



Annual Report 2004

2004

**i c o n**

St. Patrick's Day  
Listed on NASDAQ  
Ticker: ICLR

iCON

NASDAQ

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Stockholm, Sweden

Riga, Latvia

Frankfurt, Germany

The Netherlands

France

UK

Budapest, Hungary

Moscow, Russia

Tel Aviv, Israel

Chennai, India

Singapore

Taipei, Taiwan

Hong Kong, China

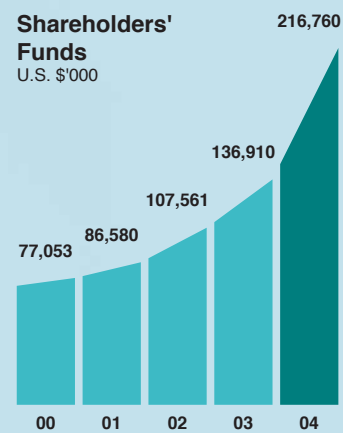
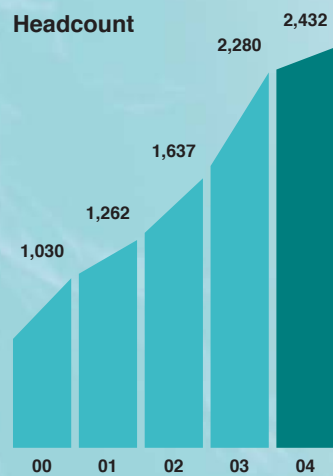
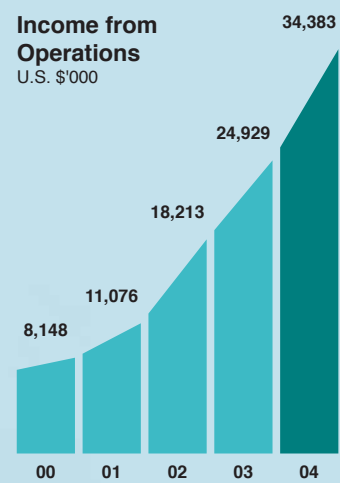
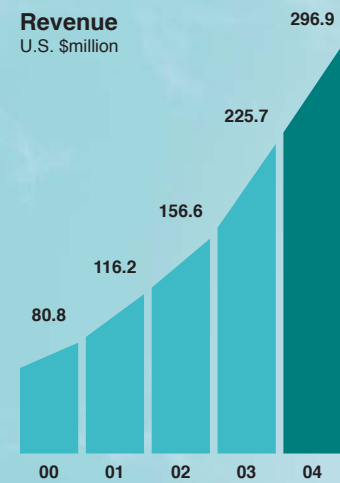
Tokyo, Japan

