trading activities are conducted through FMD.

##### **Basis of preparation**

The financial information is based on the audited consolidated financial statements of the Company for the two years ended 31 January 2003 and the audited financial statements of FMD for the year ended 31 January 2001, to which no adjustments were considered necessary.

Tenon (formerly Blueprint Audit Limited), Registered Auditors, Clifton House, Bunnian Place, Basingstoke RG21 7JE, were the auditors to FMD for the year ended 31 January 2001 and to the Group for the year ended 31 January 2002.

BDO Stoy Hayward, Chartered Accountants and Registered Auditors, Kings Wharf, 20-30 Kings Road, Reading RG1 3EX, were the auditors to the Group for the year ended 31 January 2003.

All of the audit reports throughout the period from 1 February 2000 to 31 January 2003 were unqualified.

## **Responsibility**

Such financial statements are the responsibility of the directors of FMD and the Company who approved their issue.

The Directors of the Company are responsible for the contents of the Admission Document in which this report is included.

It is our responsibility to compile the financial information set out in our report from the financial statements, 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 Statements of Investment Circular Reporting Standards issued by the Auditing Practices Board. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. The evidence included that previously obtained by us and that recorded by the previous auditors relating to the audit of the financial statements underlying the financial information. It also included an assessment of significant estimates and judgements made by those responsible for the preparation of the financial statements underlying 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, a true and fair view of the state of affairs of the Group as at the dates stated and of its consolidated losses for the years then ended.

## **Consent**

We consent to the inclusion in the Admission Document of this report and accept responsibility for this report for the purposes of paragraphs 45(1)(b)(iii) of Schedule 1 to the Public Offers of Securities Regulations 1995.

## **FINANCIAL INFORMATION**

### **Accounting policies**

The financial information has been prepared under the historical cost convention and in accordance with applicable accounting standards. The following principal accounting policies have been applied consistently in dealing with items which are considered material in relation to the financial information:

#### *1 Basis of consolidation*

The financial information has been prepared using merger accounting under the provisions of Financial Reporting Standard 6, Acquisitions and Mergers. The financial information reflects the position that would have arisen if the Company and FMD had been combined throughout the period covered by this report.

The financial information for the year ended 31 January 2001 contains the results of FMD only. The financial information for the two years ended 31 January 2003 includes the results of the Company and its subsidiary, FMD.

All intra-group sales and profit are eliminated on consolidation.

#### *2 Research and development*

Expenditure on pure and applied research is charged to the profit and loss account in the year in which it is incurred.

Development costs are also charged to the profit and loss account in the year of expenditure, unless individual projects satisfy all of the following criteria:

- The project is clearly defined and related expenditure is separately identifiable;
- The project is technically feasible and commercially viable;
- Current and future costs are expected to be exceeded by future sales; and
- Adequate resources exist for the project to be completed.

In such circumstances the costs are carried forward and amortised over the period in which economic benefit is expected to arise commencing in the year the Group starts to benefit from the expenditure.

To date, all research and development costs have been charged to the profit and loss account as the Group has not yet reached a position where all the criteria above have been met.

### *3 Tangible fixed assets and depreciation*

Tangible fixed assets are stated at cost less depreciation. Depreciation is provided at rates calculated to write off the cost less estimated residual value of each asset over its expected useful life, as follows:

Plant and machinery	25% straight line
Fixtures, fittings & equipment	25% straight line

### *4 Deferred taxation*

Deferred tax balances are recognised in respect of all timing differences that have originated but not reversed by the balance sheet date, except that the recognition of deferred tax assets is limited to the extent that the Group anticipates making sufficient taxable profits in the future to absorb the reversal of the underlying timing differences. Deferred tax balances are not discounted.

### *5 Foreign currency translation*

Monetary assets and liabilities denominated in foreign currencies are translated into sterling at the rates of exchange ruling at the balance sheet date. Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. All differences are taken to the profit and loss account.

### *6 Pension costs*

Company contributions to personal pension schemes are charged to the profit and loss account in the year in which they become payable.

### *7 Share based employee remuneration*

When shares and share options are granted to employees a charge is made to the Group profit and loss account and a reserve created in capital and reserves to record the fair value of the awards in accordance with UITF Abstract 17 "Employee Share Schemes". No charge has been made to date as all options have been issued at fair value.

### *8 National Insurance on share options*

To the extent that the share price at the balance sheet date is greater than the exercise price on options granted after 19 May 2000, provision for any National Insurance contribution has been made based on the prevailing rate of National Insurance.

### *9 Liquid resources*

For the purpose of the cash flow statement liquid resources are defined as short term money market deposits and notice accounts.

## Consolidated profit and loss accounts

	<i>Note</i>	<i>Year ended 31 January 2001 £</i>	<i>Year ended 31 January 2002 £</i>	<i>Year ended 31 January 2003 £</i>
Research and development costs		(206,557)	(682,902)	(810,754)
Other administrative expenses		(185,032)	(660,416)	(485,322)
<b>Operating loss</b>	1	(391,589)	(1,343,318)	(1,296,076)
Other interest receivable and similar income		5,760	22,163	59,534
Interest payable and similar charges	4	(16,375)	(28,872)	(714)
<b>Loss on ordinary activities before taxation</b>		(402,204)	(1,350,027)	(1,237,256)
Research and development tax credit	5	29,998	100,000	152,175
<b>Loss on ordinary activities after taxation</b>		(372,206)	(1,250,027)	(1,085,081)
<b>Retained loss</b>	14	(372,206)	(1,250,027)	(1,085,081)
<b>Basic and diluted loss per share</b>	6	(0.01)	(0.04)	(0.03)

All amounts relate to continuing activities

All recognised gains and losses are included in the profit and loss account and therefore no separate statement of recognised gains and losses has been prepared.

## Consolidated balance sheets

		<i>As at</i> 31 January 2001 £	<i>As at</i> 31 January 2002 £	<i>As at</i> 31 January 2003 £
<b>Fixed assets</b>				
Tangible assets	7	1,874	43,286	32,228
<b>Current assets</b>				
Debtors	8	44,435	174,968	223,151
Cash at bank and in hand		289,863	2,042,741	1,511,319
		334,298	2,217,709	1,734,470
<b>Creditors: amounts falling due within one year</b>	9	(102,526)	(262,213)	(234,896)
<b>Net current assets</b>		231,772	1,955,496	1,499,574
<b>Total assets less current liabilities</b>		233,646	1,998,782	1,531,802
<b>Creditors: amounts falling due after more than one year</b>	9	(526,549)	–	–
<b>Provision for liabilities and charges</b>	10	–	–	(12,416)
<b>Net (liabilities)/assets</b>		(292,903)	1,998,782	1,519,386
<b>Capital and reserves</b>				
Called up share capital	12	58,824	80,724	83,194
Share premium account	13	–	3,018,212	3,621,427
Other reserve	13	650,565	1,152,165	1,152,165
Profit and loss account (deficit)	13	(1,002,292)	(2,252,319)	(3,337,400)
<b>Equity shareholders' funds</b>		(292,903)	1,998,782	1,519,386

## Consolidated cash flow statement

		<i>Year ended</i> <i>31 January</i> <i>2001</i> £	<i>Year ended</i> <i>31 January</i> <i>2002</i> £	<i>Year ended</i> <i>31 January</i> <i>2003</i> £
<b>Net cash outflow from operating activities</b>	17	(322,575)	(1,261,481)	(1,265,974)
<b>Returns on investments and servicing of finance</b>				
Interest received		5,760	22,163	50,888
Interest paid		(28)	(45,219)	(714)
<b>Net cash inflow/(outflow) from returns on investments and servicing of finance</b>		5,732	(23,056)	50,174
<b>Corporation tax</b>				
Research and development tax credit received		–	–	153,876
<b>Tax credit received</b>		–	–	153,876
<b>Capital expenditure and financial investment</b>				
Purchase of tangible fixed assets		(2,091)	(50,155)	(2,776)
<b>Net cash outflow from capital expenditure</b>		(2,091)	(50,155)	(2,776)
<b>Net cash outflow before use of liquid resources and financing</b>		(318,934)	(1,334,692)	(1,064,700)
<b>Management of liquid resources</b>				
Decrease/(Increase) in short term deposits		–	(1,989,306)	483,411
<b>Financing</b>				
Issue of ordinary share capital		600,006	3,803,500	617,500
Expenses paid in connection with share issues		–	(189,381)	(84,222)
Increase in shareholder loans		–	150,000	–
Repayment of shareholder loans		–	(676,549)	–
<b>Net cash inflow from financing</b>		600,006	3,087,570	533,278
<b>Increase/(decrease) in cash for the year</b>	18	281,072	(236,428)	(48,011)

## NOTES TO THE CONSOLIDATED FINANCIAL INFORMATION

### 1 Operating loss

	<i>Year ended</i> <i>31 January</i> <i>2001</i>	<i>Year ended</i> <i>31 January</i> <i>2002</i>	<i>Year ended</i> <i>31 January</i> <i>2003</i>
This is arrived at after charging:	£	£	£
Depreciation	958	8,743	13,575
Auditors' remuneration			
audit services	5,000	7,750	8,536
non-audit services	–	–	3,619
	<u>          </u>	<u>          </u>	<u>          </u>

### 2 Employees

The average number of employees during the year, including directors, was:

