



i c o n

Annual Report 2003



ICON offers a full range of clinical research and development services in Phase I – IV clinical trials. These services cover all areas from trial design and set-up, through monitoring, project management and data entry to medical and statistical report writing.

Consulting - Regulatory Writing

Joel Rothman *Senior Director, Strategic Drug Development*

Heather Wallace *Medical Writer*

Eric Rotman *Associate Director, Medical Writing*

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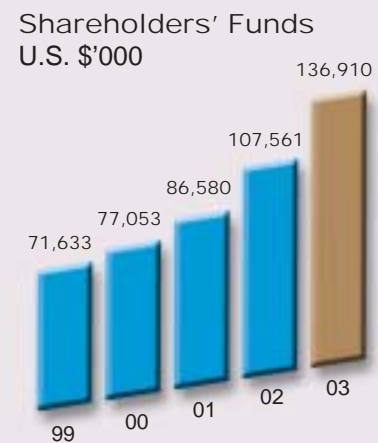
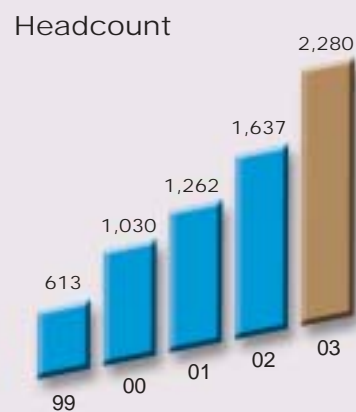
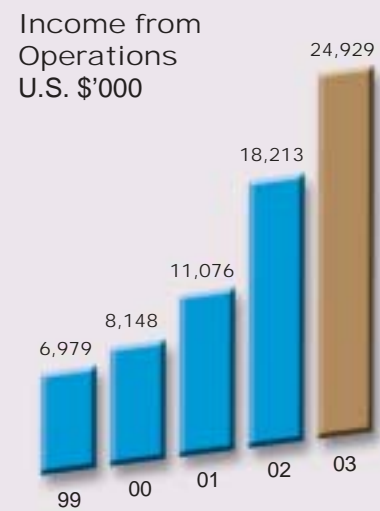
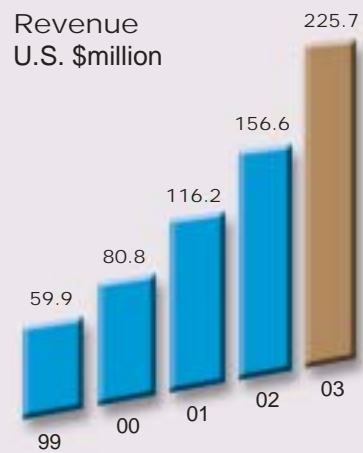
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Global Reach – 31 operations in 18 countries

Trials managed in over 55 countries



Financial Highlights





Clinical Monitoring

Jason Banks *Clinical Project Manager*
Naylon Dunbar *Clinical Research Assistant*
Nathalie Riebel *Clinical Project Manager*
Vishal Mehta *Clinical Research Associate*



Letter to Stockholders

The year to May 31, 2003 was another very satisfying year in terms of financial performance. With sales up 44% (33% excluding the impact of acquisitions) and earnings per share up 29%, we exceeded the goals we had set ourselves at the outset of the year.

The factors which could negatively influence the environment in which we are operating, which we discussed in detail in last year's report, are still present. However, underlying spending on R&D has continued to grow among our customer base at 7 – 9% per year, even through the first half of 2003, and we have continued to enjoy strong levels of new business.

The trend towards the consolidation of suppliers by our customer base continued also. In responding to this opportunity, our growing profile in clinical research (we estimate we are now the 4th largest Phase II – Phase IV CRO in the world) has helped us open new client opportunities and win more business based on the depth of our expertise. Aided by these factors, we succeeded in further diversifying our customer base, but the opportunity for growth remains exciting as we still generate over 50% of our revenue from just five clients.

The strategic development of the group continued to advance. Apart from the strong internally generated growth in our existing businesses we acquired three companies and agreed the purchase of a fourth.

In October 2002 we acquired two sister companies, Barton, Polanski & Associates (BPA) and Managed Clinical Solutions Inc (MCS), both based in New York. BPA, which had specialist therapeutic experience and some good non-overlapping client relationships, was immediately integrated into our US clinical operations. MCS provides recruitment and contract staff solutions to clinical research clients. While our clients are outsourcing an increasing amount of their clinical development work to CROs, most major companies continue to do over 50% of the work themselves. However, they regularly need to supplement internal projects with contract staff. MCS serves this need by finding, and handling the administration aspects of such staff.

