



Annual Report 2001



ICON plc

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the NASDAQ National Market (Symbol ICLR)

Depository for ADS

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ICON offers a full range of clinical research and development services in Phase II-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.

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LETTER TO STOCKHOLDERS

Last year we set out our vision for the future growth of ICON. In brief it was:

- To become one of the top 5 clinical CROs in the world by 2004;
- To achieve internal growth of over 20% per annum, through building on our existing capabilities and adding new geographic locations and therapeutic expertise;
- To strengthen our existing services and to add new services through acquisitions, including Phase I capabilities.

We are pleased with the progress we have made to date and we believe that ICON today is already the fifth largest CRO in Phase II – IV clinical trial management in the world. However, with several competitors close to us in scale, we continue to push for growth so that we are clearly seen as one of the top five players in the market.

ICON achieved an internal growth rate of 25% in the past year as a result of the strong resurgence in outsourcing activities by existing clients and through the development of new clients. In support of this growth we opened three new offices during the year: one in Houston, Texas; one in Stockholm, Sweden and another in Riga, Latvia. As we begin our new fiscal year, plans are well advanced for developing our Tokyo office, which currently only carries out marketing activities, into a fully-fledged clinical development office. We believe the time is right to capitalize on the opportunity which the Japanese market presents, as clinical research in accordance with ICH Guidelines becomes more accepted there.



The depth and breadth of our therapeutic experience also continues to develop. One of the benefits of the growth in drug candidates, which has resulted from biotechnology research, is that a large number of potentially valuable therapies for treating cancer have been and continue to be developed. ICON has been developing its expertise in oncology research to service this growth in opportunities. During fiscal 2001, 5% of our clinical revenues were generated from oncology projects, up from 2% the previous year. We will continue to develop our skills in this area so that we can fully capitalize on the opportunity we believe it will present in the coming years.

ICON's laboratory acquisition, made in the early days of fiscal 2001, has performed well. The business plan for that division, which envisaged a gradual process of winning back the confidence of customers during our first year of ownership, is being met and exceeded. We look forward to sharing further success with the management team of ICON Laboratories.

We continue to look at other acquisition targets that will be culturally compatible with ICON while further enhancing the Company's capabilities. However, with organic growth of over 20% achievable without these, we feel no pressure to make acquisitions unless they make good strategic sense, add additional strengths to our business and can be bought at realistic prices.

As we grow and develop the business, we are constantly reviewing the processes and systems which we use. As a professional services business we have to constantly validate that what we provide is what our clients want. This validation has been particularly important in the last few years as the promise of Internet technology has been explored in the clinical research arena. We believe that this technology will have, over time, a significant impact.



However, we also believe that the operational, behavioral, and regulatory issues which the use of this technology raises, means that adoption will be slow. Whereas change is challenging to large homogeneous organizations, it is immensely more so with a community of hundreds of thousands of individual physicians. Nonetheless, ICON has invested in a number of technologies, some internally developed, some purchased externally, and we continue to explore with our clients ways to execute their projects faster and more efficiently.

Last year we brought some staff skilled in the design and management of Interactive Voice Response Systems (IVRS) for clinical research into the company. This initiative has been very successful and we are receiving very strong client endorsements for our IVRS systems and support. At the same time our "MyICON" project, which will make all ICON applications accessible anywhere, at anytime, to ICON staff and clients, is nearing completion, with rollout well advanced. Client access to project specific portals is also now available. Our next major project will be to significantly reduce or modify paper based processes, using imaging and broadband technology to give access to documents on an "anywhere, anytime" basis. Our primary clinical data management tool, Oracle Clinical, now has a version incorporating a remote data capture (RDC) tool. We are currently validating and migrating to this version, and expect to pilot it in the coming months.

All of these initiatives and systems are necessary to ensure that we are competitive and that we are progressive when our clients want us to be. However, of the many factors contributing to managing projects successfully, one of the most important is to have the right investigators (physicians) participating in the trial. If this is achieved, then patient recruitment will proceed quickly – if not, patient recruitment will be slow and the project will be delayed. While many attempts have been made to date to use the Internet to significantly enhance patient recruitment, these have met with varying success. We will continue to monitor this area to ensure that we capitalize on any opportunities which may emerge. However, our primary focus will remain on choosing the right investigators and working effectively with them.



