



# **FUTURA**

## **M E D I C A L**

INTERIM REPORT

# **2005**

## COMPANY PROFILE

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Futura Medical plc ("Futura") is a pharmaceutical drug and medical device group that develops innovative products for the sexual healthcare market. Our products under development are focused on the sexual wellbeing of healthy men and women and the treatment of sexual dysfunction. Our primary focus is on non-prescription products with particular appeal to men and women who are reluctant to discuss potentially embarrassing sexual matters with their doctors. A summary of our main products under development is set out below.

### CSD500 – Condom Safety Device

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

CSD500 is aimed at reducing condom slippage by improving the rigidity, tumescence and duration of an erection through the addition of an erectogenic compound localised within the teat of a condom. Discussions with EU regulatory authorities have confirmed that the product will be classified within the EU as a Class III medical device with an ancillary medicinal substance. This classification will allow the product to be sold throughout Europe in the same way as conventional condoms.

### FLD500 – Female Lubrication Device

FLD500 is a "sister" product to CSD500. The erectogenic compound will be applied to the outside of a condom thereby coming into direct contact with the vagina during sexual intercourse.

FLD500 is aimed at helping healthy women maintain lubrication during intercourse, reducing the risk of condom failure. During sexual penetration a pharmacological dose will be delivered to the clitoral 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. The product is intended to be classified within the EU as a Class III medical device with an ancillary medicinal substance.

### MED2002 – Male Erectile Dysfunction Treatment

MED2002 will be a 'rub-on' gel applied directly to the penis for the treatment of male erectile dysfunction. The Directors believe this will become the first pharmaceutical treatment for erectile dysfunction which will be available without the need of a doctor's prescription. This will be licensed under the trademarked brand name of Eroxon™.

The Futura product is based on glyceryl trinitrate, a potent vasodilator, which has been used for the treatment of angina and associated cardio-vascular defects for more than 40 years and has been determined to be a safe and effective drug with a known side-effect profile.

### Distribution Agreements

Futura has signed a global distribution agreement with the world's largest branded condom manufacturer and distributor, SSL International plc ("SSL" – makers of the Durex™ condom range) for the lifetime of the patents for both CSD500 and FLD500.

Futura has entered into exclusive discussions with a major global pharmaceutical group on a proposed agreement for the worldwide development and marketing of MED2002.

### Website

More information regarding Futura Medical plc can be found on our website [www.futuramedical.co.uk](http://www.futuramedical.co.uk)

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**CONTENTS**

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	<b>Pages</b>
Interim Statement	2-3
Unaudited consolidated profit and loss account	4
Unaudited consolidated balance sheet	5
Unaudited consolidated cash flow statement	6
Notes to the interim financial information	7-8

## INTERIM STATEMENT

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The past six months have been the most productive and busiest in the history of Futura and we fully expect the momentum to continue increasing over the next six months. The submission of the EU dossier for marketing authorisation for CSD500 and completion of further MED2002 pilot work to conclude global commercial distribution arrangements for the first over-the-counter (“OTC”) pharmaceutical treatment for Erectile Dysfunction are two of the key milestones we expect to achieve over the coming months.

### **CSD500 – Zanafil™** **Condom safety device**

In April we announced that following satisfactory pilot stability results, SSL International plc (“SSL”) was commencing initial manufacturing trials. Since April, a series of manufacturing trials have been successfully completed. Stability studies in compliance with the relevant regulatory requirements are in progress and if the results continue to be satisfactory, the submission for EU marketing authorisation will be made in November 2005.

We have been advised that dossier review by EU regulators and subsequent approval is likely to take six months from submission. During this period we will be working closely with SSL as preparations commence for the marketing research being conducted by SSL and subsequent launch of CSD500.

### **FLD500** **Female lubrication device**

We have made significant progress with the development of FLD500. In July, we announced that SSL had exercised its option for global distribution rights. Recently, we also announced that following a review of all the clinical data and supported by preliminary feedback from an EU Competent Authority, we were not seeking to conduct further clinical studies thereby saving both time and money in the development programme.