Through their database, we have been able to find good candidates for positions within ICON and, where we have needed to achieve accelerated start-up on projects, we have been able to rapidly access contract staff to supplement our teams while waiting for permanent ICON staff to come available. We believe the potential flexibility MCS brings us, together with its position in another market niche, makes it an attractive strategic addition to our service portfolio.

In January 2003, we acquired Medeval Group Ltd, a Manchester, UK based Phase I clinical pharmacology CRO. We had been seeking such a business for over 3 years to enable us service opportunities for Phase I projects, particularly with Japanese and smaller biopharmaceutical companies. Our ultimate strategy is to develop relationships with such companies which we hope will lead to pull through work into our Phase II and Phase III business. Currently operating from a single facility in Manchester, and even though it has many US clients, we hope to use Medeval as a platform to develop Phase I capabilities within the US and to expand its bioanalytical capabilities in the years ahead.

After the end of the fiscal year, we acquired a specialist drug development support CRO, Globomax LLC, based in Baltimore, Maryland. Globomax provides a full range of advisory and support services to companies developing new drugs or new dosage forms. We intend merging our current development and regulatory consulting operations, based in San Francisco and Philadelphia into Globomax to provide a strategic drug development support service in the US. As innovation in drug discovery and development continues to diversify, aided by the willingness of the capital markets to provide funding to emerging biotech and specialist companies, we believe that by providing advice and support services to such companies, the relationships created can ultimately mature into larger later stage developing projects.

With the ability to provide early stage advice and support to execute projects from Phase I through Phase IV, to provide central laboratory services to such projects, to manage and analyse the data from such projects, to provide the technology to support such projects, and to handle the writing up, assembly and submission of the data from drug development projects, we believe we are well positioned to continue to capitalise on the growing outsourcing opportunities of the biopharmaceutical industry.

The most elegant or dynamic strategy is of no benefit, particularly in a service industry, if we do not have the employees to execute it. The dedication and enthusiasm of our staff is what has made us successful to date and is what will enable us to continue to be successful. We would like to express our sincere thanks to them.



Dr John Climax
Chairman



Peter Gray
Chief Executive Officer



ICON Laboratories

Cristina Sanciuc

Review of Operations

Overview

In the financial year to May 31, 2003 ICON had another exceptional year. Overall, revenues grew 44% to \$226 million. \$18 million of this was contributed by acquisitions. Excluding these, across ICON's regions revenues grew 35% in the US, 26% in Europe and 49% in the Rest of the World.

Business flows were strong, with new business awards totalling \$272 million in the year compared to \$178 million in the previous year. As a result, total backlog grew from \$276 million to \$352 million during the year, while the value of this expected to be earned in the following 12 months grew from \$144 million to \$221 million.