	<i>Year ended</i> <i>31 January</i> <i>2001</i> <i>Number</i>	<i>Year ended</i> <i>31 January</i> <i>2002</i> <i>Number</i>	<i>Year ended</i> <i>31 January</i> <i>2003</i> <i>Number</i>
Management and administration	<u>          1</u>	<u>          6</u>	<u>          8</u>

Staff costs for all employees, including directors, consist of:

	<i>Year ended</i> <i>31 January</i> <i>2001</i> £	<i>Year ended</i> <i>31 January</i> <i>2002</i> £	<i>Year ended</i> <i>31 January</i> <i>2003</i> £
Wages and salaries	78,000	295,518	380,437
Social security costs	9,164	31,363	40,540
Pension costs	–	19,292	22,560
	<u>          87,164</u>	<u>          346,173</u>	<u>          443,537</u>

### 3 Directors remuneration and share options

	<i>Basic salary</i>	<i>Benefits in kind</i>	<i>Pension</i>	<i>Compensation for loss of office</i>	<i>Total</i>
	£	£	£	£	£
<b>Year ended</b>					
<b>31 January 2001</b>					
C A Kemp	78,000	9,303	–	–	87,303
<b>Year ended</b>					
<b>31 January 2002</b>					
C A Kemp	96,743	1,872	7,167	–	105,782
J H Barder	68,708	1,861	6,250	–	76,819
D B Davies	50,364	1,861	4,375	–	56,600
A L Clayden	20,000	–	–	–	20,000
Dr R Pruijm	4,779	–	–	–	4,779
R Drury	3,526	–	–	–	3,526
Dr W D Potter	–	–	–	–	–
A L Staveley	–	–	–	–	–
E Verdonck	–	–	–	–	–
	<u>244,120</u>	<u>5,594</u>	<u>17,792</u>	<u>–</u>	<u>267,506</u>
<b>Year ended</b>					
<b>31 January 2003</b>					
C A Kemp	–	–	(7,167)	30,000	22,833
J H Barder	116,000	1,658	10,500	–	128,158
D B Davies	96,000	1,362	8,500	–	105,862
A L Clayden	64,200	–	–	–	64,200
Dr R Pruijm	3,125	–	–	–	3,125
R Drury	10,500	–	–	–	10,500
Dr W D Potter	10,500	–	–	–	10,500
A L Staveley	10,000	–	–	–	10,000
	<u>310,325</u>	<u>3,020</u>	<u>11,833</u>	<u>30,000</u>	<u>355,178</u>

Benefits in kind in the year ended 31 January 2001 relate to car allowance and in the two years ended 31 January 2003 relate to health and life assurance.

During the year ended 31 January 2003 consultancy services totalling £24,000 were charged to the Group by C A Kemp who resigned as a director on 8 February 2002. This amount is not included in the figures above.

### 3 Directors remuneration and share options (continued)

The share options of the directors are set out below:

#### *Enterprise Management Incentive Scheme*

Mr J H Barder, Mr A L Clayden and Mr D B Davies, being directors of the Company, are entitled to purchase the number of shares shown below at the option prices stated under an Enterprise Management Incentive Scheme. The Enterprise Management Initiative Scheme ("EMI") options were granted on 5 March 2002.

The options granted over 0.2 pence ordinary shares were as follows:

<i>Exercise price per share</i>	<i>A L Clayden</i>	<i>D B Davies</i>	<i>J H Barder</i>	<i>Total options granted</i>
33 pence	500,000	1,000,000	–	1,500,000
53 pence	–	–	250,000	250,000
70 pence	175,000	150,000	–	325,000
	<u>675,000</u>	<u>1,150,000</u>	<u>250,000</u>	<u>2,075,000</u>

#### *Pre-IPO Scheme*

Mr R Drury, Dr W D Potter, and Miss A L Staveley, being directors of the Company during the year ended 31 January 2003, were entitled to purchase the number of shares shown below at the option prices stated under a Pre-IPO Scheme. The Pre-IPO Scheme options were granted on 21 March 2002. The options can be exercised during the period 1 August 2004 until 31 January 2006 or such later date as the Board may grant.

The options granted over 0.2 pence ordinary shares were as follows:

<i>Price per share</i>	<i>Dr R Pruijm</i>	<i>R Drury</i>	<i>Dr W D Potter</i>	<i>A L Staveley</i>	<i>Total options granted</i>
33 pence	15,000	100,000	250,000	100,000	465,000
53 pence	–	–	125,000	–	125,000
	<u>15,000</u>	<u>100,000</u>	<u>375,000</u>	<u>100,000</u>	<u>590,000</u>

Medinvest Holdings Limited has granted Naylands Dibble Limited, a company controlled by James Barder, an option under a consultancy agreement dated 1 July 2000 to purchase 1,000,000 Ordinary Shares.

### 4 Interest payable and similar charges

	<i>Year ended 31 January 2001 £</i>	<i>Year ended 31 January 2002 £</i>	<i>Year ended 31 January 2003 £</i>
Shareholder loans	16,375	27,820	–
Bank interest and similar charges	–	1,052	714
	<u>16,375</u>	<u>28,872</u>	<u>714</u>

### 5 Taxation on loss from ordinary activities

	<i>Year ended 31 January 2001 £</i>	<i>Year ended 31 January 2002 £</i>	<i>Year ended 31 January 2003 £</i>
UK corporation tax in respect of year	29,998	123,878	128,297
Over/(under) provision in prior year	–	(23,878)	23,878
Research and development tax credit	<u>29,998</u>	<u>100,000</u>	<u>152,175</u>

## 6 Loss per share

Loss per ordinary share has been calculated using the weighted average number of shares in issue during the relevant financial periods. The weighted average number of equity shares in issue and the loss after tax credit are as follows:

	<i>Year ended</i> <i>31 January</i> <i>2001</i> £	<i>Year ended</i> <i>31 January</i> <i>2002</i> £	<i>Year ended</i> <i>31 January</i> <i>2003</i> £
Weighted average number of equity shares	27,206,000	30,708,918	41,096,233
Loss after tax credit	(372,206)	(1,250,027)	(1,085,081)
Loss per share, pence	(1.4)	(4.1)	(2.6)

The effect of all potential ordinary shares is anti-dilutive.

## 7 Tangible assets

	<i>Plant and</i> <i>machinery</i> £	<i>Fixtures,</i> <i>fittings and</i> <i>equipment</i> £	<i>Total</i> £
<b>Cost</b>			
As at 1 February 2000	1,399	340	1,739
Additions	–	2,091	2,091
<b>As at 31 January 2001</b>	1,399	2,431	3,830
Additions	20,722	29,433	50,155
<b>As at 31 January 2002</b>	22,121	31,864	53,985
Additions	982	1,794	2,776
Disposals	–	(1,298)	(1,298)
<b>As at 31 January 2003</b>	23,103	32,360	55,463
<b>Depreciation</b>			
As at 1 February 2000	788	210	998
Provided for the year	350	608	958
<b>As at 31 January 2001</b>	1,138	818	1,956
Provided for the year	3,335	5,408	8,743
<b>As at 31 January 2002</b>	4,473	6,226	10,699
Provided for the year	5,314	8,261	13,575
Disposals	–	(1,039)	(1,039)
<b>As at 31 January 2003</b>	9,787	13,448	23,235
<b>Net book value</b>			
<b>As at 31 January 2001</b>	261	1,613	1,874
<b>As at 31 January 2002</b>	17,648	25,638	43,286
<b>As at 31 January 2003</b>	13,316	18,912	32,228

## 8 Debtors

	<i>As at</i> <i>31 January</i> <i>2001</i> £	<i>As at</i> <i>31 January</i> <i>2002</i> £	<i>As at</i> <i>31 January</i> <i>2003</i> £
Research and development tax credit repayable	29,998	129,998	128,297
Other debtors	8,964	34,118	55,114
Prepayments	5,473	10,852	39,740
	<u>44,435</u>	<u>174,968</u>	<u>223,151</u>

All amounts fall due for payment within one year.

## 9 Creditors

	<i>As at</i> <i>31 January</i> <i>2001</i> £	<i>As at</i> <i>31 January</i> <i>2002</i> £	<i>As at</i> <i>31 January</i> <i>2003</i> £
<b>Amounts falling due within one year</b>			
Trade creditors	57,626	163,289	145,638
Other creditors	12,500	–	–
Tax and social security creditor	–	17,115	13,311
Accruals and deferred income	32,400	81,809	75,947
	<u>102,526</u>	<u>262,213</u>	<u>234,896</u>
	<i>As at</i> <i>31 January</i> <i>2001</i> £	<i>As at</i> <i>31 January</i> <i>2002</i> £	<i>As at</i> <i>31 January</i> <i>2003</i> £
<b>Amounts falling due after more than one year</b>			
Shareholder loans	<u>526,549</u>	<u>–</u>	<u>–</u>

Shareholder loans at 31 January 2001 were classified as falling due after more than one year. Repayment was at the company's discretion, up to 1 September 2003. These loans were repaid when the Company raised additional capital during the following financial year.

## 10 Provision for liabilities and charges

	<i>As at</i> <i>31 January</i> <i>2001</i> £	<i>As at</i> <i>31 January</i> <i>2002</i> £	<i>As at</i> <i>31 January</i> <i>2003</i> £
National Insurance on share options	<u>–</u>	<u>–</u>	<u>12,416</u>

The eventual liability to National Insurance is dependent on the following factors:

- The market price of the Company's shares at the date of exercise;
- the number of options that will be exercised; and
- the prevailing rate of National Insurance at the date of exercise.

