

Biocompatibles

2004 Annual Report

Biocompatibles is the medical device company focused on the treatment of cancer, cardiovascular disease, and benign tumours.

The Company's **proprietary biomedical polymer systems** provide medical devices with enhanced biocompatibility and offer a platform for drug delivery.

2004

- **Positive ruling in Isostent trial – jury finds in favour of the defendants**
 - **First patient enrolled in Abbott's Drug Eluting Stent Clinical Trial**
 - **Positive preliminary data from PRECISION clinical trials**

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- 2004 operating loss of £7.6m (2003: £7.8m).
- Net funds at 31 December 2004 of £45.2m (2003: £55.1m).
- £17.6m in escrow account, on which interest is accruing.
- £4.9m release of disposal provisions (2003: £21.6m).
- Turnover of £2.6m (2003: £2.1m).
- Loss before tax of £0.6m (2003: profit £16.0m).
- Net cash outflow before acquisitions and financing £6.5m (2003: £8.9m).

2005

- **Acquisition of CellMed AG, announced on 4 March 2005, expands product pipeline**
 - **Further data shows positive tumour response in PRECISION trial**
 - **Basis for a global, multi-centre randomised controlled trial – PRECISION IV**

OUR VISION

“*We intend to establish our Drug Eluting Bead technology as the Gold Standard treatment for Intermediate HCC and plan that our polymer systems will be recognised as the best in the field of Interventional Medicine*”

Biocompatibles made good progress in 2004.

The Principal Investigators of the Company's PRECISION clinical trial presented positive data at the CIRSE¹ conference on 26 September 2004; and Abbott announced the start of a clinical trial for the evaluation of its ZoMaxx™ Drug Eluting Stent on 14 September 2004.

The Company is delivering its plan.

The Business

Biocompatibles is a world leader in technology for "Combination Products" – medical products that combine the functionality of a medical device, like an orthopaedic hip or a coronary pacemaker, with the systemic therapeutic action of a drug, like a cytotoxic cancer drug or an anti-inflammatory steroid. The growth in the market for Drug Eluting coronary stents, from \$1.3bn² in 2003 to \$3.9bn² in 2004 was a significant factor in the growth of the wider market for Combination Products whose sales are expected to reach \$10bn in 2009³.

We are focused on two markets within Combination Products – Drug Eluting Beads and Drug Eluting Stents. Both products are delivered by means of the same keyhole surgery imaging system, fluoroscopy, used by interventional radiologists and interventional cardiologists respectively.

Our lead programme is the Drug Eluting Bead which we are developing without a partner at this stage. The Board believes that the value of this programme will grow with more clinical evidence of efficacy and that the Company has sufficient cash and management resources to continue to develop this programme in the near term. The Company's first generation Bead product, Bead Block, is distributed in a marketing alliance with Terumo, a leading supplier of products for interventional medicine, head-quartered in Japan.

We also have a programme in partnership with Abbott Laboratories in the market for Drug Eluting Stents, which is managed and financed by Abbott.

The Technology

Biocompatibles has a portfolio of granted patents around the two proprietary polymer systems – the PC Technology that formed the origin of the company and which is used by Abbott and Dideco, amongst other leading medical device companies; and the N-fil™ technology licensed from the Biocure affiliate of Novartis' Ciba Vision subsidiary and which is used in the Drug Eluting Bead programme. The patents provide a strong position over the use of these polymer systems in the target interventional products markets.

“ Current evidence on uterine artery embolisation (UAE) suggests that it is safe enough for routine use and that there is symptomatic benefit in the majority of patients in the short term. ”

The National Institute for Clinical Excellence (NICE).

1 Cardiovascular and Interventional Radiological Society of Europe

2 Merrill Lynch: 18 January 2005: Boston Scientific Corp.: Updated Stent Model

3 Reference: Navigant Consulting (2003) Combination Products: An Impact Analysis on the Convergence of Medical Devices and Therapeutic

A considerable part of Biocompatibles' intellectual property also resides in the expertise of its product development staff. For nearly a decade, Biocompatibles' team of scientists, engineers, clinical, quality and regulatory as well as other support staff, have been developing drug eluting polymer systems. This experience is vital, given the complex interaction of sophisticated Combination Products with the many facets of human biology and disease. We also have a team which has considerable experience in dealing with the requirements of the agencies that regulate the marketing of our products.

Strategic Milestones

The Board is measuring the implementation of the Company's plan with strategic milestones, adapted from previous years. These are as follows:

- 2005 PRECISION establishes our Drug Eluting Bead as a safe and effective treatment for intermediate HCC. We establish the PRECISION IV Randomised Control Trial.
- 2006 We intend to become the market leader in spherical embolic devices.
- 2007 Abbott launch the Drug Eluting Stent in the United States.
- 2008 PRECISION IV shows a survival benefit and our Drug Eluting Bead becomes the global gold standard treatment for Intermediate HCC.

We intend to establish a similar strategic roadmap for CellMed which was acquired in March 2005 as their programmes develop.

The strategic milestones form the basis of the annual goals which are described in the Operational Review.

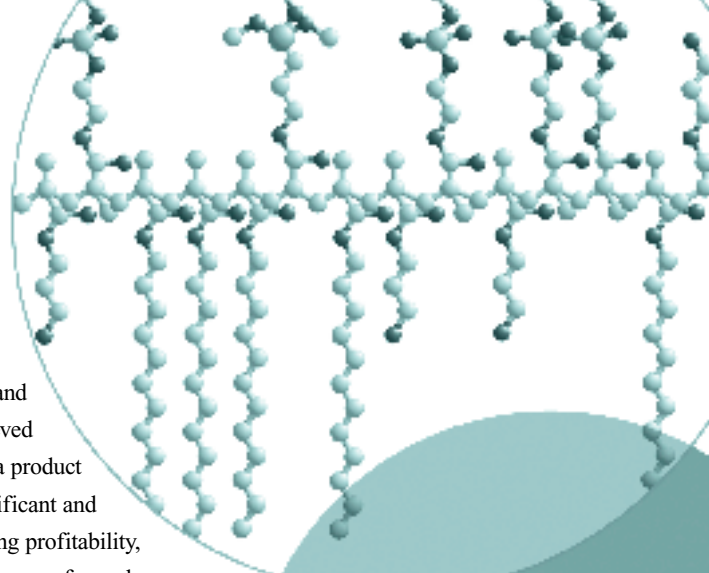
Crystallising Value

The Company's principal objective is to maximise shareholder value and this might be achieved either by growing a product line to deliver significant and sustainable operating profitability, or by the sale or licence of a package of products and technologies. The latter approach was taken in 2002 with the sale of the cardiovascular stent and contact lens businesses, and the subsequent return to shareholders of £111m of capital, with a further £12m to come.

Business Development

In the 2004 Annual Report, the Chief Executive Officer commented that, with the Drug Eluting Bead in clinical trials, the Board had concluded that it was appropriate to narrow the focus of business development on the two key areas identified – medical device and pharmaceutical technologies to support the Company's strategic focus on drug-device combinations; and small investments in sensibly valued medical device programmes that offered the prospect of high value growth without consuming excessive financial or managerial resource.

We were pleased to identify a German medical technology company that met these criteria and we completed the acquisition of CellMed after the year-end. CellMed is described in more detail in the Operational Review.



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drug-eluting stent and
licensing programmes

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