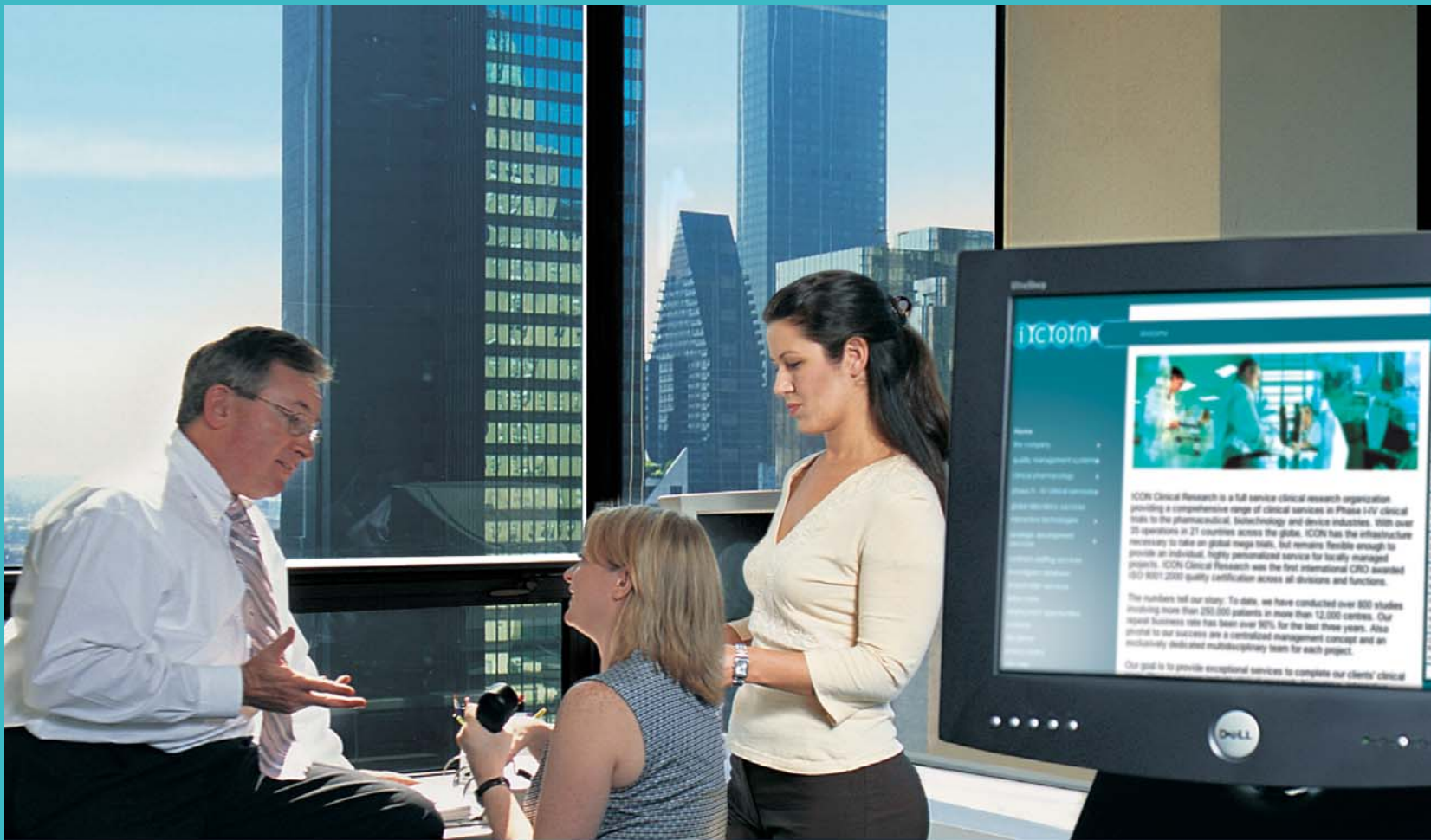
Johannesburg, South Africa

Sydney, Australia

## Financial Highlights

ICON offers a full range of clinical research and related support services to the biopharmaceutical and medical device industries. These services include strategic development and regulatory support, project management and execution of phase I-IV clinical trials, medical and safety support, data management, statistical analysis, central laboratory services for samples and images, interactive voice response systems and bioanalysis.





## Letter to Stockholders

The year to May 31, 2004 was another excellent year for ICON. Sales increased by 32% (21% excluding the impact of acquisitions) and earnings per share were up 25%. Early in the year we successfully completed a secondary offering of shares, which enabled us to improve the liquidity of our stock (with our founders selling some of their considerable holdings in the company), while also allowing ICON to strengthen its balance sheet and position itself to take advantage of further acquisition opportunities in the years ahead.

As the year progressed, the market environment for our services in the US was more challenging than in recent years and this, combined with a spike in our cancellation rates (in no way related to performance), led to lower levels of business bookings than we had expected. We have experienced this type of soft patch in the past and we are therefore confident that the dip is temporary. Conversely, the flow of opportunities in Europe and the Rest of the World was very satisfactory. We achieved excellent growth in these regions throughout the year and we expect this trend to continue through fiscal 2005.

The selection of ICON during the year as a preferred provider to a number of major companies with whom we had, heretofore, only been awarded occasional business, has been a significant development and we anticipate stronger levels of business from a broader number of clients in the future.