There is a corresponding balance within "Other debtors". In terms of the share option agreement, the option holders indemnify the Company against National Insurance that may become due on the exercise of the options.

## 11 Deferred taxation

Due to the losses incurred by FMD and the Group to date, a deferred tax asset existed at each of the year ends. Due to the uncertainty of the generation of future profits to absorb the reversal of the underlying timing differences, no deferred tax asset has been recognised at any point to date.

## 12 Share capital

	<i>As at</i> <i>31 January</i> 2002 £	<i>As at</i> <i>31 January</i> 2003 £
<b>Authorised</b>		
500,000,000 ordinary shares of 0.2p each	<u>1,000,000</u>	<u>1,000,000</u>
<b>Allotted, called up and fully paid</b>		
2003: 41,597,000 ordinary shares of 0.2p each (2002: 40,362,000)	<u>80,724</u>	<u>83,194</u>

On incorporation the Company's authorised share capital was 1,000,000 ordinary shares of £1 each.

Two ordinary shares of £1 each were issued at par.

### *Year ended 31 January 2001*

During the year 8,824 ordinary shares of £1 each were issued by FMD at a premium of £591,180 for cash consideration to provide additional working capital.

As at 31 January 2001, FMD had allotted share capital of £58,824 and share premium of £650,565.

### *Year ended 31 January 2002*

1,900 ordinary shares of £1 each in FMD were allotted and fully paid at a premium of £501,600 for cash consideration.

On 6 June 2001 the Company acquired the whole of the issued share capital of FMD in exchange for 60,724 ordinary £1 shares, credited as fully paid. In accordance with Section 131 of the Companies Act 1985, a share premium account has not been set up.

On 12 June 2001 the Company sub-divided each of its issued and unissued £1 ordinary shares into 500 ordinary shares of 0.2 pence each.

On 2 January 2002 the Company issued 10,000,000 ordinary shares of 0.2 pence each through a private placing at 33 pence each. The shares were issued at a premium of £3,280,000.

### *Year ended 31 January 2003*

On 29 July 2002 the Company issued 1,235,000 ordinary shares of 0.2 pence each through a private placing at 50 pence each. The shares were issued at a premium of £615,030.

### *Shares issued after 31 January 2003*

Private subscription of 2,428,571 ordinary shares.

The Company entered into an agreement with Long Fleet Systems Incorporated ("Long Fleet") on 19 June 2003 whereby Long Fleet will procure subscription for 2,428,571 ordinary shares of 0.2 pence in the Company at 70 pence per share on the date that the Company is admitted to the Alternative Investment Market.

This share issue will raise £1,524,000 being £1,700,000 for the shares issued less commission and expenses of £176,000.

According to the subscription agreement with Long Fleet Systems Inc., the amount for the share issue will be lodged with Memery Crystal prior to Admission. Memery Crystal will release the funds on Admission.

The shares will be issued at a premium of £1,695,143.

## 12 Share capital (continued)

### Share options

All of the share options granted by the Company are listed below:

#### *Executive & Staff EMI scheme, including directors*

	<i>No of share options granted</i>	<i>Option price</i>	<i>Date of grant</i>	<i>Exercise period</i>	
				<i>start date</i>	<i>expiry date</i>
<b>Share options under the EMI Scheme</b>					
	1,500,000	0.33	5 Mar 2002	1 Aug 2004	31 Jan 2006
	250,000	0.53	5 Mar 2002	1 Aug 2004	31 Jan 2006
	120,000	0.50	25 Oct 2002	1 Aug 2004	31 Jan 2006
	360,000	0.70	8 Jul 2003	1 Aug 2005	31 Jul 2007
	<u>2,230,000</u>				

#### **PRE-IPO SCHEME (Inland Revenue “unapproved”)**

	<i>No of share options granted</i>	<i>Option price</i>	<i>Date of grant</i>	<i>Exercise period</i>	
				<i>start date</i>	<i>expiry date</i>
<b>Pre-IPO options to current directors</b>					
	125,000	0.53	21 Mar 2002	1 Aug 2004	31 Jan 2006
	250,000	0.33	21 Mar 2002	1 Aug 2004	31 Jan 2006
	<u>375,000</u>				
<b>Pre-IPO options to former directors</b>					
	855,000	0.53	21 Mar 2002	1 Aug 2004	31 Jan 2006
	215,000	0.33	21 Mar 2002	1 Aug 2004	31 Jan 2006
	260,000	0.50	6 Aug 2002	1 Aug 2004	31 Jan 2006
	<u>1,330,000</u>				
<b>Pre-IPO options to former consultants</b>					
	125,000	0.53	21 Mar 2002	1 Aug 2004	31 Jan 2006
	<u>125,000</u>				
<b>Pre-IPO options to consultants</b>					
	50,000	0.70	8 Jul 2003	1 Aug 2005	31 Jul 2007
	<u>50,000</u>				
<b>Pre-IPO options to providers of bridging finance</b>					
	20,000	0.33	21 Mar 2002	1 Aug 2004	31 Jan 2006
	<u>20,000</u>				
<b>Total pre-IPO options</b>	<u>1,900,000</u>				
<b>Total options granted as at 30 June 2003</b>	<u>4,130,000</u>				

### 13 Reserves

	<i>Share premium account</i>	<i>Other reserve</i>	<i>Profit and loss account</i>	<i>Total</i>
	£	£	£	£
<b>As at 1 February 2000</b>	–	59,385	(630,086)	(570,701)
Premium on shares issued during the year	–	591,180	–	591,180
Loss for the year	–	–	(372,206)	(372,206)
<b>As at 31 January 2001</b>	–	650,565	(1,002,292)	(351,727)
Premium on shares issued during the year	3,280,000	501,600	–	3,781,600
Expenses of share issues	(261,788)	–	–	(261,788)
Loss for the year	–	–	(1,250,027)	(1,250,027)
<b>As at 31 January 2002</b>	3,018,212	1,152,165	(2,252,319)	1,918,058
Premium on shares issued during the year	615,030	–	–	615,030
Expenses of share issues	(11,815)	–	–	(11,815)
Loss for the year	–	–	(1,085,081)	(1,085,081)
<b>As at 31 January 2003</b>	3,621,427	1,152,165	(3,337,400)	1,436,192

The other reserve is the difference between the aggregate of the issued share capital and share premium accounts of FMD at the year end prior to the formation of the Company and upon the acquisition of FMD by the Company and the nominal value of shares issued by the Company in consideration for the acquisition of the entire share capital of FMD.

### 14 Reconciliation of movements in shareholders' funds

	<i>Year ended 31 January 2001</i>	<i>Year ended 31 January 2002</i>	<i>Year ended 31 January 2003</i>
	£	£	£
<b>At beginning of the year</b>	(520,701)	(292,903)	1,998,782
Issue of shares	8,824	21,900	2,470
Premium on shares allotted	591,180	3,781,600	615,030
Expenses of share issue	–	(261,788)	(11,815)
Loss for the year	(372,206)	(1,250,027)	(1,085,081)
<b>At end of the year</b>	(292,903)	1,998,782	1,519,386

### 15 Pensions

All staff pensions are paid into their nominated defined contribution schemes. No staff have taken up the offer to join the company stakeholder scheme.

## 16 Related party transactions

### *Year ended 31 January 2001*

Included within shareholder loans were amounts due to directors and related parties. Interest was accruing on these loans at a rate of 1% above libor.

	<i>Balance owing at 31/01/01</i>	<i>Accrued interest at 31/01/01</i>
C J Crabtree	100,000	3,105
R Lamb	57,747	1,793
Mrs R Lamb (associated with R Lamb)	2,224	69
W T Lamb investments (associated with R Lamb)	26,650	827
A Barder (associated with J H Barder)	1,706	53
	<u>188,327</u>	<u>5,847</u>

### *Year ended 31 January 2002*

Prior to signing a contract of employment and becoming Chief Executive on 18 June 2001, J H Barder provided consulting services through Naylands Dibble Limited. Of the total fees of £23,517, none were outstanding at 31 January 2002.

Dr W D Potter also provided consulting services to FMD through Stapleford Scientific Services. Of the total fees and expenses of £19,056, the amount outstanding at 31 January 2002 was £2,063.

### *Year ended 31 January 2003*

Dr W D Potter, a director of the Company, provided consulting services to FMD through Stapleford Scientific Services and, more recently, Stapleford Scientific Services Limited. Of the total fees and expenses invoiced by these businesses of £38,197, the amount outstanding at 31 January 2003 to Stapleford Scientific Services Limited was £4,777. There was no amount outstanding at 31 January 2003 to Stapleford Scientific Services.

R D Drury, a director of the Company, provided consulting services to FMD through Swan Lane Limited. Of the total fees and expenses invoiced of £12,840, there was no amount outstanding at 31 January 2003.

### *Controlling party*

The directors do not believe there to be an ultimate controlling party.

