

Annual Report 2006



A Symbol of Excellence

**Listen.  
Think.  
Achieve.**

**We listen before we act.**

We connect with our clients to offer highly flexible and responsive services that meet their needs.

**We think hard about everything we do.**

Across the spectrum of Phase I-IV development services we're known for our superior quality, service excellence and unique project management.

**We work to achieve results.**

Our dedicated teams have the experience and knowledge to solve the challenges that arise during any development project. We have successfully conducted thousands of projects on a worldwide basis across all therapeutic areas.



# Global Reach. Local Knowledge.

**52 locations in 30 countries with trials managed in over 60 countries.**

We are one of a small group of organisations with the capability to conduct clinical trials and development projects on either a local or global basis.

## Europe

- Amsterdam, The Netherlands
- Barcelona, Spain
- Budapest, Hungary
- Dublin, Ireland
- Eastleigh, UK
- Frankfurt, Germany
- Manchester, UK
- Marlow, UK
- Milan, Italy
- Moscow, Russia
- Novosibirsk, Russia
- Paris, France
- Riga, Latvia
- Stockholm, Sweden
- Tel Aviv, Israel
- Vilnius, Lithuania
- Warsaw, Poland

## North America

- Baltimore, USA
- Chicago, USA x2
- Houston, USA
- Irvine, USA
- Montreal, Canada
- Nashville, USA
- New York, USA x2
- Philadelphia, USA x2
- Raleigh, USA
- Salt Lake City, USA
- San Antonio, USA
- San Diego, USA
- San Francisco, USA x2
- Tampa, USA
- Wilmington, USA

## Asia & Australia

- Bangalore, India
- Bangkok, Thailand
- Beijing, China
- Chennai, India
- Hong Kong, China
- Seoul, Korea
- Singapore, Singapore
- Sydney, Australia
- Taipei, Taiwan
- Tokyo, Japan

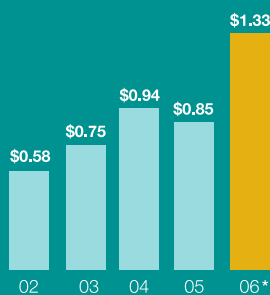
## South America & Africa

- Buenos Aires, Argentina
- Johannesburg, South Africa
- Lima, Peru
- Mexico City, Mexico
- Santiago, Chile
- São Paulo, Brazil

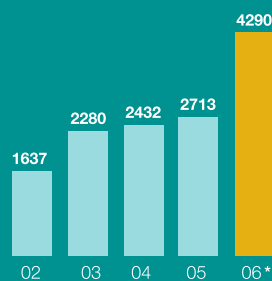


# Our Financial Highlights

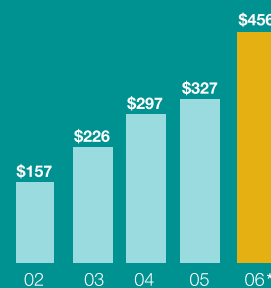
Earnings Per Share Growth  
U.S. \$



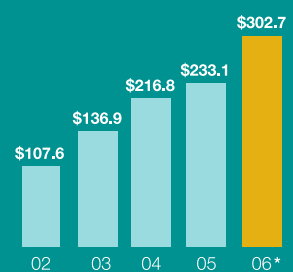
Headcount



Net Revenue Growth  
U.S. \$million



Shareholders Funds  
U.S. \$million



We operate across all major therapeutic areas. We focus on the delivery of data, on or ahead of schedule. We have the resources, systems and infrastructure to take on both global mega trials and localised studies. We are flexible and set up to provide individual, highly personalised services. We thrive on achievement and are constantly in the pursuit of excellence.

## We are no ordinary company.

\*06 figures 12 months to December 31st  
All other years 12 months to May 31st

**The significant upsurge in Pre-Clinical and Phase I activity, which has been evident in the market for over five years and which is continuing, began to flow into the Phase II and Phase III areas in late 2005...**

## Letter to Stockholders

It is a pleasure to write to you at the end of a year in which ICON recovered from the challenges of 2005 and accelerated again to very high levels of growth. With earnings per share, on a like for like basis, up 69%, which contributed to a share price increase of 84% since January 1st 2006, our market capitalisation now exceeds \$1 billion for the first time.