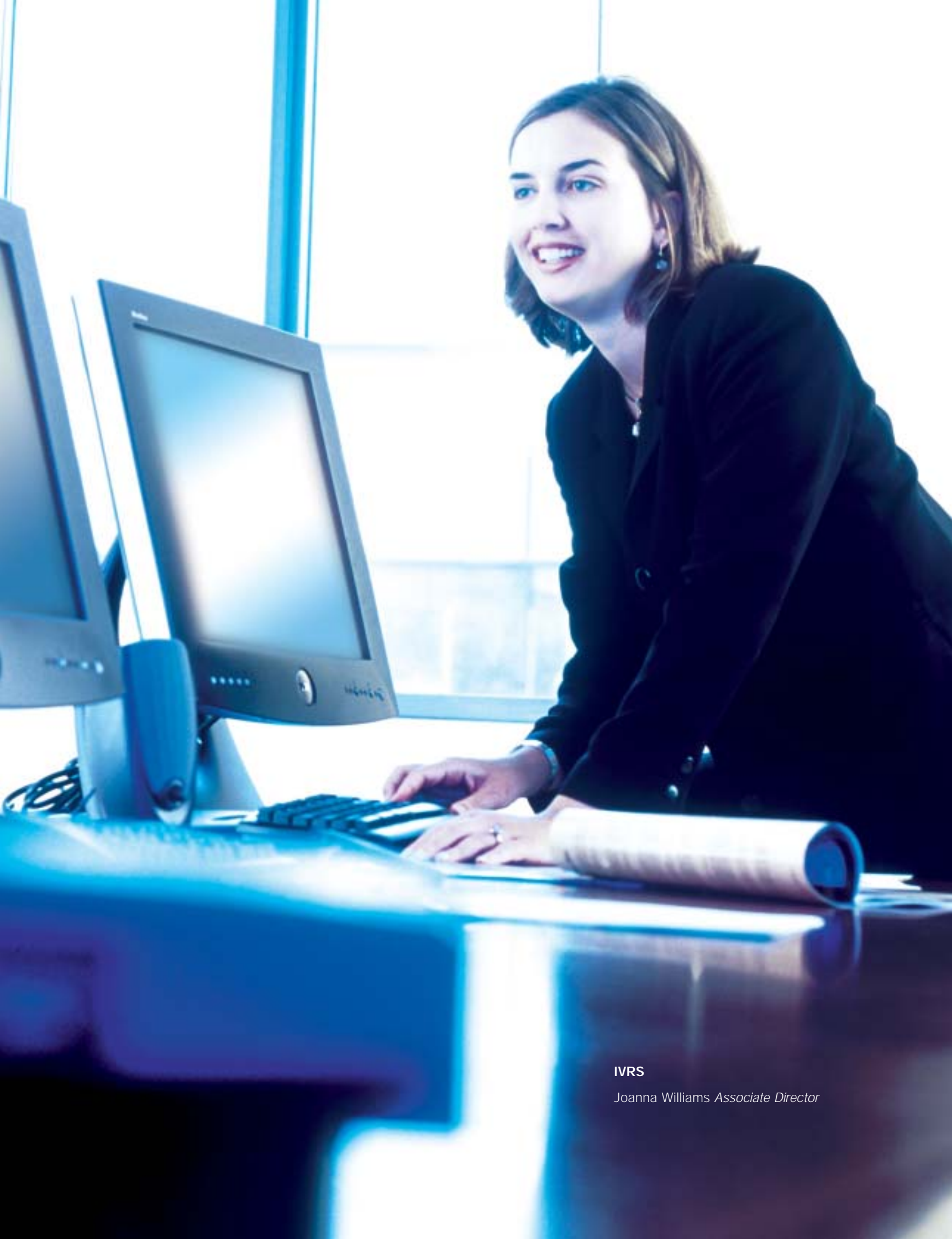
Operating margins declined from 11.6% to 11.0%. Unfortunately, margins in the Central Laboratory business fell from 14.1% to zero as a significant number of project cancellations early in the year impacted volumes and new business wins, while steadily improving, were not sufficient to replace this lost volume. The disappointing performance of the Lab business obscured the excellent improvement in margins in the Clinical Research business which grew from 11.1% to 12.4%.

Growth

At May 31, 2003 ICON employed 2,280 people of whom 1,369 were located in the USA, 823 were located in Europe and 88 were located in ICON's Rest of World region. The acquisition of BPA & MCS added 165 employees in the USA during the year, while Medeval added 168 employees in Europe. Excluding these, staff numbers increased on an organic growth basis from 1,637 on May 31, 2002 to 1,947 which supported a 33% organic revenue increase.

To facilitate this further rapid growth in staff, ICON continued to open new offices including Tampa, Florida, Raleigh, North Carolina, Moscow, Russia and Montreal, Canada during the year, and Budapest, Hungary since year end. The company also moved to new offices in Redwood City, California, thus merging its previous Mountain View and San Bruno offices.

The main driver of growth was increasing numbers of, and larger, projects for the management and execution of Phase I – Phase IV clinical trials.



IVRS

Joanna Williams Associate Director

ICON's investments in new IT systems also continued with all of the major projects mentioned in last years preview making significant progress. None are yet complete with timescales of between 6 months to 18 months envisaged to completion for these projects. All are major initiatives aimed at increasing efficiency and quality, and as such have required extensive planning and resources.

The only disappointment of the year was the disimprovement in the performance of ICON Laboratories, and its minimal growth. Having made spectacular progress in 2002, it suffered a succession of project cancellations in the last quarter of fiscal 2002 and first quarter of fiscal 2003. While its business wins returned to more normal levels in quarter 2, and have continued to grow steadily since, the volume lost was not recovered quickly enough and the business performance has been very disappointing. ICON expects improvement to emerge during fiscal 2004 although this is likely to be steady rather than dramatic.

The addition of a Phase I unit to ICON was the most significant new service introduced during the year. Medeval's excellent reputation as a first-time-in-man clinical pharmacology facility matches well with ICON's quality reputation. Originally a 56 bed unit, providing, in addition, bio-analytical, pharmacokinetic and data management services, Medeval increased its bed capacity to 80 beds just at the time it joined ICON. This gives it good opportunities to grow over the next 2 years while ICON integrates it into its organisation and structures.

