



Annual Report 2000



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.

Financial Highlights 2000



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Letter to Stockholders

When we wrote to you last year, it was against the background of a major project scaleback in our US business, which had significantly impacted our fourth quarter that year, and was also impacting the first quarter of the year to May 31, 2000. Subsequently, despite a series of further project cancellations and delays experienced across our business, particularly in Europe, we recovered strongly, at a time when most of our competitors were suffering difficulties.

The problems which the CRO industry experienced in 1999 and in the first half of 2000 were, in our view, temporary setbacks on the road to increased outsourcing. As we write this letter, we can report on a very strong flow of RFPs (Requests For Proposals) from our clients during the first seven months of 2000, and several instances of clients who have discussed with us their plans to increase the amount of clinical research which they outsource. We therefore look forward with confidence to the financial year to May 2001.

To capitalise on the continuing opportunity we see in the clinical CRO sector, our vision is to become one of the top five clinical CROs worldwide by 2004. To achieve this goal, we plan to grow at over 20% per annum organically, while at the same time adding acquisitions to strengthen some of our existing services and to introduce new and broader services to our clients. During fiscal 2000, we completed our first three transactions and, in the early weeks of the new financial year, made our fourth. ICON now has over 1,000 employees, 800 of whom are "home grown", and the balance are "new arrivals" who we are pleased to welcome into the ICON family.

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At the time of our IPO in 1998, we indicated that we wished to strengthen our data management and statistical analysis capabilities. Pacific Research Associates, based in Mountain View, California, was an ideal fit with this strategic objective. Today, with data management and statistics operations located in Philadelphia, Chicago, Mountain View and Irvine, we have capabilities and services in this area which are of an appropriate scale to support our entire clinical business in the US. We are now looking for a similar opportunity in Europe and would hope to achieve this objective in the year ahead. Our future target is to derive 25-30% of our revenues from data management and statistical analysis services.

Our second transaction was the acquisition of YRCR Ltd, a regulatory consulting group located near London which, when added to our regulatory consulting capabilities in the US, now enables ICON to offer such services on a US and pan-European basis. We plan to add further consulting expertise to this group, and to further expand our consulting capabilities into earlier stage development.



Our third transaction was the acquisition of an animal health consulting group based in Paris. This group complements our animal health group in Nashville, Tennessee, enabling ICON to offer global services to our growing animal health client base. By using ICON's existing infrastructure and, where practical, our clinical research staff, this initiative in animal health provides us with flexibility in capitalising on the skills of our staff and adds a new area for potential revenue growth.

Our most recent acquisition, that of UCT (US) Inc., a clinical trials central laboratory located in Long Island, New York, enables us to offer clinical trial laboratory services globally to our client base and to the existing client base of UCT. ICON has had a similar laboratory in Europe since the company's inception, but had difficulty growing this business due to its lack of global reach. We are confident that the combination of these two laboratories will provide real synergies and create significant growth opportunities over the next three years.

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“...quality systems will only be effective if they are operated by quality people”

Following these transactions, ICON has become a well developed full service CRO in the clinical development field. Our strategic plan is to further expand our clinical services by the acquisition of Phase I capabilities, by adding new geographic locations and additional therapeutic expertise and by broadening our specialist consulting services. We also plan to add pre-clinical consultancy services and pre-marketing advisory services when suitable acquisition candidates become available.