CSD500 is a gel localised within the teat of a condom whilst FLD500 is a thin elastomer film coating the exterior of a condom. Although there is considerable overlap in the technical aspects of the development programme with CSD500, the elastomer film does present some different technical manufacturing challenges. These technical challenges are currently being evaluated and we hope to make an announcement shortly relating to the expected timetable for the completion of the EU dossier for marketing authorisation.

### **MED2002 – Eroxon™** **Treatment for Erectile Dysfunction (“ED”)**

In our most recent year-end statement we announced that we had entered into confidential and exclusive discussions with a major global pharmaceutical group (“MGPG”) on a proposed agreement for the worldwide development and marketing of MED2002.

The commitment of both parties to an exclusivity period has enabled Futura and MGPG to allocate resources to the joint development of MED2002. In our view, the commercial benefits such as a major development and distribution partner could bring to MED2002 increases the potential for the product to become the first OTC pharmaceutical treatment for Erectile Dysfunction.

Since March, considerable work has been conducted by MGPG to confirm the optimum regulatory strategy for MED2002 in the key consumer markets and evaluate the market opportunity for MED2002. This work, as agreed under the planned schedule of joint development between Futura and MGPG, will complete this autumn.

As we reported during July 2004, *in vitro* tests of our revised formulation, MED2002, showed dramatically improved dermal absorption rates. In recent *in vivo* trials in healthy men absorption rates were even higher than predicted from the *in vitro* data, demonstrating the significant improvements that have been made to the formulation. These initial results support the potential for this product to offer an effective, rapid-onset, locally active dose with a low systemic uptake which will help to reduce unwanted side effects.

## INTERIM STATEMENT

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Further *in vivo* trials, financed by Futura, are ongoing with the objective of determining the optimum dose and formulation to maximise local effects in the penis whilst minimising systemic uptake throughout the body. It is intended that this will reduce the potential for adverse interaction with other centrally acting drugs that may also be taken concomitantly by the patient, especially PDE5 inhibitors such as Viagra®, Cialis® or Levitra®. Greater dermal absorption rates will also deliver the active ingredient more rapidly to the penis, which should be reflected in an improved time to onset of an erection.

We remain optimistic of the positive outcome of these trials and expect to be able to report to our shareholders on the results of the studies in November and conclude our negotiations with MGPG thereafter as planned.

### Business analysis

Our overall loss for the six months ended 30 June 2005 was £856,027. Research and development costs of £686,116 are 90% higher compared with last year's interim results. This reflects the increased activity as we seek to aggressively push through our development programme. Other administrative costs of £380,378 are broadly in line with the comparative six month period, rising only 4%, as overheads stabilise having absorbed the charges associated with becoming an AIM quoted company. We continue to maintain a tight control on expenditure. Cash at the end of June 2005 was £2.7 million.

### An eye on the future

The revised carrier formulation for MED2002 has delivered significantly improved absorption profiles with rates of up to 1,000% greater than those of previous versions of MED2002. Moreover, this new topical delivery platform has enabled us to apply for further intellectual property rights. In recent months we have commissioned an investigation into other topically applied medications that could benefit from such a vastly improved absorption profile. Critical to this analysis was identifying existing topical medications where a significant increase in efficacy would have consequences greater than just a reduction in dosage.

We have identified two products that fit these criteria. This development is a by-product of the MED2002 programme and we have been careful to ensure this has had limited cost and resource consequences for Futura. Moreover, as we shall be seeking to improve existing pharmaceutical products rather than develop new ones, the regulatory challenges are considerably reduced. We expect to report further on this over the next few months.

We continue to evaluate other external opportunities. Nevertheless our priority remains the completion of the development of our three lead products and our resources and energies are focused on this.

Once more this leads us to thank all the Futura team for their continuing commitment and work which continues to build value for our shareholders.

**Dr W D Potter**, Chairman

**J H Barder**, Chief Executive

### Board changes

Over the past few months Dr Bill Potter has become increasingly involved in the product development programme of Futura. We expect that this role will continue to increase as the exciting developments at Futura gain momentum and with this in mind Bill has agreed to commit more time to us. The rest of the Board are delighted that Futura will be able to further leverage the undisputed talents and expertise of Bill. However, in light of Bill adopting a more executive role, the Board has decided that Bill should step down from the Audit Committee and he has agreed to this. The Board has appointed Andrew Slater to the Audit Committee in his place.