Our central clinical trial laboratory, which we consider to be an important strategic element in our service offering, had a difficult year. Despite achieving strong levels of bookings, revenues were slow to grow and it continued to make losses. As part of our commitment to this business, the laboratory moved to new state-of-the-art facilities in Long Island. While this increased the cost base substantially, we believe it will enable the business to provide higher levels of service to our customers and should therefore enhance its competitive position in the long term. We also plan to make significant investments in the laboratory's core IT system over the next two years in order to further improve its service capabilities. The strong margin potential of this business makes us determined to provide it the support it needs to achieve our goals.

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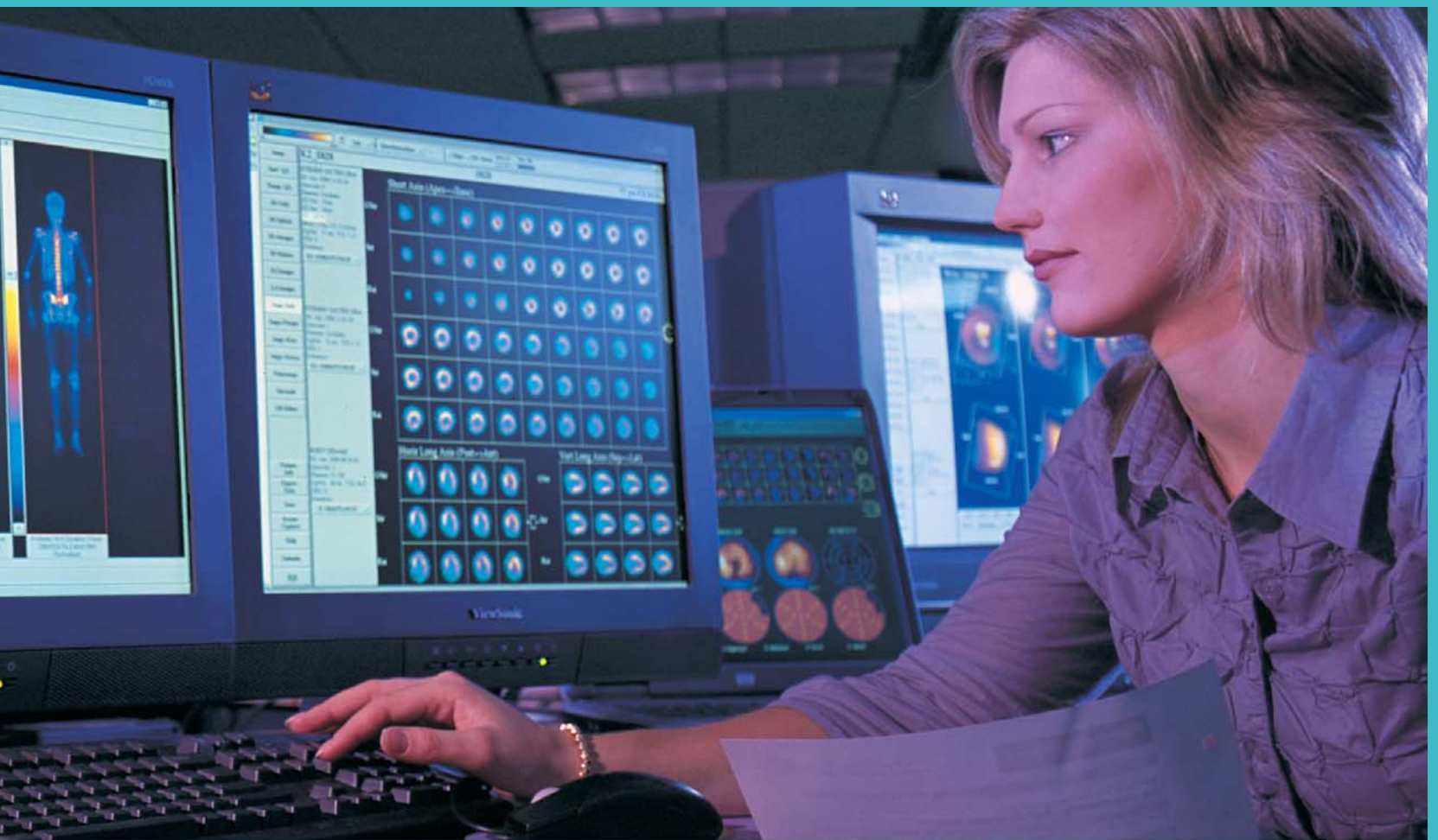