The acquisition of MCS in New York also added a new service; the provision of contract staff to companies seeking "in-sourced" clinical research staff. As ICON got frequent requests for such staff, a request it was usually not in a position to satisfactorily fulfil, MCS helps meet a client need, further building relationships with such clients. In addition, the database of professionals maintained by MCS further enhances ICON's ability to react quickly to opportunities which require rapid start-up.

The mix of revenues derived from different therapeutic areas continued to evolve as pipelines and priorities of ICON's customers evolved. As indicated last year, the large number of oncology studies awarded to us at that time, on the back of the recruitment of some key staff, has increased our penetration into this area of clinical research with 7% of our revenues coming from this area compared with 5% last year. Another significant area of growth for ICON in 2003 was in gastroenterology, with 19% of revenues being derived from this specialty, compared to 10% in the previous year. With such growing experience, ICON continues to offer it's clients clinical trial services across a broad spectrum of therapeutic categories and is constantly adding new expertise in areas where clients require it.


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set stat_1;

length n mean $ 22;

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else n = trim(left(put(n_n, 5.0)));

if (mean_n eq .) then mean = '-';
else mean = trim(left(put(mean_n, 8.3)));

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by sortkey1 treat;

run;

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var n mean;
id treat;

run;

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set flipstat;

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Biometrics

Kajjie Pan Senior Biostatistician

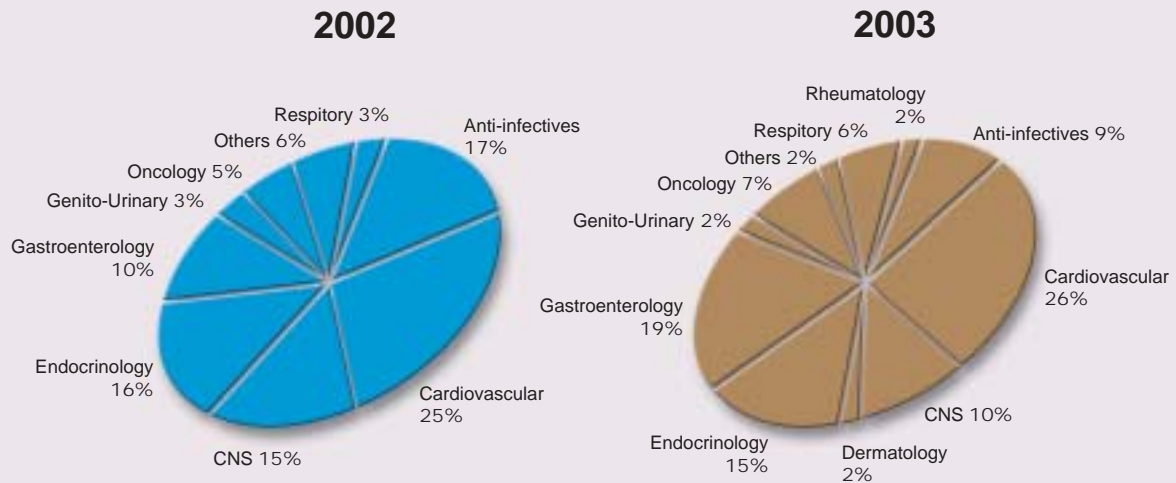


Phase I Trials at Medeval

Pauline Jamieson-Spencer *Clinical Research Nurse*

The Future

The strong wins reported in the first section of this commentary demonstrate that the fundamentals driving the company still appear strong. Into the new fiscal year these trends are continuing. Therefore, ICON expects further strong growth for fiscal 2004. To support this, investment in facilities, systems and people will continue.



Directors and Other Information

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Peter Gray Chief Executive Officer
Ronan Lambe Director
Edward R Roberts Director †§
Thomas G Lynch Director †§
Lee Jones Director †
Shuji Higuchi Director

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John Climax
Chairman



Peter Gray
Chief Executive Officer



Ronan Lambe
Director



Dr. Shuji Higuchi
Director



Thomas G Lynch
Director



Edward R Roberts
Director



Lee Jones
Director

† Member of Audit Committee
§ Member of Compensation Committee

Statements made in the Annual Report that are not descriptions of historical fact may be forward-looking statements that are subject to risks and uncertainties. ICON's actual results could differ materially from those currently anticipated due to a number of factors including, but not limited to, those identified in Form F-1 and Form 20-F as filed with the SEC. All references to historical financial information are based on US accounting principles.

ICON plc

American Depository Shares are traded on the NASDAQ National Market (Symbol ICLR)

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