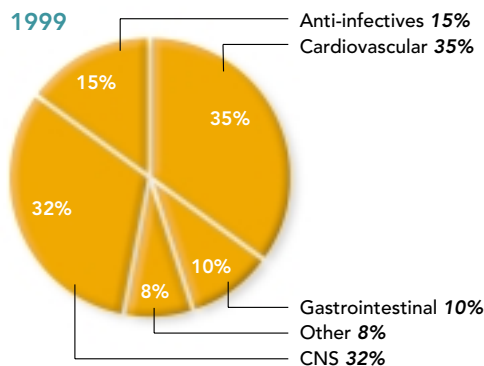
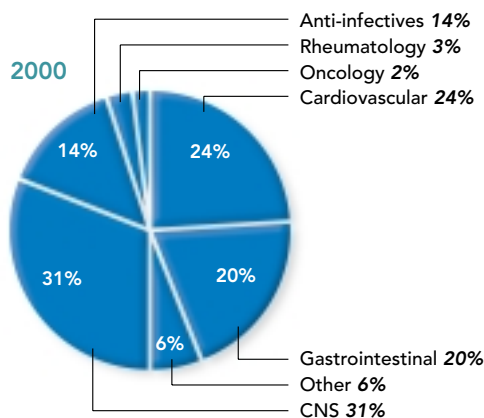
We are pleased that our client base continues to expand and that the volume of ongoing business with our major clients continues to grow. These successes have been achieved primarily by providing services of exceptional quality and by a continuing focus on our clients’ needs. We believe that our company has been successfully inculcated with a quality culture, thus ensuring uniformly high levels of efficiency and consistency worldwide. Without such efficiency and consistency, the CRO industry would struggle to deliver the standard of service rightfully expected by its clients.

Finally, we must add that quality systems will only be effective if they are operated by quality people. We believe that ICON has the best trained, best qualified and most highly motivated staff in the industry. With their continuing commitment, we look forward to further success for ICON in the years ahead.

Dr. Ronan Lambe
Chairman

Dr. John Climax
Chief Executive Officer

REVENUE BY THERAPEUTIC CATEGORY



Review of Operations

Overview

In the fiscal year to May 31, 2000, ICON continued to grow strongly with revenues up 35% while operating profits, excluding merger related costs, were up 17%. This growth was achieved against a background of recovery from a major contract scale-back and general sluggishness in the sector, as evidenced by difficulties experienced by our competitors.



Having suffered a major contract scale-back in the final quarter of fiscal 1999, ICON started fiscal 2000 with a strong order book in Europe and a significant gap in its order book in the US. In the first quarter, the position in the US improved dramatically, with the result that a rapid hiring programme had to be undertaken, while the position in Europe deteriorated as a series of projects were cancelled or delayed. The net result was a rapid return to profitability in the US but a decline in profitability in Europe as the year progressed, which prevented overall margins returning to previous levels. Nonetheless, we achieved margins close to 11% during the second half of the year.

During the year, ICON opened a number of new offices in order to take advantage of global business opportunities and to continue to implement the company's strategic development. Later in the year, we completed a merger and a number of acquisitions each of which brought additional depth and geographic spread to ICON's existing services. As these were our first transactions, we focused on ensuring they were fully integrated into ICON's operations. With our goal of maintaining high quality service on a consistent basis globally, the successful integration is a key objective for us.

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Merger and Acquisition Integration

In the case of Pacific Research Associates, our California based specialist statistics, data management, medical and regulatory merger, the four principals became Vice Presidents of specific functions in ICON’s US operations when the transaction was completed. Each of them took responsibility for the relevant ICON staff in other offices as well as those within their existing operations. At the same time, the office connected to ICON’s wide area network, installed our communications platform and integrated into ICON’s global financial administration systems. To date the integration has worked well, and we continue to refine the implementation plan as we get feedback from clients and staff.

YRCR, the regulatory consulting group located in Henley, UK, has remained as a stand alone unit within ICON Europe providing regulatory consulting to their existing client base in addition to servicing the regulatory requirements of ICON’s clients. However, within two months of the transaction, YRCR’s financial administration had been integrated into ICON’s global financial system while their IT systems have been standardised to the same platform as ICON. In the coming year, YRCR will relocate to a new office close to its current location which will become ICON’s second office in the UK from which a broad range of services, including clinical research and data management, will be provided. When this is accomplished the integration of YRCR with ICON will be complete.



Protocole S.A., the French animal health consulting group which we acquired in March, moved into our existing offices in Paris at the end of April and are now administratively, financially and electronically integrated with ICON's systems worldwide.

Since its acquisition in June, UCT, which has now been renamed ICON Laboratories, has been working with our laboratory in Dublin to standardise their technology and systems. By the end of August 2000, we expect the two labs to be operating to harmonised standards, using identical systems and equipment. The management of ICON Laboratories has been integrated under Eddie Caffrey, who joined ICON in January 2000.