## 17 Reconciliation of operating loss to net cash flow from operating activities

	<i>Year ended 31 January 2001 £</i>	<i>Year ended 31 January 2002 £</i>	<i>Year ended 31 January 2003 £</i>
Operating loss	(391,589)	(1,343,318)	(1,296,076)
Brought forward patent costs written off	22,602	–	–
Depreciation	958	8,743	13,575
Loss on sale of fixed assets	–	–	259
Increase in debtors	(8,270)	(30,535)	(28,822)
Increase in creditors	53,724	103,629	45,090
Net cash flow from operating activities	<u>(322,575)</u>	<u>(1,261,481)</u>	<u>(1,265,974)</u>

**18 Reconciliation of net cash flow to movement in net funds/(debt)**

	<i>Year ended 31 January 2001 £</i>	<i>Year ended 31 January 2002 £</i>	<i>Year ended 31 January 2003 £</i>
(Decrease)/increase in cash in the year	281,072	(236,428)	(48,011)
Cash outflow from decrease in debt	–	526,549	–
Cash (inflow)/outflow from changes in liquid resources	–	1,989,306	(483,411)
Movement in net funds/(debt) in the year	281,072	2,279,427	(531,422)
Net funds/(debt) at the beginning of the year	(517,758)	(236,686)	2,042,741
Net funds/(debt) at the end of the year	<u>(236,686)</u>	<u>2,042,741</u>	<u>1,511,319</u>

**19 Analysis of net funds/(debt)**

	<i>At start of the year £</i>	<i>Cash flow £</i>	<i>At end of the year £</i>
<b>Year ended 31 January 2001</b>			
Cash in hand and at bank	8,791	281,072	289,863
Debt due after one year	(526,549)	–	(526,549)
Total	<u>(517,758)</u>	<u>281,072</u>	<u>(236,686)</u>
<b>Year ended 31 January 2002</b>			
Cash in hand and at bank	289,863	1,752,878	2,042,741
Debt due after one year	(526,549)	526,549	–
Total	<u>(236,686)</u>	<u>2,279,427</u>	<u>2,042,741</u>
<b>Year ended 31 January 2003</b>			
Cash at bank and in hand	53,435	(48,011)	5,424
Other liquid resources	1,989,306	(483,411)	1,505,895
	<u>2,042,741</u>	<u>(531,422)</u>	<u>1,511,319</u>

Yours faithfully

**BDO Stoy Hayward**  
*Chartered Accountants*

## PART V

### PRO FORMA STATEMENT OF NET ASSETS

The following unaudited pro forma statement of net assets of the Group has been prepared on the basis of the notes below to provide information about the impact of the private subscription for new ordinary shares on the Group. It has been prepared on the basis that the subscription for new ordinary shares was undertaken as at 31 January 2003. This statement is prepared for illustrative purposes only and, because of its nature, may not give a true reflection of the financial position of the Group.

	<i>As at</i>		<i>Pro forma</i>
	<i>31 January</i>	<i>Adjustments</i>	<i>net assets</i>
	<i>2003</i>	<i>(notes 2 and 3)</i>	<i>of the</i>
	<i>(note 1)</i>	<i>(notes 2 and 3)</i>	<i>Group</i>
	<i>£</i>	<i>£</i>	<i>£</i>
<b>Fixed assets</b>			
Tangible assets	32,228	0	32,228
	<u>32,228</u>	<u>0</u>	<u>32,228</u>
<b>Current assets</b>			
Debtors	223,151	0	223,151
Cash at bank and in hand	1,511,319	1,164,000	2,675,319
	<u>1,734,470</u>	<u>1,164,000</u>	<u>2,898,470</u>
<b>Creditors:</b>			
amounts falling due within one year	(234,896)	0	(234,896)
<b>Net current assets</b>	<u>1,499,574</u>	<u>1,164,000</u>	<u>2,663,574</u>
<b>Total assets less current liabilities</b>	<u>1,531,802</u>	<u>1,164,000</u>	<u>2,695,802</u>
<b>Provision for liabilities and charges</b>	(12,416)	0	(12,416)
<b>Net assets</b>	<u>1,519,386</u>	<u>1,164,000</u>	<u>2,683,386</u>

#### Notes:

The pro forma statement of net assets has been prepared on the following basis:

1. The net assets of the Group at 31 January 2003 have been extracted without adjustment from the Accountants' Report set out in Part IV of this document.

Adjustments:

2. Private subscription for 2,428,571 ordinary shares
  - The Company entered into an agreement with Long Fleet Systems Incorporated ("Long Fleet") on 19 June 2003 whereby Long Fleet will procure subscription for 2,428,571 ordinary shares of 0.2 pence in the Company at 70 pence per share on the date that the Company is admitted to the Alternative Investment Market.
  - This share issue will raise £1,524,000 being £1,700,000 for the shares issued less expenses of £176,000.
3. The estimated expenses payable by the Company in connection with Admission are £360,000.
4. No adjustments have been made to reflect the trading results of the Group since the balance sheet date.

## PART VI

### ADDITIONAL INFORMATION

#### 1. Incorporation and Status of the Company

- 1.1 The Company was incorporated and registered in England and Wales on 25 April 2001 as a public limited company with the name Futura (Holdings) plc and with registered number 4206001. The name of the Company was changed to Futura Medical Plc on 11 July 2001. The Company's registered office is located at Surrey Technology Centre, 40 Occam Road, Guildford, Surrey, GU2 7YG.
- 1.2 The liability of the members of the Company is limited.

#### 2. Share capital of the Company

- 2.1 The authorised and issued share capital of the Company at the date of this document and on Admission are and will be as follows:

<i>Authorised share capital</i>			<i>Issued and fully paid up share capital</i>	
<i>£</i>	<i>Number</i>		<i>£</i>	<i>Number</i>
1,000,000	500,000,000	Ordinary Shares of 0.2 pence	88,051	44,025,571

- 2.2 The Company was incorporated with an authorised share capital of £1 million divided into 1,000,000 Ordinary Shares of £1 each of which two shares were issued to the subscribers to the Memorandum of Association of the Company, Colin Kemp and James Barder.
- 2.3 By an agreement dated 6 June 2001 between (1) Colin Kemp and others (2) the Company and (3) the Subsidiary, the Company acquired the whole of the issued share capital of the Subsidiary by way of a share for share exchange in consideration of the issue to the shareholders of the Subsidiary of a total of 60,722 ordinary shares of £1 each in the Company.
- 2.4 On 11 July 2001, pursuant to a written resolution of the Company passed on that date, each ordinary share of £1 each in the Company's authorised and issued share capital was subdivided into and redesignated as 500 Ordinary Shares of 0.2 pence each.
- 2.5 Pursuant to a placing agreement dated 25 October 2001 between the Company (1) its directors (2) and Collins Stewart Limited (3), the Company issued 10,000,000 new Ordinary Shares for cash on 2 January 2002 at a price of 33 pence per share to placees.
- 2.6 On 15 October 2002 the Company issued 1,235,000 Ordinary Shares at 50 pence per share by way of a private subscription.
- 2.7 Pursuant to resolutions passed at the last Annual General Meeting of the Company held on 14 July 2003:
- (a) the Directors were authorised and empowered generally and unconditionally authorised in accordance with Section 80 of the Act to exercise all the powers of the Company to allot relevant securities (within the meaning of Section 80(2) of the Act) up to a nominal value of £60,000; and
  - (b) the Directors were authorised pursuant to Section 95 of the Act to allot equity securities (as defined in Section 94(2) of the Act) for cash pursuant to the authority referred to in sub-paragraph (a) above as if Section 89(1) of the Act did not apply to such allotment, provided that such power was limited to:
    - (i) the allotment and issue of equity securities in connection with offers to existing shareholders where such offer is made in proportion to existing holdings;
    - (ii) the allotment and issue of equity securities over up to 10,285,714 new Ordinary Shares pursuant to the Subscription Agreement;

- (iii) the allotment and issue of equity securities over up to 20,000,000 new Ordinary Shares in connection with a fund raising agreement entered in to on or prior to Admission if completion of the Subscription Agreement does not take place;
  - (iv) the allotment and issue otherwise of equity securities up to an aggregate nominal amount of £4,400.
- 2.8 Pursuant to the Subscription Agreement, the Company has agreed, to issue 2,428,571 new Ordinary Shares to subscribers procured by Long Fleet Systems Inc. at a price per share of 70p on Admission.
- 2.9 Save for the 1,000,000 Ordinary Shares which are the subject of the Warrants (as defined in the Subscription Agreement) and for the 4,130,000 Ordinary Shares in respect of which options have been granted under the Share Option Schemes and in respect of such shares as may be the subject of any call option which is exercised by the Company pursuant to the Subscription Agreement, no share or loan capital of the Company is proposed to be issued or is under option or agreed, conditionally or unconditionally, to be put under option, other than as set out in this paragraph 2.

### 3. Memorandum and Articles of Association

#### 3.1 *Memorandum of Association*

The Memorandum of Association of the Company provides that the Company's principal objects are as a holding company. The objects of the Company are set out in clause 3 of its Memorandum of Association.

- 3.2 The Articles of Association of the Company ("the Articles") contain provisions, *inter alia*, to the following effect:-

#### (a) *Variation of class rights and changes of capital*

- (i) The special rights attached to any class of shares may, subject to any applicable law, be varied or abrogated in such manner (if any) as may be provided by such rights or, in the absence of any such provision, either with the consent in writing of the holders of three fourths in nominal value of the issued shares of the class or with the sanction of an extraordinary resolution passed at a separate general meeting of the holders of shares of the class.
- (ii) The Company may by ordinary resolution increase its share capital, consolidate and divide all or any of its shares into shares of a larger amount, cancel any shares not taken or agreed to be taken by any person and sub-divide its shares into shares of a smaller amount.
- (iii) The Company may by special resolution reduce its share capital or any capital redemption fund, share premium account or other undistributable reserve subject to authority required by law. Subject to applicable law, the Company may purchase its own shares.