Our growth has been underpinned by strong market conditions. The significant upsurge in Pre-Clinical and Phase I activity, which has been evident in the market for over five years and which is continuing, began to flow into the Phase II and Phase III areas in late 2005 and we anticipate that this will continue for some time to come. One indicator of the growing pipeline is an increase of over 30% in the number of active INDs with the FDA since 2000. At the same time, strong funding has been flowing to biotech and specialty companies. Less than \$20 billion was channelled to such companies in 2001, but this has grown to over \$45 billion in 2006. As a consequence, the number of companies conducting clinical projects grew from approximately 1,100 in 2000 to over 1,700 in 2004, and this number continues to expand. The increase in compounds being developed and companies developing them has created a very positive environment for CROs like ICON. This contributed to the significant increase in the value of RFPs we received last year and the acceleration of revenue growth to over 30% for 2006.

Simultaneously, the regulatory environment continues to tighten. Safety concerns about new and existing products are leading to more trials being requested by regulatory agencies and larger patient numbers in such trials. In addition, there is growing pressure to conduct post-marketing safety surveillance studies on all products to ensure that unforeseen side effects are identified early in the commercial life of a compound, rather than only being identified much later after millions of prescriptions have been written. In 2006 ICON acquired Ovation Research, a specialist in outcomes and registry trials, to expand our capability in serving the needs of our clients as this market opportunity develops.

One consequence of the increasing number and size of trials is the difficulty in recruiting sufficient numbers of patients. To overcome this, trials are increasingly being conducted across the globe in regions where there are large 'treatment naive' patient populations. This creates a further opportunity for CROs as our clients are not naturally geared to conducting research in these areas. During 2006 ICON opened 8 new offices in 3 new countries and significantly expanded our staff numbers in places like Latin America, China, Eastern Europe and India.

During the year we made significant progress in our quest to penetrate the Japanese market. By the end of the year we had over 50 operational staff and were working on 7 projects for a variety of clients. While we continued to make losses, we expect to break even in 2007 and see Japan as a major strategic opportunity, both as a market in its own right and in terms of building relationships with Japanese companies who subsequently develop their compounds in Europe and the United States using CROs.

**Trials are increasingly being conducted across the globe in regions where there are large 'treatment naive' patient populations. This creates a further opportunity for CROs as our clients are not naturally geared to conducting research in these areas. During 2006 ICON opened 8 new offices in 3 new countries and significantly expanded our staff numbers in places like Latin America, China, Eastern Europe and India.**

**A satisfying feature of 2006 was the turnaround we achieved in our central laboratory business and, less publicly, in our contract staffing business. Having now returned to profit in both, we intend to invest further in these businesses to expand their capacity and footprint.**

**/cont.**

After many years of promise, electronic data capture (EDC) finally began to gain momentum as a tool in clinical trials. Clinical research is highly regulated and the industry is very conservative. These factors have militated against the adoption of innovative technologies in the past. However, web based systems have made EDC systems easier to implement at the physician site level, which has always been the key rate limiting factor. By the end of 2006 ICON had completed 25 EDC studies and had a further 53 ongoing, involving over 2,500 sites and 25,000 patients.

At the beginning of the year, our three early phase development businesses were merged into a new division called ICON Development Solutions. The rationale for creating this single division was to ensure that our clients could seamlessly access our regulatory expertise as they planned their first clinical studies, execute these with our Phase I and Phase IIa staff and have the data from these analysed by our bioanalytical laboratory and pharmacokinetic analysts. We intend to continue to build this group so we can capitalise on the growing number of compounds in early stage development as outlined above.

A satisfying feature of 2006 was the turnaround we achieved in our central laboratory business and, less publicly, in our contract staffing business. Having now returned to profit in both, we intend to invest further in these businesses to expand their capacity and footprint.

Our vision for ICON is to continue with the primary strategy of organic growth using our existing platforms. We believe however, that further acquisitions in additional service areas, or in areas where we are currently sub scale, can strengthen the business and better position us to take advantage of the strong market. We expect our clients to gradually embrace more full service outsourcing i.e. the outsourcing of complete projects rather than discrete services, and our mission is to ensure ICON can meet these needs and deliver real added value through effective integrated project management services.