During the year we acquired GloboMax LLC, a company that provides regulatory, pharmacokinetic, consulting, and strategic project management services to companies developing pharmaceutical products. We merged our west coast based, early development support group into GloboMax and now offer strategic drug development services across the US to the pharmaceutical and biotech industries. We also broadened the services of our regulatory consulting division in the UK during the year and will be strengthening the links between these two groups in the year ahead. These businesses represent an important platform for us in contracting and winning business from emerging companies.

Shortly after the end of the year, we acquired a 70% interest in Beacon Biosciences Inc., a Pennsylvania based company, which specialises in the centralised processing of medical images for clinical trials. In several therapeutic areas, such as oncology, CNS, cardiovascular and musculoskeletal, the use of images in clinical research is becoming increasingly prevalent. In partnering with Beacon, ICON intends to participate in the strong growth that is expected to occur in this field, and add Beacon's services to our own full service offering.

Responding to the increasing globalisation of clinical research, we continue to expand across the globe. During the course of the year we opened additional operations in South America, Eastern Europe and Asia. We are investing significantly in Japan to take advantage of the strong growth in outsourced clinical research in that market. We are also well advanced in creating a significant presence in India, initially to support our data management and biostatistics activities. In due course, we will also expand our clinical research activities there.





As outlined in our “Review of Operations”, we continue to invest heavily in technology. However, although electronic data capture (EDC) has been much touted for several years, its use remains limited in later stage clinical trials. Therefore, while ICON has invested in Oracle Clinical EDC, it is also working with a number of specialist vendors to provide this service to clients who require it. As no major winner has yet emerged in this technology field, ICON has adopted a strategy of providing maximum flexibility to its clients, rather than selecting a single technology solution. To date, we have evaluated 12 systems, have partnered on projects with 8 different EDC vendors, and have also run projects using a client's internally developed system.

Responding to the increasing globalisation of clinical research, we continue to expand across the globe.

# ICON has grown from a small European-based CRO to a global CRO, 4th-largest in the world in its phase II-IV core business.

We are of the view that web-based technologies are not necessary or cost effective for every trial – so we often advise clients to use simpler solutions, such as DataFax, or “ICOPhone”, our internally developed IVR system for telephone-based data collection. Our experience in the technology area is broad, and as client demands for different technology solutions increase, we will continue to make further investments, and partner with leading innovators. However, recognising our role as a service provider we will retain our flexible approach.