ICON has a clear understanding of its business and of what its clients want. Accordingly, we have a simple strategy for growth – build on the existing strengths of the company (quality and execution) to capitalize on the underlying growth of the market, while developing our drug development services to win new clients and deepen our relationship with current ones. With the help of our excellent staff, we will continue to execute that strategy in the year ahead.

In conclusion, ICON has enjoyed a very successful year and we look forward to another year of strong organic growth for fiscal 2002. Our main focus for the year ahead is to further develop our data management division, to expand our range of services into Phase I clinical trials, to grow our geographic presence with additional offices in Europe, the United States and the Pacific Rim, and to provide a consultancy service for the burgeoning biotech sector.

Dr. Ronan Lambe
Chairman

Dr. John Climax
Chief Executive Officer

REVIEW OF OPERATIONS

Overview

In the fiscal year to May 31, 2001, ICON continued its strong growth, with revenues up 44% (or 25% when acquisitions are excluded), while operating profits were up 36% (or 30% excluding acquisitions). This growth was achieved against the background of a renewed buoyancy in clinical trial outsourcing, with Request for Proposal (RFP) volumes up significantly as the year progressed, which, in turn, led to increased levels of business wins. By the end of fiscal 2001 ICON had booked business amounting to 80% of our projected revenues of \$138m to May 2002 (i.e. \$110.4m). This compares favourably with 76% of projected revenues of \$110m to May 2000 (i.e. \$83.6m) which had been booked at the same time last year – a 31% increase. Operating margins also improved through the year as staff utilization levels steadily progressed on the back of strong business wins.

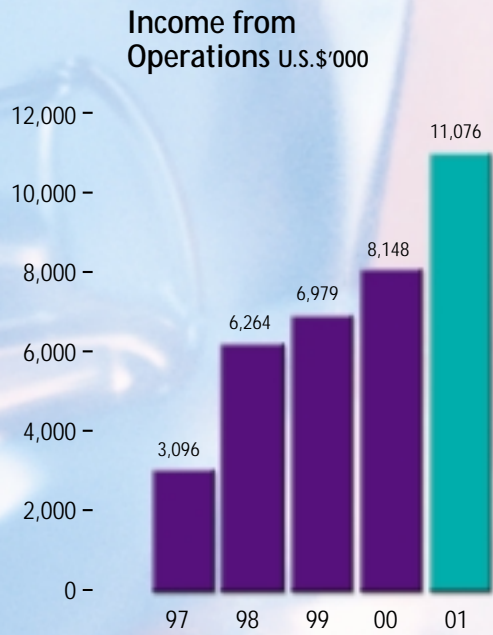
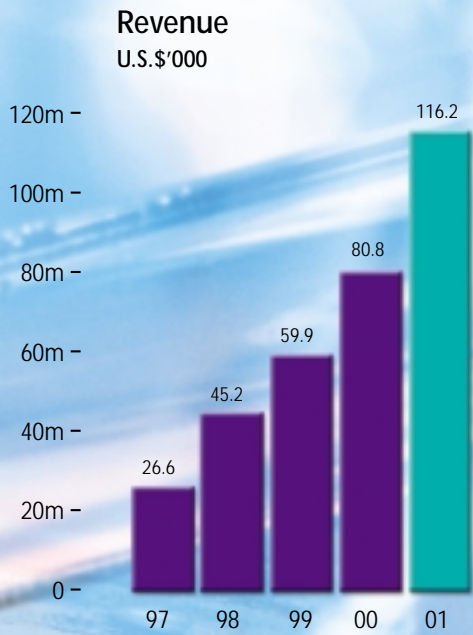
However, all was not smooth. In the first half of the year a major hiring/training program was implemented in the US to support a very large project on behalf of one of our clients. Although the product was withdrawn from the market before the project began, we were able to quickly replace the lost business, with no significant impact on margins or profits. This was a very satisfactory achievement.