#### (b) *Class Meetings*

The provisions of the Articles relating to general meetings apply *mutatis mutandis* to every such meeting but the necessary quorum is two persons holding or representing by proxy one third in nominal amount of the issued shares of the class except where there is only one holder of the relevant class of shares in which case the quorum shall be that holder.

#### (c) *Votes of members*

Subject to any special rights or restrictions as to voting attached to any class of shares, at any general meeting, on a show of hands, every member who is present in person has one vote and, in the case of a poll, every member present in person or by proxy has one vote for every share of which he is the holder. No member is entitled to attend or vote at a general meeting either personally or by proxy if he or any person appearing to be interested in shares held by him has been duly served with a notice under Section 212 of the Act and is in default for the prescribed

period in supplying to the Company the information required thereby or, unless the Directors determine otherwise, if any calls from him have not been paid.

(d) *Borrowing powers*

The Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property, assets and uncalled capital and, subject to applicable law, to issue debentures and other securities.

(e) *Directors*

(i) A Director is not required to hold any qualification shares.

(ii) The amount of any fees payable to Directors shall be determined by the Directors provided that they shall not in any year exceed an aggregate amount of £800,000 or such other sum as may from time to time be approved by ordinary resolution. Any such fees shall be divisible among the Directors as they may agree, or failing agreement, equally. The Directors are also entitled to be repaid all reasonable expenses incurred by them respectively in the performance of their duties. Any Director holding an executive office or otherwise performing services which in the opinion of the Directors are outside the scope of his ordinary duties as a Director may be paid such remuneration as the Directors may determine.

(iii) The Directors may establish and maintain the establishment of any non-contributory or contributory pension or superannuation funds for the benefit of, and give donations, gratuities, pensions, allowances or emoluments to, any persons who are or were at any time in the employment or service of, or Directors or officers of and holding any salaried employment or office in, the Company or any other company which is its holding company or in which the Company or such holding company has any interest or which is allied to or associated with the Company or of any company which is a subsidiary undertaking of the Company or of any such other company ("associated companies") and the families and dependents of any such persons; and the Directors shall have power to purchase and maintain insurance against liability for any persons who are or were at any time Directors, officers, employees or auditors of, the Company or, its associated companies and for trustees of any pension fund in which employees of the Company or its associated companies are interested.

(iv) The Directors may from time to time appoint one or more of their body to be the holder of any executive office (including the office of chairman, deputy chairman, managing director or chief executive) on such terms and for such period as they may determine.

(v) Subject to the provisions of applicable law and provided that he has disclosed to the Directors the nature and extent of any material interest of his, a Director notwithstanding his office:-

(A) may be a party to, or otherwise interested in, any contract, transaction or arrangement with the Company or in which the Company is otherwise interested;

(B) may be a director or other officer of, or employed by, or a party to, any transaction or arrangement with, or otherwise interested in any body corporate promoted by the Company or in which the Company is otherwise interested;

(C) may hold any other office or place of profit under the Company (except that of auditor or auditor of a subsidiary of the Company) in conjunction with the office of Director and may act by himself or through his firm in a professional capacity to the Company and in any such case on such terms as to remuneration and otherwise as the Directors may arrange; and

(D) shall not, by reason of his office, be accountable to the Company for any benefit which he derives from any such office or employment or from any such contract, transaction

or arrangement or from any interest in any such body corporate, and no such contract, transaction or arrangement shall be liable to be avoided on the grounds of any such interest or benefit.

- (vi) Save as specifically provided in the Articles, a Director may not vote in respect of any contract, transaction or arrangement or any other proposal whatsoever in which he has any material interest otherwise than by virtue of his interests in shares or debentures or other securities of, or otherwise in or through, the Company. A Director will not be counted in the quorum of a meeting in relation to any resolution on which he is debarred from voting.
- (vii) Subject to applicable law, a Director is (in the absence of some other material interest than is indicated below) entitled to vote (and will be counted in the quorum) in respect of any resolution concerning any of the following matters, namely:
  - (A) the giving of any guarantee, security or indemnity to him in respect of money lent or obligations incurred by him at the request or for the benefit of the Company or of its subsidiary undertakings;
  - (B) the giving of any guarantee, security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiary undertakings for which he himself has assumed responsibility in whole or in part under a guarantee or indemnity or by the giving of security;
  - (C) any contract, transaction, arrangement or proposal concerning an offer of shares or debentures or other securities of or by the Company or any of its subsidiary undertakings for subscription or purchase in which offer he is or is to be interested as a participant in the underwriting or sub-underwriting thereof;
  - (D) any contract, transaction, arrangement or proposal concerning any other body corporate in which he is interested directly or indirectly and whether as an officer or shareholder or otherwise howsoever, provided that he (together with persons connected with him within the meaning of section 346(2) of the Act) is not the holder of or beneficially interested in one per cent, or more of the issued shares of any such body corporate (or of any third body corporate through which his interest is derived) or of the voting rights available to members of the relevant body corporate (any such interest being deemed to be a material interest);
  - (E) any contract, transaction, arrangement or proposal concerning the adoption, modification or operation of a superannuation fund or retirement, death or disability benefits scheme under which he may benefit and which has been approved by, or is subject to and conditional on approval by, the Board of Inland Revenue for taxation purposes;
  - (F) any contract, transaction, arrangement or proposal concerning the adoption, modification or operation of any scheme for enabling employees, including full-time executive Directors, to acquire shares in the Company and/or its subsidiary undertakings or of any arrangement for the benefit of employees of the Group under which the Director benefits in a similar manner to employees, and which does not accord any Director as such, any privilege or advantage not generally accorded to the employees to whom such scheme or arrangement relates; and
  - (G) any contract, transaction, arrangement or proposal concerning any insurance against liability which the Company is empowered to purchase and/or maintain for, or for the benefit of, any Directors or group of persons who include Directors.
- (viii) Subject to any applicable law, the Company may by ordinary resolution suspend or relax the provisions summarised under paragraphs (6) and (7) above either generally or in relation to

any particular matter, or ratify any transaction not duly authorised by reason of a contravention of such provision.

- (ix) A resolution for the appointment of two or more persons as Directors by a single resolution shall not be moved at any general meeting unless a resolution that it shall be so moved has first been agreed by the meeting without any vote being given against it, and any resolution moved in contravention of this provision of the Articles shall be void.
  - (x) The Articles provide that no Director shall be or become incapable of being appointed or remaining a Director by reason of his having attained the age of 70 or any other age.
- (f) *Transfer of Shares*
- All transfers of shares may be effected by transfer in writing in any usual form or in any other form acceptable to the Directors and shall be executed by or on behalf of the transferor and, if the share is partly paid, the transferee. The Directors may refuse to register any transfer of a share which is not fully paid or over which the Company has a lien. The Articles do not contain any restriction on the transferability of fully paid shares, provided that the Company has no lien over the shares, the instrument of transfer is in favour of not more than four transferees and in respect of only one class of shares and is duly stamped (if so required), the provisions in the Articles relating to the deposit of instruments of transfer have been complied with and the member is not in default of any notice duly served under section 212 of the Act as referred to in the Articles.
- (g) *Dividends and distribution of assets on liquidation*
- The holders of shares are entitled, *pari passu*, amongst themselves, but in proportion to the number of shares held by them and to the amounts paid up or credited as paid up, to share in the whole of the profits of the Company paid out as dividends and the whole of any surplus in the event of liquidation of the Company.
- (h) *Unclaimed dividends*
- Any dividend unclaimed after a period of 12 years from the date of its declaration shall be forfeited and shall revert to the Company.
- (i) *Forfeiture and Lien*
- (i) If a member fails to pay in full any call or instrument of a call on the due date for payment, the Board may at any time serve a notice on him/her requiring payment and stating that in the event of non-payment in accordance with such notice the shares on which the call was made will be liable to be forfeited. Any share so forfeited may be disposed of by the company within three years, otherwise it shall be cancelled.
  - (ii) The Company shall have a first and paramount lien on every share (not being a fully paid share) for all monies (whether presently or not) called or payable at a fixed time in respect of such share.
  - (iii) The Company may sell in such manner as the Board thinks fit any share on which the Company has a lien fourteen days after a notice in writing stating and demanding payment of the sum presently payable and giving notice of intention to sell.

#### **4. Directors and Other Interests**

- 4.1 The interests of the Directors (all of which are beneficial) in the issued share capital of the Company as they are expected to be on Admission which are required to be notified by each Director to the Company under the provisions of sections 324 and 328 of the Act or which are required to be disclosed in the Register of Directors interests required to be maintained pursuant to section 325 of the Act or which are interests of persons connected with the Directors within the meaning of section 346 of the

Act, the existence of which is known or which could, with reasonable diligence, be ascertained by a Director are, as follows:

<i>Director</i>	<i>Number of Ordinary Shares held</i>	<i>Percentage of issued ordinary share capital</i>
James Barder	653,497	1.48%
David Davies	15,152	0.03%

The following options over unissued Ordinary Shares have been granted to certain of the Directors on 21 March 2002 under the Share Option Schemes, all exercisable from 1 August 2004 to 31 January 2006 except in specific circumstances

<i>Director</i>	<i>Number of Ordinary Shares</i>	<i>Exercise Price per share</i>
James Barder	250,000	53 pence
Anthony Clayden	500,000	33 pence
David Davies	1,000,000	33 pence
William Potter	125,000	53 pence
William Potter	250,000	33 pence

In addition, the following options over unissued Ordinary Shares have been granted to certain of the Directors on 8 July 2003 under the Share Option Schemes save that the exercise period will be from 1 August 2005 to 31 July 2007 except in specific circumstances:

<i>Director</i>	<i>Number of Ordinary Shares</i>	<i>Exercise Price per share</i>
Anthony Clayden	175,000	70 pence
David Davies	150,000	70 pence

In addition, Medinvest Holdings Limited has granted Naylands Dibble Limited, a company controlled by James Barder, an option under a consultancy agreement dated 1 July 2000 to purchase 1,000,000 Ordinary Shares.