**J H Barder**, Chief Executive

**CONSOLIDATED PROFIT AND LOSS ACCOUNT**

	Notes	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
<b>Turnover</b>		–	4,646	129,863
Research and development costs		(686,116)	(360,391)	(960,141)
Other administrative costs		(380,378)	(364,297)	(745,806)
Administrative expenses		(1,066,494)	(724,688)	(1,705,947)
<b>Operating loss</b>		(1,066,494)	(720,042)	(1,576,084)
Other interest receivable and similar income		77,937	76,159	177,047
<b>Loss on ordinary activities before taxation</b>		(988,557)	(643,883)	(1,399,037)
Tax on loss on ordinary activities	2	132,530	65,181	170,086
<b>Loss on ordinary activities after taxation and retained loss for the period</b>	3	(856,027)	(578,702)	(1,228,951)
Basic and diluted loss per share (pence)	4	(1.8)	(1.2)	(2.6)

All amounts relate to continuing activities.

**Statement of Total Recognised Gains and Losses**

There were no recognised gains and losses in the period, or in the prior periods, other than those passing through the profit and loss account above and therefore no separate statement of total recognised gains and losses has been presented.

**CONSOLIDATED BALANCE SHEET**

	Notes	Unaudited 30 June 2005 £	Unaudited 30 June 2004 £	Audited 31 December 2004 £
<b>Fixed Assets</b>				
Tangible assets		27,914	24,567	28,120
		27,914	24,567	28,120
<b>Current Assets</b>				
Stock		5,320	16,045	14,812
Debtors		398,445	260,187	258,211
Cash at bank and in hand		2,661,562	4,299,913	3,672,647
		3,065,327	4,576,145	3,945,670
<b>Creditors: amounts falling due within one year</b>		(200,753)	(242,498)	(225,275)
<b>Net current assets</b>		2,864,574	4,333,647	3,720,395
<b>Total net assets</b>		2,892,488	4,358,214	3,748,515
<b>Capital and reserves</b>				
Called up share capital		97,357	97,167	97,357
Share premium account	5	8,425,707	8,385,347	8,425,707
Other reserves		1,152,165	1,152,165	1,152,165
Profit and loss account		(6,782,741)	(5,276,465)	(5,926,714)
<b>Equity shareholders' funds</b>	6	2,892,488	4,358,214	3,748,515

**CONSOLIDATED CASH FLOW STATEMENT**

	Notes	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
<b>Net cash outflow from operating activities</b>	7	(1,064,305)	(691,259)	(1,559,590)
<b>Returns on investments and servicing of finance</b>				
Interest received		64,154	69,056	175,141
<b>Net cash inflow from returns on investments and servicing of finance</b>		64,154	69,056	175,141
<b>Corporation Tax</b>				
Research and development tax credit received		–	–	108,436
		–	–	108,436
<b>Capital expenditure</b>				
Payments to acquire tangible assets		(10,934)	(10,357)	(21,648)
Proceeds on disposal of fixed assets		–	–	170
<b>Net cash outflow from capital expenditure</b>		(10,934)	(10,357)	(21,478)
<b>Net cash outflow before use of liquid resources and financing</b>		(1,011,085)	(632,560)	(1,297,491)
<b>Management of liquid resources</b>				
Decrease/(Increase) in short term deposits	8	986,301	(1,888,089)	(1,160,993)
<b>Financing</b>				
Issue of ordinary shares		–	2,604,000	2,644,550
Expenses paid in connection with share issues		–	(76,120)	(76,120)
<b>Net cash inflow from financing</b>		–	2,527,880	2,568,430
<b>(Decrease)/Increase in net cash</b>	8	(24,784)	7,231	109,946

**NOTES TO THE INTERIM FINANCIAL INFORMATION**

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**1. Basis of preparation**

The unaudited Interim Report was approved by the Board of Directors on 2 September 2005.

The financial information contained in this Interim Report has been prepared on the basis of the accounting policies set out in the Group's Annual Report for the year ended 31 December 2004.