During the year, new offices were opened in Riga, Stockholm and Houston. We continued the integration of our earlier acquisitions and in June made our only acquisition of fiscal 2001. This was UCT (US) Inc, a central laboratory subsequently re-named ICON Laboratories Inc. Although initially loss-making, from February 2001 a pattern of new orders exceeding sales each month has been achieved and we anticipate the laboratory making a significant contribution to profits in fiscal 2002.



*“ICON continued its strong growth,
with revenues up 44%, while
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Financial Highlights 2001





Growth

In the course of the financial year our staff numbers increased from 923 to 1262, including those who joined us through acquisitions. To accommodate growth, in addition to the new offices already mentioned, we continued to grow in our existing locations. Additional space was taken in Philadelphia, Nashville, Chicago and Mountain View in the USA and in Dublin, Frankfurt and our two locations in the UK, in Europe.

To support the growth in staff and facilities, we have continued to develop our communications systems and IT infrastructure. One major platform project, which we call the "MyICON" initiative, was developed through the year and is currently being rolled out. MyICON is designed to concentrate ICON's IT systems and IT support into two major hubs worldwide, to which all locations are connected through a Wide Area Network (WAN) and to which all remote or mobile staff can connect through a Virtual Private Network (VPN). All ICON systems will be accessible through these connections. The advantages of such an infrastructure will be: "anywhere, anytime" access to our systems for our staff, and to their data for our clients; reduced support costs through the use of centralized hubs, with connected sites being supported from the hubs; use of "thin client" technology, where appropriate, to further reduce equipment and support costs; and improved communications.

Another major initiative during the year was the purchase of a system designed to integrate and manage our business development, resource management and time tracking systems. This system is expected to go live in late calendar 2001.

Business Development

Fiscal 2001 saw a major improvement in the business environment for our services. Requests for Proposal (RFP) volumes increased significantly, and business wins were very satisfactory, leading to the strong backlog already mentioned in this report. Aided by our acquisitions, our client list grew to over 300 companies, and a number of major Pharma companies who had previously done limited or no work with ICON started to become significant clients. At the same time, biotech companies contributed more significantly to revenues, contributing approximately 12% in total. As a result, while we continued to have two major customers each contributing 19% and 15% of revenues respectively, 90% of revenues came from approximately 30 companies in fiscal year 2001, compared to only 14 companies in fiscal 2000. We expect this trend of client diversification to continue in the current year, albeit at a less dramatic pace.

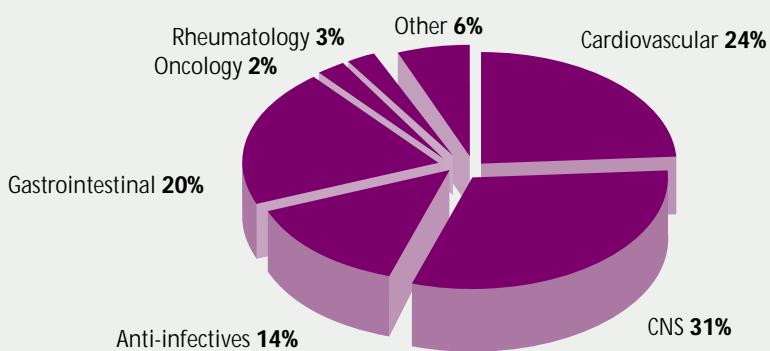


The Future

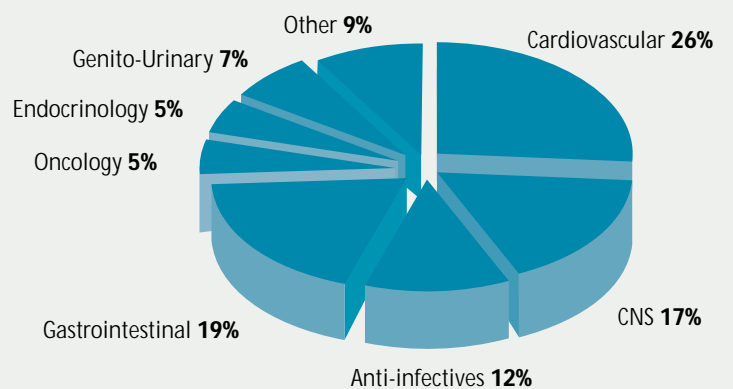
ICON continues to grow, and as it does so, it continues to develop and change. We have many challenging projects planned for fiscal 2002, including the review and revision of all our Standard Operating Procedures (SOPs), the adoption of the new ISO Guidelines for Service Companies, ISO 9001, and the implementation of remote data capture technology on some projects. At the same time there may be further acquisitions made and we would expect to integrate these, while maintaining our quality and customer focus. As our company grows, and as outsourcing becomes a more mature process, we continue to develop our management structures and systems to ensure ICON remains focused on client service and quality.