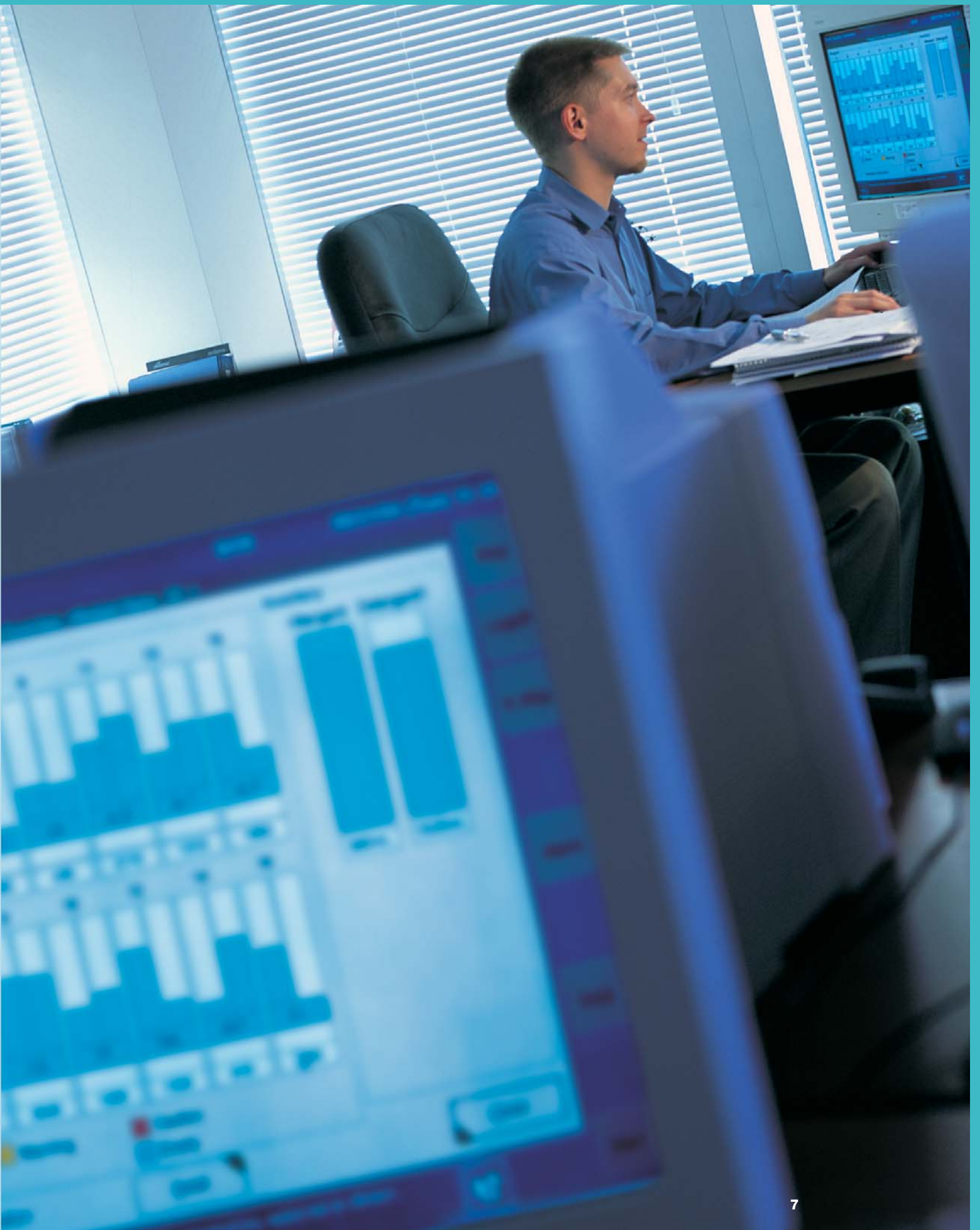
Since the mid-1990s, ICON has grown from a small European-based CRO focused on managing phase II – III clinical trials, to a global CRO, 4th-largest in the world in its phase II – IV core business, with a broad range of services including regulatory and development consulting and support, Phase I, data management and statistical analysis, safety monitoring, technology services including IVR systems, central clinical trials laboratory, and most recently, central imaging laboratory services. We will continue to add complimentary services to our offering while seeking strong organic growth in all our business areas.

We expect fiscal 2005 to be a challenging year for ICON. Growth will slow during the course of the year, but with the many initiatives we have in place and with our expanding customer base we anticipate acceleration again towards the end of the year.

No letter to stockholders is complete without acknowledging that ICON's achievements are based on the work and dedication of its global workforce. We would like to thank them all for their considerable contribution to the ongoing success of our business.

**Dr. John Climax**  
Chairman

**Peter Gray**  
Chief Executive



## Review of Operations

### Overview

ICON had another excellent year in fiscal 2004. Overall, revenues grew 32% to \$297 million, \$25 million of which was contributed by acquisitions. Excluding these, across ICON's regions revenues grew 7% in the US, 51% in Europe and 76% in Rest of the World.