Organic Growth

While these transactions were taking place, our business continued to grow organically. In the US, our Nashville, Philadelphia, Chicago, San Bruno and Irvine offices all expanded during the year. Although growth in Europe was more modest, nevertheless, a new office was opened in Amsterdam, and Tel Aviv became an established ICON location. In the Far East, our Australian office continued to perform well while our new office in Singapore grew steadily through the year and was successful in winning a number of stand alone projects in the region.

As we move into fiscal 2001, we now have an operation in South Africa and plan, based on current business indications, to open further satellite offices in Scandinavia and Eastern Europe. We also expect to move to a new purpose-built facility in Frankfurt, significantly increasing our capacity in Germany and to a second office in the UK, as mentioned earlier. In the US, we will move to larger premises in Chicago, and expect to take additional space in Nashville and San Francisco, as the company's strong growth continues.



“As we move into fiscal 2001, we now have an operation in South Africa and plan, based on current business indications, to open further satellite offices in Scandinavia and Eastern Europe”





Clients

At the beginning of fiscal 2000, ICON had a client list of approximately 70 clients. At the end of the financial year, following successful organic business development activities and with our mergers and acquisition activity, our client list exceeded 200 clients. We have already had success in cross selling services and we expect this activity to grow in the years ahead.

IT Systems

Throughout the year, ICON continued to develop its IT systems and infrastructure. As the financial year came to a close, we initiated a major project to web-enable ICON's internal applications to provide global access for staff and clients from any location. We expect this project to be complete by the end of fiscal 2001. At the same time, we are planning the introduction of a number of new "off-the-shelf" applications, some of which are designed to enhance ICON's service offerings, and some to ensure we manage our business and resources as efficiently as possible. After 10 years of operation, with revenues set to exceed US\$100 million in the year ahead and with over 1,000 employees, ICON is one of the major global players in the CRO sector. Through practical and cost effective IT investments, we expect to continue to provide the highest level of quality and service to our clients and to continue to successfully grow our business.

The Future

In spite of some setbacks over the past year, we believe that outsourcing to the CRO industry will continue to grow strongly. As the recent consolidation within the major pharma industry beds down and in view of the strong business flows occurring in our core business, we expect fiscal 2001 to be another year of growth for ICON.



A Day in the Life of ICON...



Heike Degenhardt

Clinical Trial Management ICON Germany

Heike arrives at the office after a 2-day on-site assessment visit in Barcelona with Miguel Ruda ICON France.

- **8:15 am:** Responds to emails from management and the study team. Reviews monitoring reports and contact record forms from the "Global Cancer" study. Completes the 'on-site' assessment report and forwards it by email to Miguel for review and comment.
- **10:10 am:** Finalises agenda and attendee list for videoconference with client and weekly teleconference with ICON Europe Oncology team.
- **10:43 am:** Reviews and signs off query forms from clinical team and then addresses and authorises approval of administrative tasks (travel forms, expenses, investigator payment requests etc.).
- **12:00 pm:** Meets team to check the progress of the study against the plan and to hold their weekly teleconference with other offices. The focus is on protocol violations, laboratory and data management issues.

The team agrees to have an in-house 'working lunch'.

- **2:35 pm:** Reviews and authorises payment for all incoming invoices over the past week and calls Nathalie Florent *ICON Laboratories, Dublin* for clarification of a lab invoice received.
- **3:05 pm:** Reviews the latest Data Management Status Report and Query Report from Rebecca Goodrich *Clinical Data Monitor II, ICON Irvine* with the lead CRA. Emails Rebecca to request clarification on some unresolved issues.
- **3:30 pm:** Miguel calls in from site with a question in relation to drug accountability.
- **5:45 pm:** Calls Linc Bynum *Medical Consulting, ICON Mountain View* to discuss timelines in "Global Oncology" project.
- **6:00 pm:** Receives call from Nathalie about alert values discovered in the lab. Agrees to discuss with Miguel for immediate follow-up.