- 4.2 Save as disclosed in paragraph 4.1 above, following Admission no Director will have, and no person connected with them within the meaning of section 346 of the Act is expected to have, any interest in the share capital of the Company or its subsidiary.
- 4.3 No Director has or has had any interest, whether direct or indirect, in any transaction which is or was unusual in its nature and conditions or significant to the business of the Company taken as a whole and which was entered into by the Company during the current or immediately preceding financial year or which was effected during any earlier financial year and which remains in any respect outstanding or unperformed.
- 4.4 There are no outstanding loans granted by the Group to any of the Directors nor any guarantees provided by the Group for their benefit.
- 4.5 Save as disclosed in paragraph 4.1 above and this sub-paragraph 4.5, the Directors are not aware of any interest (within the meaning of Part VI of the Act) held directly or indirectly in three per cent. or more of the ordinary share capital of the Company on Admission:

As at 11 July 2003

<i>Shareholder</i>	<i>Number of Ordinary Shares held</i>	<i>Percentage of issued share capital</i>
Morstan Nominees Limited	5,031,515	12.10%
Medinvest Holdings Limited	4,053,030	9.74%
Christopher J Crabtree	3,828,030	9.20%
Robin A Lamb	2,200,000	5.29%

- 4.6 As at 11 July 2003 (being the last practicable date prior to publication of this document) and save as disclosed in this paragraph 4, the Directors are not aware of any person or persons who, directly or indirectly, jointly or severally, at the date of this document, exercise or could exercise control over the Company.

## **5. Directors' Service Agreements/Letters of Appointment**

- 5.1 On 18 June 2001, James Barder entered into an executive service agreement with the Company under the terms of which Mr Barder agreed to act as Chief Executive of the Company at a current annual salary of £112,875 to be reviewed annually. Benefits include life insurance and disability insurance for himself, private medical insurance for himself, wife/partner and children under 18 and an annual car allowance of £11,000 per annum and a pension contribution of 10 per cent. of his annual salary. The agreement is terminable by either party giving not less than 6 months written notice. The agreement contains post-termination restrictions for a period of 12 months.
- 5.2 On 28 June 2001, David Davies entered into an executive service agreement with the Company under the terms of which Mr Davies agreed to act as Director of Clinical Research of the Company at a current annual salary of £91,375 to be reviewed annually. Benefits include life insurance and disability insurance for himself, private medical insurance for himself, wife/ partner and children under 18 and an annual car allowance of £11,000 per annum and a pension contribution of 10 per cent. of his annual salary. The agreement is terminable by either party giving not less than 6 months written notice. The agreement contains post-termination restrictions for a period of 12 months.
- 5.3 On 1 October 2001, Anthony Clayden entered into an executive service agreement with the Company under the terms of which Mr Clayden agreed to act as Finance Director at a current annual salary of £95,000 to be reviewed annually. In May 2003 the terms of the agreement were varied to reflect Mr Clayden's move to full-time employment with the Company save that Mr Clayden has reserved a maximum of two days per month to devote to his consultancy business and other non-executive roles. The agreement is terminable by either party giving not less than 6 months written notice. The agreement contains post-termination restrictions for a period of 12 months.
- 5.4 On 17 May 2001, Dr. William Potter entered into a letter of appointment with the Company under the terms of which Mr Potter agreed to act as non-executive director of the Company. His fee is £20,000 per annum to be reviewed annually. The initial term of the engagement ran from the commencement date to the date of the subsequent AGM of the Company. After this initial term the Company have continually renewed the engagement however, it is not under any obligation to do so. The appointment is terminable at any time by 3 months notice on either side.
- 5.5 On 14 July 2003 Mr Andrew Slater entered into a letter of appointment with the Company under the terms of which Mr Slater agreed to act as a non-executive director of the Company for a fee of £18,000 per annum to be reviewed annually. The initial term of the engagement is to run from the commencement date to the date of the subsequent AGM of the Company. After this initial term the Company may continually renew the engagement, however, it is not under any obligation to do so. The appointment is terminable at any time by 3 months notice on either side.
- 5.6 On 14 July 2003 Mr Jonathan Freeman entered into a letter of appointment with the Company under the terms of which Mr Freeman agreed to act as a non-executive director of the Company for a fee of £18,000 per annum to be reviewed annually. The initial term of the engagement is to run from the

commencement date to the date of the subsequent AGM of the Company. After this initial term the Company may continually renew the engagement, however, it is not under any obligation to do so. The appointment is terminable at any time by 3 months notice on either side.

5.7 Save as disclosed in paragraphs 5.1 to 5.6 above, there are no service contracts or letters of appointment, existing or proposed, between any Director and the Company.

5.8 It is estimated that under arrangements currently in force, the aggregate remuneration and benefits in kind to be paid to the Directors for the 11 month financial period ending 31 December 2003 will be approximately £360,000.

## 6. Additional Information on the Board

6.1 Other than their directorships of the Company, directorships and partnerships currently held by the Directors and held over the five years preceding the date of this document are as follows:

<i>Director</i>	<i>Current</i>	<i>Past</i>
William Potter	Futura Medical Developments Limited Incobar Limited Ace Three (UK) Limited Stapleford Scientific Services Limited	London International Group plc Lombard Medical plc
James Barder	Futura Medical Developments Limited The Loss Recovery Group Limited Naylands Dibble Limited	AON Capital Markets Limited
David Davies	Futura Medical Developments Limited	None
Anthony Clayden	Futura Medical Developments Limited Flexible FD Limited	None
Jonathan Freeman	Gambit Venture Capital Limited Gambit Corporate Finance Movision 39 Film Partnership	Beeson Gregory Limited
Andrew Slater		Brevet Hospital Products (UK) Ltd Cupal Ltd Earex Products Ltd London International Group Ltd LRC Overseas Limited LRC Products Ltd Open Championship Ltd Pharmalab Ltd Prebbles Ltd Scholl Consumer Products Ltd Scholl (Investments) Ltd Scholl Ltd Scholl (UK) Ltd Seton Group Ltd Seton Healthcare Ltd Seton Investments Ltd Seton Prebbles Ltd Seton Products Ltd Seton Scholl Healthcare International Ltd Seton Scholl Overseas Investments Ltd Seton Scholl UK Limited Silipos (UK) Ltd Sondico International Ltd

<i>Director</i>	<i>Current</i>	<i>Past</i>
Andrew Slater		SSL(CC Manufacturing) Ltd SSL (CC Services) Ltd SSL International Plc SSL Products Ltd Tubifoam Ltd Ultra Chemical Ltd Ultra Laboratories Ltd

6.2 Save as disclosed above, no director has:

- (a) any unspent convictions in relation to indictable offences;
- (b) had a bankruptcy order made against him or made an individual voluntary arrangement;
- (c) been a director of a company which has been placed in receivership, compulsory liquidation, creditors' voluntary arrangement or made any composition or arrangement with its creditors generally or of any class of its creditors whilst he was a director of that company or within twelve months after he ceased to be a director of that company;
- (d) been a partner in a partnership which has been placed in compulsory liquidation, administration or made a partnership voluntary arrangement whilst he was a partner in that partnership or within twelve months after he ceased to be a partner in that partnership;
- (e) had any asset placed in receivership or any asset of a partnership in which he was a partner placed in receivership whilst he was a partner in that partnership or within twelve months after he ceased to be a partner in that partnership;
- (f) been publicly criticised by any statutory or regulatory authority (including recognised professional bodies) or 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;
- (g) been disqualified by a court from acting as a director of any company or from acting in the management or conduct of the affairs of a company.

## **7. Share Option Schemes**

The Company has adopted, on 25 February 2002, the pre-IPO Share Option Scheme ("the Unapproved Scheme") and the EMI Share Option Scheme ("the Approved Scheme"). The Approved Scheme has been approved by the Inland Revenue.

The following summary relates to the rules of the Approved Scheme. The terms of the Unapproved Scheme are the same unless expressly stated to the contrary.

### *7.1 Eligibility*

Options to acquire Ordinary Shares in the capital of the Company may be granted at the discretion of the board to any employee, who, in respect of the Approved Scheme only, is required to devote a minimum of 25 hours per week, or if less, 75 per cent. of his working time to his duties and who does not have, or has not had within the previous 12 months, a material interest in any company in the Group. There is no such restriction on the Unapproved Scheme. Under the Approved Scheme the number of shares over which an option may be granted to a participant is limited to the extent that the total value at the time of grant (as agreed with the share valuation division of the Inland Revenue) of the shares over which options have been granted but not exercised, does not exceed £100,000. No such limitation exists in the Unapproved Scheme.

## 7.2 *Limitations on the size of the schemes*

The number of shares over which options may be granted under the schemes is limited so that, when combined with the number of shares issued, or remaining to be issued, it does not exceed a board-determined percentage of paid-up share capital.