Business flows were good, with new business awards totalling \$383 million in the year compared to \$272 million in the prior year. As a result, total backlog grew from \$352 million to \$464 million, while the value of this expected to be earned in the following 12 months grew from \$221 million to \$238 million. As our backlog increased, the proportion of revenues earned from our top five clients decreased from 51% to 40%, and that from our top ten clients decreased from 68% to 58%. An important development in the year was the increase in the number of clients with whom we agreed preferred provider relationships. While penetration of these new accounts will take time, we expect they will be a significant contributor to growth over the next couple of years.

Operating margins increased from 11.0% to 11.6%. This increase was achieved despite losses of \$3.3 million incurred in our Central Laboratory. The growth in margins arose due to the continued strong improvement in our Clinical Research business, which grew its margins from 12.4% to 13.9%.

### Growth

At May 31, 2004 ICON employed 2,432 people of whom 1,387 were located in the USA, 928 were located in Europe and 117 were located in ICON's Rest of the World region. The acquisition of GloboMax added approximately 80 employees in the USA during the year.

To facilitate this growth in staff, and to support the expanding needs of our clients, ICON continued to open new offices during the year, including Barcelona, Budapest, Hong Kong, and Taipei. Since year end, further offices have been established in Chennai, Mexico City and São Paulo. ICON Labs also moved to new state-of-the-art facilities in New York.

GloboMax, our strategic drug development group, was acquired in the first half of the year and its positioning within ICON is discussed in our "Letter to Stockholders". The integration of GloboMax and our consultancy business on the west coast was successfully achieved within the year, giving us a strong platform to support the growth that is occurring in biotech and specialty pharma business opportunities.

Subsequent to year-end, we acquired a 70% interest in Beacon Biosciences Inc., the strategic rationale for which is also discussed in our "Letter to Stockholders". The integration of Beacon is progressing as this report is written, although this integration will be limited due to the 30% holding retained by its management. We believe the business synergies between Beacon and ICON are potentially significant and we are focusing our integration efforts in the area of combined selling.





Oncology continued to grow as an area of importance to us. The proportion of our Phase II – IV revenues generated in oncology grew from 7% to 10% in the course of the year. Endocrinology and Gastroenterology also grew as a proportion of revenues. These changes in the mix of the therapeutic categories from which we derive our revenues are a function of the pipelines of our clients and of the industry generally, and will be an ongoing feature of our development.

## Systems and Technology

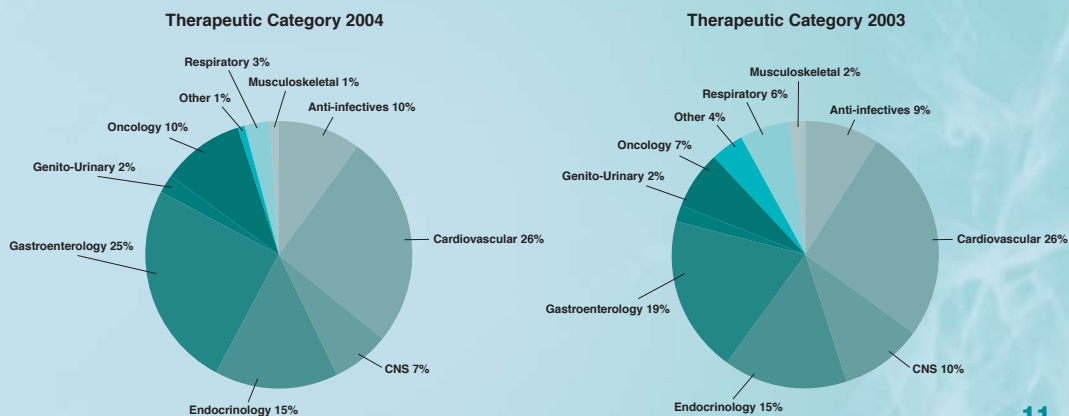
During the year we completed the global implementation of a new system, OptICON, to convert paper-based case record forms from clinical trials to electronic images which link to our core data management system, Oracle Clinical. This technology has improved productivity and allows us to process data from anywhere in the world at any of our data management centres. Our new clinical trial management system, being developed with a software development partner, is currently in beta testing and is expected to be implemented on initial projects in early 2005. We are also implementing a new system to enhance project collaboration globally and are in the final stages of selection for an e-learning tool to enable us to enhance our training and knowledge capture and transfer capabilities. These investments are designed to improve efficiency while enhancing service to our clients and is part of our strategy to reinforce our position as a leader in managing clinical projects, and in delivering high levels of quality and customer service.