Miguel Ruda

Clinical Research Associate ICON Paris, France

- **8:00 am:** Miguel takes a flight from Paris to Madrid and on by taxi to the hospital for a meeting with his investigators.
- **10:00 am:** Over coffee discusses with the investigators the problems the site has been having since the last visit.
- **10:30 am:** Reviews some of the problem case report forms (CRFs), and discusses these with the investigators. Reviews completed CRFs, comparing them to the patients' medical history notes.
- **12:30 pm:** Miguel meets a co-investigator over lunch at the hospital canteen.



- **1:00 pm:** Concerned about a medical event that has occurred for a patient, he decides to phone the ICON safety department. After discussion they decide the issue isn't urgent but needs to be closely followed.
- **3:30 pm:** Visits the hospital pharmacy responsible for dispensing the drug for the study to review drug dispensing forms. Notices a problem which needs to be resolved immediately and telephones his project manager Heike Degenhardt *ICON Germany* to discuss.
- **4:30 pm:** Issues found during the day are discussed with the investigators, and tentative dates are discussed for the next visit.
- **6:00 pm:** Back to the airport...



Rebecca Goodrich

Clinical Data Monitor II ICON Irvine, CA

- **8:30 am:** Reads email from Heike Degenhardt *ICON Germany* requesting clarification on the Query Report for the cancer study. (Rebecca is responsible for completing the initial “log in” and entry of Case Report Forms for this study).
- **9:30 am:** Trainees from *ICON Singapore* arrive for 2 months in-house training.

Rebecca introduces the trainees to the Oncology Data Manager and team over coffee.
- **By 10:30 am:** Rebecca begins the training on data entry and handling conventions. By 12:15 the trainees are reviewing the case report forms for their first patient.

The Oncology data team go to lunch together.
- **2:10 pm:** Rebecca reviews the query resolution updates that arrived from Heike this morning.
- **3:40 pm:** She performs edit checks and reviews the edit discrepancy reports to determine what needs to be queried, based on the data in the CRF.
- **5:05 pm:** Rebecca finalises the edit discrepancy reports, updates the status reports and forwards them by email to Heike for review.
- **6:00 pm:** Brings trainees out for dinner on their first night in California.

Mitchell J. Rosen

Biostatistician *ICON Philadelphia*

- **8:30 am:** Prepares for a meeting with “Client A” to discuss the statistical analysis plan for an upcoming study.
- **9:25 am:** Client arrives at the office. Following a quick tour of the building they settle down for the meeting. The statistical methods, analysis populations, and table formats to be used in the study are discussed in detail. Mitchell agrees to finalise the document by the end of the week.
- **12:30 pm:** Lunch with the client before they leave.
- **1:40 pm:** As Biometrics Team Leader for an ongoing Cardiovascular study, Mitchell drafts an agenda for next week’s team meeting. Data formats and protocol violations are to be discussed with data management and the clinical project manager respectively.



- **2:25 pm:** Discusses an upcoming integrated clinical/statistical report due for a client with one of the statisticians in his team. Calls the clinical project manager to discuss a problem with interpreting some clinical data.
- **3:40 pm:** Reviews his notes from the morning meeting and starts to work on the final draft of the statistical plan.
- **4:10 pm:** Receives a call from business development requiring his input on a proposed study received from a client. This takes priority, the draft plan will have to wait until tomorrow.
- **7:00 pm:** Emails his comments to business development before finishing up for the day.

Linc Bynum

Medical Consulting ICON Mountain View, CA

Linc arrives in the office at 8:00 am for the quarterly staff breakfast meeting.

- **8:45 am:** Accepts call from Heike Degenhardt ICON Germany to discuss the timelines for finalising the "Global Oncology" protocol.
- **8:55 am:** Reviews the draft "Global Oncology" protocol, then discusses it with the medical team. Responsibilities and deadlines are assigned.
- **9:30 am:** Joins the video conference for the study start up meeting for the upcoming "Global CNS" study.



- **12:15 pm:** Joins "B Pharma" for a business lunch to discuss product development strategies for a Phase III study in diabetes.
- **2:30 pm:** Reviews a "Request for Proposal" received from Business Development and assigns costs for the medical writing component of a program of three asthma studies.
- **3:40 pm:** Addresses action points from this morning's meeting on the "Global CNS" protocol. Forwards his comments to the medical team and begins developing the final protocol.
- **6:00 pm:** Before he leaves, Linc forwards the draft "Global Oncology" protocol to Heike by email.