## 7.3 *Grant of options*

The grant of an option is recorded in an Option Agreement, or in the case of the Unapproved Scheme, a letter which must state (*inter alia*) the number of shares that may be acquired and the subscription price (which, under the Approved Scheme must not be less than the higher of the nominal value of the share and the market value of the share). Following the grant of an option, the Company must give notice to the Inland Revenue within 92 days of the date of the grant, or, if granted under the Unapproved Scheme, must issue an option certificate.

## 7.4 *Conditions of options*

An option is personal to the participant and is not capable of transfer or assignment. On the bankruptcy of the participant, and in addition, under the Unapproved Scheme, on insolvency by any other means, or on the death of the participant, the option will lapse. Under the Unapproved Scheme, on the death of a participant, his personal representative has 40 days within which to exercise the option before such lapse.

## 7.5 *Exercise of options*

An option is capable of exercise between 1 February 2004 and 31 January 2006, save where the board permits otherwise. No option, however, is capable of exercise later than the tenth anniversary of the date of grant. If a disqualifying event occurs, the board may at its discretion allow the option to be exercised within 40 days of the disqualifying event. No such provision exists in the Unapproved Scheme.

## 7.6 *Termination of employment*

If a participant ceases to be employed by the group, all options shall lapse. If however, employment ceases due to permanent ill health, redundancy, retirement or any other reason at the discretion of the board, the participant has 40 days in which to exercise the option. No such provisions exist in the Unapproved Scheme.

## 7.7 *Take-over and amalgamation*

In the event that the company is taken-over, or the court sanctions a compromise or arrangement the participant has 40 days, or in the case of the Unapproved Scheme, 6 months within which to exercise the option, after such period, the option shall lapse. In such circumstances, the participant may also release his outstanding rights under any option in consideration of the grant of a new option. In some circumstances this new option must be granted within six months, and further may qualify as a replacement option, although these will never be the case under the Unapproved Scheme. The company may give notice of an exercise event so that participants may exercise their options prior to the event.

## 7.8 *Variation of capital*

In the event of variation of share capital, then the number of shares comprised in the option and/or subscription price may be adjusted subject to the approval of the Inland Revenue, or in the case of the Unapproved Scheme, subject to the auditors confirming that such adjustment is fair and reasonable. If the board is so authorised, such adjustment may be to below the nominal value of the share. In the case of the Unapproved Scheme, the board may, subject to authority by ordinary resolution, utilise funds available for dividends to make up the difference.

### 7.9 *Liquidation*

Under the Unapproved Scheme, the board must give notice to all participants of any proposed voluntary winding up of the company. Between such notice and the commencement of the winding up, options may be exercised. After commencement of the winding up, all options will lapse.

### 7.10 *Administration and amendment of the schemes*

The board has the power to make such regulations as it sees fit. The Inland Revenue may, on giving notice to the company vary any term it deems necessary. Participants have 7 days in which to object. No amendment shall adversely affect the rights of the participants, save in certain circumstances. These provisions do not apply to the Unapproved Scheme.

### 7.11 *Duration of the scheme*

The board may suspend or terminate the Approved Scheme.

### 7.12 *Tax and National Insurance*

Parts VI and VII of Schedule 14 to the Finance Act 2000 apply, but not to the Unapproved Scheme. Each participant is liable for any income tax and national insurance on the income from the exercise of the option and each participant shall indemnify the Company.

## **8. Material Contracts**

The following contracts, not being contracts entered into the ordinary course of business, have been entered into by the Company or the Subsidiary within the two years up to the date of this document and are, or may be, material:

- 8.1 an agreement (“Introduction Agreement”) dated 14 July 2003 between the Company and Williams de Broë pursuant to which the Company has appointed Williams de Broë to act as Nominated Adviser and Broker to the Company in connection with Admission.

The Introduction Agreement provides for the payment by the Company of certain fees, costs and expenses incurred by Williams de Broë in connection with the application for Admission, including the Registrars’ fees, other professional advisers’ fees and printing and distribution expenses.

The Introduction Agreement contains certain representations, warranties and undertakings given by the Company to Williams de Broë as to the accuracy of the information contained in this document and in relation to other matters relating to the Group and its business, an indemnity from the Company in favour of Williams de Broë and undertakings from the Company to Williams de Broë relating to its appointment as Nominated Adviser and Broker.

James Barder and David Davies have agreed with Williams de Broë that, for a period of 12 months from Admission, they will not, without the prior written consent of Williams de Broë and subject to certain limited exceptions, dispose of their Ordinary Shares. After the period of twelve months whilst Williams de Broë is broker to the Company any disposal through Williams de Broë should be made in an orderly manner.

- 8.2 By a lock-in agreement dated 14 July 2003 (“Lock-in Agreement”), Medinvest Holdings Limited have agreed with Williams de Broë that, for a period of 12 months from Admission, they will not, without the prior written consent of Williams de Broë Plc and subject to certain limited exceptions, dispose of their Ordinary Shares. After the period of twelve months whilst Williams de Broë Plc is broker to the Company any disposal through Williams de Broë should be made in an orderly manner.
- 8.3 a licence agreement dated 14 March 2003 between (1) the Subsidiary, (2) LRC Products Limited (“LRC”) and (3) the Company, pursuant to which the Subsidiary has granted an exclusive licence to LRC to manufacture, market, distribute and sell condom products incorporating the Subsidiary’s CSD 500 product (“Product”) for the lifetime of the relevant patents. The licence is worldwide, save that it will not initially extend to Japan.

LRC has agreed to make certain milestone payments to the Subsidiary following the grant of the first product licence in each of the USA, the EU, Asia Pacific and Japan.

LRC has agreed to pay the Subsidiary a significant royalty at an agreed percentage of the net sales value (after transport costs, sales tax, credit notes for returns and defective products and any settlement, retrospective, volume and promotional discounts) charged by LRC or any sub-licensee in relation to the Product. LRC has agreed to pay the Subsidiary minimum royalty advances in respect of each region on an annual basis for each of the first five years following product launch.

The royalty and the royalty advance may be reduced by such amount (if any) as is agreed or determined by an expert to be fair and reasonable if: (i) any patent application does not proceed to grant or any patent rights are determined to be unenforceable or are revoked or lapse; or (ii) an event occurs which in LRC's reasonable opinion adversely affects the commercial viability of the licence agreement or the margins on sales of the Product; or (iii) a competing product is offered for sale.

The Product is to be marketed under the Durex™ brand with a separate sub-name and with the Company's ZANIFIL™ trademark being displayed.

LRC has agreed to undertake to commence the supply of the Product on a commercial basis in each market, under normal circumstances within six months of the date on which final regulatory approval is given for that market or completion of the Licencee Product Study. LRC has agreed to use its reasonable endeavours to promote the Product as part of its condom range of products.

LRC will have the option to extend the licence to Japan which is exercisable at any time within 12 months of the date of the licence agreement. If this option is exercised, development costs will be borne equally by LRC and the Subsidiary.

The Subsidiary has agreed to be responsible for all costs incurred associated with: (i) the patent applications relating to the Product; (ii) any patent granted pursuant thereto; (iii) the development of the Product; and (iv) the performance of any tasks necessary to secure the necessary regulatory approvals and product licences for the Product. LRC has agreed to be responsible for all costs incurred associated with: (i) the consumer marketing study; (ii) regulatory costs associated with manufacturing scale up and type testing; (iii) all ongoing regulatory costs to maintain product licences once granted; (iv) all fees associated with CE marks and (v) all marketing, promotion and distribution costs associated with the sale of the Product.

Should LRC require any additional trials, the Subsidiary and LRC will share the cost of these equally; save that, if the Subsidiary considers such cost to be prohibitive, then LRC will bear the cost but, in that event, twice the amount of such cost will then be deducted from the Subsidiary's royalties for the relevant geographical area and the Subsidiary will receive no royalty advance until this debt has been cleared. LRC will be responsible for maintaining the regulatory licences once they have been granted. LRC have agreed that they will not market, promote or distribute any product which makes similar claims to the Product.

LRC can take action in respect of any patent infringement or claim and the Subsidiary has agreed to be responsible for all reasonable costs incurred by LRC in connection therewith. If LRC does not take such action, then the Subsidiary may do so itself.

The Subsidiary makes certain representations and gives certain warranties to LRC in respect of, amongst other things, the intellectual property rights in the Product, its patent applications and the indications relating to regulatory approval. The Subsidiary has agreed to indemnify LRC for any loss, arising as a result of a breach of these representations and warranties, subject to a £2 million cap. Subject to certain exceptions, each party's tortious and contractual liability under the agreement is limited to £1 million. The Company has agreed to act as guarantor in respect of the obligations of the Subsidiary.

LRC have an option to take a licence over the Subsidiary's female product, known as FLD 500, at any time within the longer of: (i) the period of 12 months from the date of the licence agreement; or (ii) the

period ending 60 days after LRC has been supplied with reasonably sufficient information relating to the female product to enable it to determine whether or not to exercise the option. The licence will be granted on the same terms as that for CSD 500, save that: (a) there will be no royalty advance and (b) the amounts of the milestone payments will be higher.

The agreement remains subject to certain conditions including satisfactory performance of the product and regulatory approval.

LRC may terminate the agreement in a number of specified circumstances and a termination fee shall be payable if the agreement is terminated within 5 years but only if such termination does not fall within any of the circumstances previously set out.