ICON achieved outstanding growth in 2006 and has seen staff numbers increase from 3,000 to approximately 4,300. Achieving this growth whilst still delivering excellent service to our clients has only been possible through the dedication and professionalism of all our staff. We would like to express our appreciation of them on behalf of you, our shareholders.



**Dr. John Climax**  
Chairman



**Peter Gray**  
Chief Executive Officer

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**We're flexible, knowledgeable and experienced in delivering outsourced development services to the global pharmaceutical, biotechnology and medical device industries. We're one of the few organisations who consistently provide excellence in service delivery. Our solutions help our clients to establish the benefits of new drugs or treatments.**

**We specialise in the strategic development, management and analysis of programmes that support clinical development - from compound selection to Phase I-IV clinical studies across our 5 divisions based in 52 locations throughout 30 countries.**

## **Our global services are offered through the expertise of our 5 international divisions.**

### Central Laboratories

ICON Central Laboratories provides central laboratory testing and associated services dedicated exclusively to clinical trials. Our comprehensive service portfolio ranges from safety testing and biomarkers to custom flow cytometry.

CAP accredited, ICON Central Laboratories works according to globally recognised processes that conform to the ISO 17025 certification, to consistently deliver quality data to clients, investigators and patients.

### Clinical Research

ICON Clinical Research specialises in the planning, management, execution and analysis of Phase IIb-IV clinical trials, from small studies to complex, multinational projects.

Our services can be deployed on a stand alone basis or as part of an integrated "full-service" solution. Our therapeutic, regulatory and operational expertise underpins a reputation for the quality execution of clinical studies. We were the first CRO to be awarded ISO 9001:2000.

### Contracting Solutions

ICON Contracting Solutions has over 14 years experience of providing contract and permanent staffing solutions to leading pharmaceutical and biotech companies.

We are staffed by clinical research professionals who apply their knowledge of clinical trials to deliver the most effective staffing solutions for clients, leading to extremely high contract completion and renewal rates.

### Development Solutions

With expertise in clinical pharmacology, regulatory affairs, pharmacokinetics, pharmacometrics, biopharmaceutics and bioanalytical, ICON Development Solutions specialises in the strategy, management and execution of product development and early phase clinical development.

Our global team has the operational flexibility to meet sponsor's specific needs, whether these are driven by time constraints, expertise required or location.

### Medical Imaging

ICON Medical Imaging provides imaging based product development solutions, including independent imaging review and database delivery to regulatory authorities. We ensure medical imaging is successfully integrated into clinical trial design, implementation and analysis.

We have the flexibility and experience to lead an imaging trial independently or jointly with a sponsor's in-house or preferred imaging team.



**ICON Services Include:**

- Bioanalytical
- Clinical Pathology
- PK Analysis
- Protocol Design
- Regulatory Affairs Strategy/Submissions

Phase I study conduct including:

- First in Man
- Phase I Patient Studies
- Bioequivalence
- Special Population Studies
- Proof of Concept Studies



## Phase I

**Phase I clinical trials are primarily concerned with assessing a drug's safety and tolerability in man. This initial phase of testing in humans is usually done in a small number of healthy volunteers (20-100) and is designed to determine what happens to the drug in the human body - how it is absorbed, metabolised and excreted. However, additional regulatory requirements include studies evaluating drug to drug interactions, effects of food on absorption and metabolism, special populations such as the elderly, renally-impaired, or hepatically-impaired subjects, and other studies targeted to better understand the characteristics of the drug before broad exposure to patients.**

In modern drug development, it is increasingly critical that companies decide quickly whether to proceed with their development strategies or to abandon further development based on safety, tolerability, pharmacodynamic and pharmacokinetic properties on biologicals and new chemical entities (NCEs).

ICON has extensive experience in the design, implementation and interpretation of early phase clinical pharmacology studies in all major therapeutic areas. We have one of the world's most innovative and internationally recognised Phase I units.

This clinical pharmacology team implement the traditional pharmacokinetic "First in Man" studies as well as cutting edge pharmacodynamic assessment to assess the potential efficacy of biologicals and NCEs prior to Phase II studies in patients.