Nathalie Florent

Laboratory Technician ICON Dublin, Ireland

- **9:00 am:** Nathalie conducts maintenance of lab instruments and prepares reagents and controls for the day.
- **9:30 am:** Patient samples arrive by courier, are registered and checked. Calls investigator in Poland to confirm patient details on some sample tubes.
- **10:30 am:** Internal quality control is performed on the automated biochemistry analyser. The results are acceptable.

- **11:00 am:** Runs the analyser for routine safety analysis on the verified patient samples.

Between analytical runs, Nathalie has lunch at the ICON canteen.

- **1:35 pm:** Receives a query from Heike Degenhardt Project Manager, ICON Germany regarding a lab invoice and follows this up.
- **2:00 pm:** Performs some specialised tests on an ongoing HIV study while routine safety analyses are ongoing.
- **3:30 pm:** Calls the ICON laboratory in New York to discuss issues regarding standardisation of laboratory equipment and procedures.
- **4:00 pm:** Reviews results from the day and faxes alert values to two hospitals in Spain participating in the cancer study.
- **5:00 pm:** Calls Heike to discuss the alert values, who agrees to bring them to the attention of Miguel Ruda Clinical Monitor, ICON France for immediate follow up.

Zoe Robertson

Regulatory Consultancy ICON Henley, UK

- **8:15 am:** Sends a reply email to "Client C" who has requested that ICON prepare and submit a Type I variation application. Plans the timelines and work required for the submission of this application.
- **10:10 am:** Prior to teleconference with "Client D", she gathers her team to review the draft clinical expert report (written by the medical team in ICON UK) and discuss the relevant issues.

During the teleconference, Zoe is given a fax from "Client E" which necessitates urgent response to the French Medicines Agency.

- **11:40 am:** Zoe being a member of the "E" Project team, is aware of the status of this project. She sends the fax to our French advisor for careful checking and immediate response.

During lunch Zoe conducts a dry run for her presentation tomorrow to "Client F" on "Regulatory Requirements in Asia and Eastern Europe".

- **2:15 pm:** Works on an orphan drug application dossier. Starts from published papers and reports supplied by "Client G". Begins writing in line with guidelines relating to new legislation.



Leland Vickers Animal Health Director ICON Nashville, TN

- **8:30 am:** Leland responds to a number of emails received, including a proposed teleconference with Dr. Marie-Paul LeFay Director for animal health in ICON Paris.
- **9:30 am:** Joins the teleconference with the animal health division in Paris to discuss potential upcoming global studies.
- **11:30 am:** Receives a call from one of the monitors in the cardiovascular study on cats. They discuss the issue of performing an autopsy on a cat that has died during the study.
- **12:00 pm:** Calls a couple of other veterinarian clinics participating in the study to discuss the autopsy issue and prepares a memo for circulation.
- **1:00 pm:** A light lunch.
- **1:30 pm:** Receives a call from a sponsor proposing to conduct an osteoarthritis study in dogs. The general study design is discussed and the sponsor agrees to send Leland the outline of the study for a cost proposal.
- **2:30 pm:** Reviews draft of a new standard operating procedure, which includes procedures for pet ownership.
- **5:30 pm:** Leaves the office for the airport, to be at a meeting in an Animal Health Institute the next day...



- **3:30 pm:** Receives comments back from French advisor, drafts a response and sends the document to "Client E" for comments.
- **5:30 pm:** Calls "Client E" to discuss the draft response sent earlier. As all are happy with the draft, it is faxed to the French Medicines Agency.

Catch 7:00 flight from Heathrow to Copenhagen to attend tomorrow's presentation to "Client F".

Directors and Other Information

Officers and Directors

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

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§ Member of Compensation Committee



Ronan Lambe
Chairman



John Climax
Chief Executive Officer



Peter Gray
Chief Financial Officer



Edward R Roberts
Director



Thomas G Lynch
Director

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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