- 8.4 A licence (“the Licence”) dated 6 January 2003 between the Company (1) and Goldshield Pharmaceuticals Limited (“Goldshield”) (2), pursuant to which the Company assigned to Goldshield its rights under the trademark EROXON (pending grant of trademark) in the UK together with all rights in relation to the MED2001 Product and Product Licence in respect of the Product (as such terms as are defined in the Licence) in the UK and the Republic of Ireland.

Under the Licence, Goldshield is to make a number of non-refundable payments to the Company payable in 4 tranches, such payments being conditional upon, *inter alia*, the Company’s submission for UK product registration, and moving annual total sales of Goldshield reaching £4,000,000. In addition, Goldshield shall pay to the Company a share of Goldshield’s margins.

Under the Licence, Goldshield is responsible for the marketing of the product and maintaining the Licence. In the event of a breach, either party may terminate the Licence, if within 90 days that breach has not been remedied. In the event of a dispute, the parties shall attend arbitration proceedings. Further, the Company may terminate the Licence if Goldshield fails to achieve the sales representing the minimum margins.

- 8.5 An Agreement (“Subscription Agreement”) dated 19 June 2003 and made between the Company and Long Fleet Systems Inc. for Long Fleet to procure subscriptions for 2,428,571 new Ordinary Shares at a price of 70 pence per share (the “Subscription”) totalling approximately £1.7 million on Admission.

Under the Subscription Agreement, Long Fleet have granted the Company 3 call options, pursuant to which the Company will be entitled to require Long Fleet to procure the subscription of a further £2.4 million (£800,000 under each call option) for new Ordinary Shares (the “Call Options”). The first of the Call Options will be exercisable in November 2003, the second in February 2004 and the third in July 2004. The Call Options will be exercisable at an exercise price equal to a 10 per cent. discount to the average middle market quotations of the Company’s shares on AIM for the 5 dealing days prior to the date of exercise, subject to a minimum price equal to the nominal value of such shares.

Upon completion in full of the Subscription, the Company will pay Long Fleet a cash commission of £170,000, being equal to 10 per cent. of the amount of the Subscription, and issue warrants to Long Fleet over 250,000 Ordinary Shares exercisable at any time within 12 months of issue at a price equal to 63 pence per share.

Upon completion of each subscription for Call Option Shares, the Company will pay Long Fleet a cash commission of £20,000 and issue warrants (“Warrants”) to Long Fleet over 250,000 Ordinary Shares exercisable at any time within 12 months of issue at a price equal to the exercise price of the relevant Call Option.

The total commission, assuming exercise of all the Call Options, will, therefore comprise £230,000 in cash, representing 5.6 per cent. of the funds subscriptions procured by Long Fleet, and the issue of Warrants over 1,000,000 Ordinary Shares.

- 8.6 An agreement dated 17 December 1998 between the Subsidiary (1) and Zotiades Trading & Consulting Limited (“the Licensee”) (“the Cyprus Licence”) (2) under which the Subsidiary granted to the Licensee an exclusive right to register, manufacture, promote, distribute and sell MED 900 (a precursor to MED2001) in Cyprus. In consideration for this, the Licensee shall pay to the Subsidiary,

certain royalties on the signing of the Cyprus Licence on the approval of MED900 by the MCA in the UK and on the first anniversary of such approval. In addition, the Licensee shall pay to the Subsidiary a percentage of net sales by the end of each year. It is the Licensee's responsibility to register the MED900 trademark and it must use diligent and expedient efforts to do so. The Licensee must also use diligent efforts to market and promote MED900. Either party may terminate the Cyprus Licence on the occurrence of any material breach. Unless such termination occurs, the Cyprus Licence shall continue for 10 years after which it will be deemed to be automatically renewed unless either party gives 6 months written notice.

## **9. Related party transaction**

Jonathan Freeman is a Director of the Company and is a partner in Gambit Corporate Finance which has provided corporate finance advice to the Company during the course of 2003. Gambit Corporate Finance will be paid £25,000 upon Admission. There is no ongoing contractual relationship between Gambit Corporate Finance and the Company following Admission, save in relation to the provision of the services of Jonathan Freeman in the role of Non-executive Director.

## **10. Litigation**

The Group is not involved in any legal or arbitration proceedings which may have or have had since incorporation a significant effect on the Group's financial position and, so far as the Directors are aware, there are no such proceedings pending or threatened against the Group.

## **11. Working capital**

The Directors are of the opinion, having made due and careful enquiry, that following Admission, the Group will have sufficient working capital for its present requirements, that is for at least 12 months from the date of Admission.

## **12. Taxation**

The following paragraphs are intended as a general guide only for shareholders who are resident and ordinarily resident in the United Kingdom for tax purposes, holding Ordinary Shares as investments and not as securities to be realised in the course of a trade, and are based on current legislation and UK Inland Revenue practice. Any prospective purchaser of Ordinary shares who is in any doubt about his tax position or who is subject to taxation in a jurisdiction other than the UK, should consult his own professional adviser immediately.

### *12.1 Inheritance Tax*

#### **Business Property Relief**

Unquoted Ordinary shares representing minority interests in trading companies such as the Company potentially qualify for 100 per cent. business property relief which gives up to 100 per cent. exemption from Inheritance Tax. Therefore, where an investor makes a lifetime gift of shares or dies while still owner of the shares, no inheritance tax will be payable in respect of the value of the shares, provided certain conditions are met. The main condition is that the investor held the shares for two years before the date of transfer or death.

### *12.2 Stamp duty and Stamp Duty Reserve Tax*

No stamp duty or stamp duty reserve tax ("SDRT") will generally be payable on the issue of the Ordinary Shares.

### *12.3 Dividends and other Distributions*

Dividends paid by the Company will carry an associated tax credit of one-ninth of the cash dividend or ten per cent. of the aggregate of the cash dividend and associated tax credit. Individual shareholders resident in the UK receiving such dividends will be liable to income tax on the aggregate of the

dividend and associated tax credit at the Schedule F ordinary rate (10 per cent) or the Schedule F upper rate (32.5 per cent.).

The effect will be that taxpayers who are otherwise liable to pay tax at only the lower rate or basic rate of income tax will have no further liability to income tax in respect of such a dividend. Higher rate taxpayers will have an additional tax liability (after taking onto account the tax credit) of 22.5 per cent. of the aggregate of the individual and associated tax credit. Individual shareholders whose income tax liability is less than the tax credit will not be entitled to claim a repayment of all or part of the tax credit associated with such dividends.

A UK resident corporate shareholder should not be liable to corporation tax or income tax in respect of dividends received from the Company unless that company is carrying on a trade of dealing in shares.

Trustees of discretionary trusts are liable to account for income tax at the rate applicable to trusts on the trust's income are required to account for tax at the Schedule F trust rate, currently 34 per cent.

Persons who are not resident in the UK should consult their own tax advisers on the possible application of such provisions and on what relief or credit may be claimed for any such tax credit in the jurisdiction in which they are resident. These comments are intended only as a general guide to the current tax position in the UK as at the date of this document. The comments assume that Ordinary Shares are held as an investment and not as an asset of financial trade.

If you are in any doubt as to your tax position, or are subject to tax in a jurisdiction other than the UK, you should consult your professional adviser.

### **13. General**

- 13.1 The total costs and expenses relating to Admission are payable by the Company and are estimated to amount to approximately £360,000 (excluding Value Added Tax).
- 13.2 Williams de Broë Plc has given and not withdrawn its written consent to the inclusion in this document of reference to its name in the form and context in which it appears.
- 13.3 Withers and Rogers has given and not withdrawn its written consent to the inclusion in this document of reference to its name in the form and context in which it appears and to the inclusion of their report in this document.
- 13.4 Other than the current application for Admission, the Ordinary Shares have not been admitted to dealings on any recognised investment exchange nor has any application for such admission been made nor are there intended to be any other arrangements for dealings in the Ordinary Shares.
- 13.5 The accounting reference date of the Company and the Subsidiary was 31 January up to and including the year ended 31 January 2003. The accounting reference has since been changed to 31 December, commencing with the period ending 31 December 2003.
- 13.6 Save as disclosed in this document, the Directors are not aware of any patents or other intellectual property rights, licences or particular contract which are or may be of fundamental importance to the Company's business.
- 13.7 The Directors are not aware of any exceptional factors which have influenced the Group's activities.
- 13.8 Other than in the normal course of business and save as disclosed in this document, there have been no recent significant trends concerning the development of the Group's business or any significant acquisitions or disposals of assets since 31 January 2003.
- 13.9 Other than in the normal course of business and save as disclosed in this document, there has been no significant change in the trading or financial position of the Group since 31 January 2003, being the date to which the audited accounts of the Group were prepared.

13.10 In consideration of consultancy services provided to the Company in 2001, Stewarts Marketing Limited will be paid a consultancy fee of £50,000 on Admission.

13.11 Save as disclosed above, no person directly or indirectly (other than the Company's professional advisers and trade suppliers or save as disclosed in this document) in the last twelve months received or is contractually entitled to receive, directly or indirectly, from the Company on or after Admission (excluding in either case persons who are professional advisers otherwise disclosed in this document and persons who are trade suppliers) any payment or benefit from the Company to the value of £10,000 or more or securities in the Company to such value or entered into any contractual arrangements to receive the same from the Company at the date of Admission.

#### **14. Availability of Admission Document**

Copies of this Admission Document are available free of charge from the offices of Williams de Broë at 6 Broadgate, London EC2M 2RP, during normal business hours on any weekday (Saturdays and public holidays excepted) and shall remain available for at least one month from Admission.

Dated: 14 July 2003