Revenue by Therapeutic Category

2000



2001



MANAGEMENT DEVELOPMENT

ICON was founded in 1990 by Dr. Ronan Lambe and Dr. John Climax, both of whom had at that time, over 15 years experience in the CRO industry, in laboratory and clinical development environments. As the company grew and internationalized, further experience and management capabilities have been added including: Allan Morgan (1990), Bill Taaffe (1993), Markus Weissbach (1996), Peter Gray (1997), John Hubbard (1999), Sean Leech (1999), Thomas Frey (2000), and Eddie Caffrey (2000). Along with the founders, this group comprises the Global Executive Committee. Reporting to the members of this committee is a further layer of talented and experienced managers. As the Company continues to grow and develop, the pool of experience will be further grown to maintain and enhance ICON's ability to deliver focused, customer responsive, quality services to its clients.

Dr. Ronan Lambe, one of ICON's co-founders, has served as Chairman of the Board since June 1990. Dr. Lambe has over 25 years of experience in the contract research industry in Europe. Previously, Dr. Lambe held senior managerial positions in both the clinical research and laboratory divisions of the Institute of Clinical Pharmacology plc. Dr. Lambe attended the National University of Ireland where he received his Bachelor of Science degree in chemistry in 1959, his Master's in biochemistry in 1962 and his PhD in pharmacology in 1976. On August 1, 2001, Dr. Lambe retired as an executive officer of ICON. However he remains as Chairman of the Group and will continue his involvement with the development of the business from our Japanese clients.

Dr. John Climax, another of ICON's co-founders, has served as a Director and Chief Executive Officer of the Group since June 1990. Dr. Climax has over 25 years of experience in the contract research industry in both Europe and the United States. Prior to this, Dr. Climax held senior managerial positions in both the clinical research and laboratory divisions of the Institute of Clinical Pharmacology plc. Dr. Climax received his primary degree in pharmacy in 1977 from the University of Singapore, his Master's in applied pharmacology in 1979 from the University of Wales and his PhD in pharmacology from the National University of Ireland in 1982.

"ICON was founded in 1990 by Dr. Ronan Lambe and Dr. John Climax... As the company grew and internationalized, further experience and management capabilities have been added"





Dr. Allan Morgan has served as Chief Medical Officer and Managing Director of ICON Clinical Research (UK) Limited since December 1990. Dr. Morgan has 22 years of experience in the pharmaceutical industry and received his medical degree from the Welsh National School of Medicine in 1978. Prior to joining ICON Dr. Morgan was International Director of Clinical Research at Ayerst Laboratories from 1982 to 1987 and European Medical Director of Abbott Laboratories from 1987 to 1989.

William Taaffe has served as President of ICON Clinical Research (US) since November 1993 and in June 2001 was appointed CEO of ICON Clinical Research (US). Mr. Taaffe has over 25 years of experience in the contract research and pharmaceutical industries. From 1990 to 1993, Mr. Taaffe was the Vice President of Business Development at Circa Pharmaceuticals. Mr. Taaffe received his Bachelor of Science degree in 1970 from the University College Dublin.

Dr. Markus Weissbach served as President of ICON Clinical Research GmbH from 1996 to 1999 and currently holds the position of President of ICON Clinical Research (Europe). Dr. Weissbach started his industrial career in 1987 with BASF and was the head of the cardiovascular department of Takeda Euro R&D center from January 1994 to December 1996 and the Associate Director of Clinical Cardiology/Nephrology at BASF Pharmaceuticals from January 1990 to January 1994. Dr. Weissbach received his degree in medicine from the University of Freiburg in 1982.