The financial information for the six months ended 30 June 2005 and for the six months ended 30 June 2004 is unaudited.

The financial information for the Group set out above does not constitute "statutory accounts" within the meaning of Section 240 of the Companies Act 1985. The information for the year ended 31 December 2004 has been extracted from the statutory accounts of Futura Medical plc for that period which received an unqualified audit report and have been delivered to the Registrar of Companies.

**2. Taxation**

Taxation represents tax credits for certain research and development expenditure based on the expenditure incurred in the relevant period or year. Deferred tax assets have not been recognised on the basis that their future economic benefit is not certain.

**3. Dividends**

No dividends have been paid and none are proposed.

**4. Loss per ordinary share**

The loss attributable to ordinary shareholders and weighted average number of ordinary shares for the purpose of calculating the diluted earnings per ordinary share are identical to those used for basic earnings per share. This is because the exercise of share options would have the effect of reducing the loss per ordinary share and is therefore not dilutive under the terms of Financial Reporting Standard 14.

The calculation of the loss per ordinary share is based on a loss of £856,027 (six months to 30 June 2004: loss of £578,702; year to 31 December 2004: loss of £1,228,951) and on a weighted average of 48,678,601 shares in issue (six months to 30 June 2004: 47,471,613 shares; year to 31 December 2004: 48,069,839 shares).

**5. Share premium**

	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
Opening share premium	8,425,707	5,864,117	5,864,117
Premium on shares issued	–	2,597,350	2,637,710
Less: share issues costs	–	(76,120)	(76,120)
Closing share premium	8,425,707	8,385,347	8,425,707

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**NOTES TO THE INTERIM FINANCIAL INFORMATION**
**6. Reconciliation of movements in shareholders' funds**

	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
Retained loss for the period	(856,027)	(578,702)	(1,228,951)
Net proceeds from issue of shares	–	2,527,880	2,568,430
Net (decrease)/increase in shareholders' funds	(856,027)	1,949,178	1,339,479
Opening shareholders' funds	3,748,515	2,409,036	2,409,036
Closing shareholders' funds	2,892,488	4,358,214	3,748,515

**7. Reconciliation of operating profit to operating cashflows**

	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
Operating loss	(1,066,494)	(720,042)	(1,576,084)
Depreciation	7,758	7,690	15,414
Loss on sale of fixed assets	–	–	3,897
Decrease in stocks	9,492	1,234	2,467
Decrease/(increase) in debtors	6,079	(39,711)	(46,463)
(Decrease)/increase in creditors	(21,140)	59,570	41,179
Net cash outflow from operating activities	(1,064,305)	(691,259)	(1,559,590)

**8. Reconciliation of net cash flow to movement in net funds**

	Unaudited 6 months ended 30 June 2005 £	Unaudited 6 months ended 30 June 2004 £	Audited year ended 31 December 2004 £
(Decrease)/increase in cash in the period	(24,784)	7,231	109,946
Cash (outflow)/inflow from changes in liquid resources	(986,301)	1,888,089	1,160,993
Movement in net funds in the period	(1,011,085)	1,895,320	1,270,939
Net funds at start of period	3,672,647	2,401,708	2,401,708
Net funds at end of period	2,661,562	4,297,028	3,672,647

**COMPANY INFORMATION**

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**Company Number**

4206001

**Directors**

Dr W D Potter, Chairman  
J H Barder, Chief Executive  
A L Clayden, Finance Director  
D B Davies, Product Development Director  
J D Freeman, Non-executive Director  
A Slater, Non-executive Director

**Audit Committee**

A Slater  
J D Freeman

**Remuneration Committee**

J D Freeman  
A Slater  
Dr W D Potter (Adviser to  
Committee)

**Nominations Committee**

Dr W D Potter  
J D Freeman  
A Slater

**Secretary and registered office**

Anthony L Clayden  
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**Registrars**

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**Nominated advisor and joint broker**

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The interim report will be posted to shareholders and copies are available to the public at the Company's registered office or can be downloaded from the Company's website [www.futuramedical.co.uk](http://www.futuramedical.co.uk).

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