## The Future

With R&D spending forecast to grow at over 10% per annum, and outsourcing, with variations from company to company, an embedded part of development strategy in the biotech and pharmaceutical industries, we expect to continue to achieve high levels of growth in the years ahead. Due to high cancellations in the early part of fiscal 2005, growth this year will be a little slower than in recent years, but we anticipate re-acceleration in the second half and have strong confidence in the longer-term outlook.

For our ability to meet demanding client objectives and to provide high quality work, we rely on first class people. We are committed to supporting and developing them, and we thank them for the excellence of the work they have done, and continue to do, to make ICON the CRO that always cares about its clients, their projects and the quality of what we do.



## Directors and Other Information

### Directors

John Climax Chairman  
 Peter Gray Chief Executive Officer  
 Ronan Lambe Director  
 Edward R. Roberts Director †§x  
 Thomas G. Lynch Director †§x  
 Shuji Higuchi Director  
 Bruce Given Director †§x

### Headquarters

ICON plc.  
 South County Business Park  
 Leopardstown  
 Dublin 18  
 Ireland

ICON Clinical Research Inc.  
 212 Church Road  
 North Wales, PA  
 19454 USA

### Secretary

Brian O'Dwyer

### Solicitors - General Counsel

A&L Goodbody  
 IFSC  
 25-28 North Wall Quay  
 Dublin 1  
 Ireland

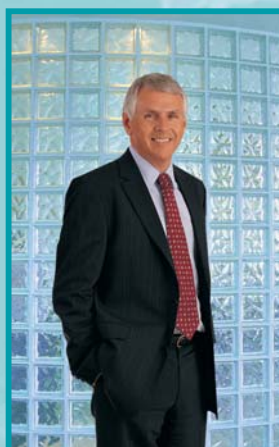
Cahill Gordon & Reindel  
 Eighty Pine Street  
 New York, New York  
 10005 USA

### Auditors

KPMG  
 Chartered Accountants  
 5 George's Dock  
 IFSC  
 Dublin 1  
 Ireland



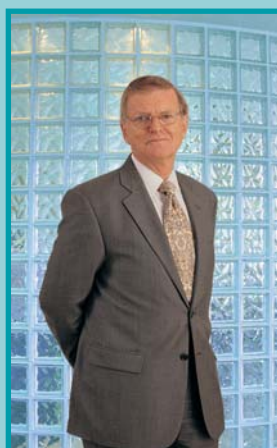
John Climax  
Chairman



Peter Gray  
Chief Executive Officer



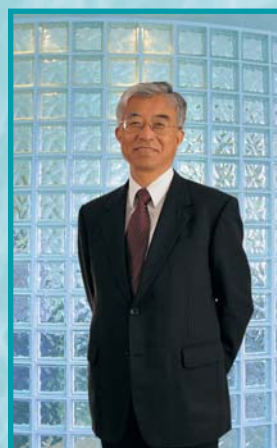
Ronan Lambe  
Director



Edward R. Roberts  
Director



Thomas G. Lynch  
Director



Shuji Higuchi  
Director



Bruce Given  
Director

- † Member of Audit Committee
- § Member of Compensation Committee
- x Member of Nomination 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)

**Depository for ADS**

Bank of New York  
101 Barclay Street  
New York 10286

**Register for Ordinary Shares**

Computershare Services (Irl) Limited  
Heron House  
Corrig Road  
Sandyford Industrial Estate  
Dublin 18

**For further information contact**

Jennifer Martin  
Telephone 1 888 381 7293  
or +353 1 291 2000  
Email [martinj@iconirl.com](mailto:martinj@iconirl.com)  
Website [www.iconclinical.com](http://www.iconclinical.com)