Peter Gray is a Director of ICON and has served as Group Chief Operating Officer since June 2001. Prior to this, Mr. Gray served as the Chief Financial Officer of the Group from July 1997. Mr. Gray was the Finance Director of Unidare plc., an engineering distribution company based in Ireland, from November 1991 through June 1997. From 1983 to 1989 Mr. Gray held various positions with Elan Corporation plc., including Executive Vice President and CFO. Mr. Gray received a degree in Law from Trinity College Dublin in 1977 and became a chartered accountant in 1980.



Dr. John W. Hubbard has served as Chief Operating Officer of ICON Clinical Research (US) since October 1999. Dr. Hubbard has more than 17 years of experience in pharmaceutical research and development. He has held senior management positions at Clinical Studies, a division of Innovative Clinical Solutions, Ltd., PAREXEL International Corporation and Hoechst Marion Roussel Pharmaceuticals. Dr. Hubbard received a Ph.D. in Cardiovascular Physiology from the University of Tennessee and a B.S. in Psychology/Biology from the University of Santa Clara.

Sean Leech has served as Chief Financial Officer of the Group since June 2001. Previously, Mr. Leech was the Group Vice President of Finance since joining the Company in June 1999. Mr. Leech was Group Financial Controller of Jones Group plc., a shipping, manufacturing and fuel distribution company based in Ireland, from 1997 to 1999. Mr. Leech is an associate member of the Chartered Institute of Management Accountants.

Dr. Thomas Frey served as Vice President of ICON Clinical Operations Europe from January 2000 to June 2001 and is now the Chief Operating Officer of ICON Clinical Research (Europe). Dr. Frey has 14 years of experience in pharmaceutical research and development. He started his career in 1987 with Hoechst Pharmaceuticals. From 1995 to the end of 1999 he was Senior Director of Clinical Development (Europe) at Hoechst Marion Roussel. Dr. Frey received his medical degree in 1980 from the University of Heidelberg.

Edward Caffrey has served as President of ICON Laboratories since June 2000. Mr. Caffrey has over 20 years experience in the contract research industry. Before joining ICON, Mr. Caffrey was Senior Vice President of Clinical Operations at Covance North America. Mr. Caffrey is a fellow of the Institute of Biomedical Sciences in London and holds an MSc. from Dublin City University.

DIRECTORS

AND OTHER INFORMATION

Officers and Directors

Ronan Lambe *Chairman*[†]
John Climax *Chief Executive Officer*[§]
Peter Gray *Chief Operating Officer*
Edward R Roberts *Director*^{†§}
Thomas G Lynch *Director*^{†§}
Lee Jones *Director*[†]

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Tom Finn

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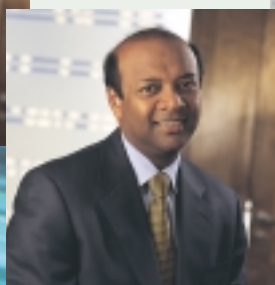
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Auditors

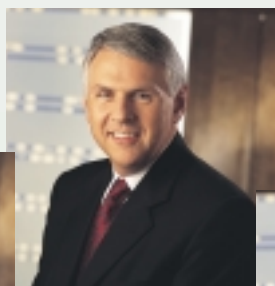
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Chartered Accountants
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IFSC
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Ronan Lambe
Chairman



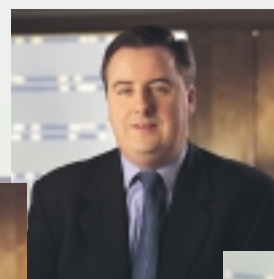
John Climax
Chief Executive Officer



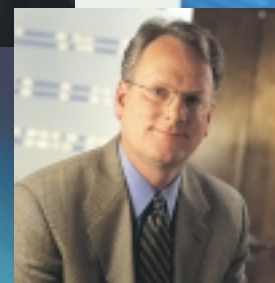
Peter Gray
Chief Operating Officer



Edward R Roberts
Director



Thomas G Lynch
Director



Lee Jones
Director