Our broad experience with biologicals and novel NCEs also enables us to identify and develop potential surrogate markers and models for use in later clinical development phases. We also provide extensive product development consultancy services.

Once the biologicals and NCEs have been extensively studied in normal volunteers they can be introduced into the target patient population.

**Excellence in Action**

ICON Development Solutions has conducted over 1,000 clinical studies, from Phase I healthy volunteer studies to Phase II patient studies.

ICON Medical Imaging experts have conducted over 250 Phase I-IV clinical trials.

ICON Development Solutions expertise in Pharmacokinetics and Biopharmaceutics, extends to over 300 PK projects and 80 Population PK and PK/PD analyses and reports.

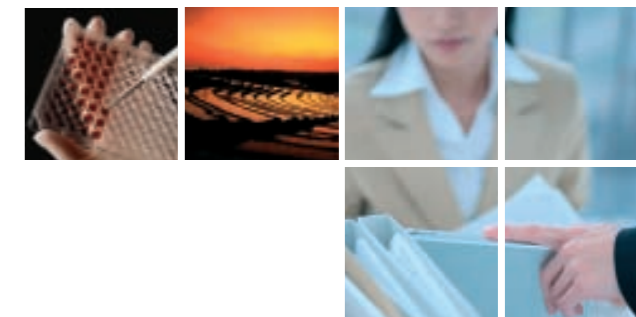




**ICON Services Include:**

Biostatistics and Programming  
Central Laboratory Services  
Clinical Trials Management/Monitoring  
Contract Staffing  
Data Management  
IVRS

Medical Affairs  
Medical Imaging  
Medical Writing and Publishing  
Product Development Consulting  
Proof of Concept Studies  
Regulatory Affairs



## Phase II

Once a drug has been shown to be safe, it must be tested for efficacy. Phase II studies are designed to evaluate the short-term effectiveness of biologicals and NCEs and to enhance the understanding of its dose-response and safety profile in patients. Identifying the right patient population is essential when entering into this phase of drug development, which may last from several months to two years, and involve up to several hundred patients.

Most Phase II studies are randomised trials. One group of patients will receive the experimental drug, while a second “control” group will receive a standard treatment or placebo. Often these studies are “blinded” with neither the patients nor researchers knowing who is getting the experimental drug. In this way, the study can provide the pharmaceutical company and FDA with comparative information about the relative safety of the new drug and its effectiveness. Only about one-third of experimental drugs successfully complete both Phase I and Phase II studies.

ICON's global feasibility group has conducted hundreds of feasibility assessments for our clients across all therapeutic areas. This focused expertise reduces the risks inherent in patient identification and recruitment through systematic evaluation of the clinical investigator site, standard of care and the regional distribution of centres to meet the objectives of the study protocol.

Regulatory agencies often require an end of Phase II meeting and review of the data before companies can expand their development programme into larger (increasingly global) Phase III studies.

These meetings help companies to define protocol efficacy and safety measures as well as total patient exposure to the NCE. From these meetings, a final Phase III development plan is agreed upon, and Phase III trials can begin.

**Excellence in Action**

ICON Medical Imaging has conducted over 75 oncology Phase II and III studies.

ICON Central Laboratories has supported thousands of clinical investigators in over 60 countries in virtually every therapeutic area.

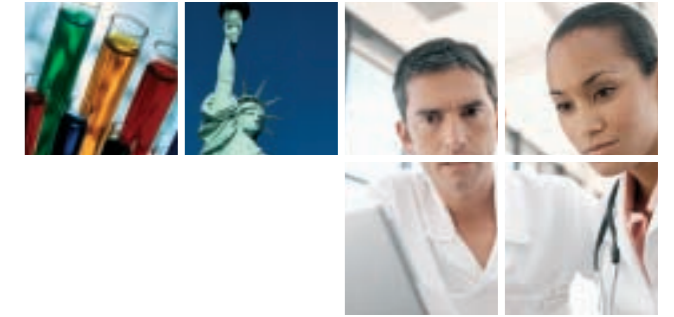
Almost 95% of contractors supplied by ICON Contracting Solutions complete their assignments and 80% are renewed.



**ICON Services Include:**

Biostatistics and Programming  
Central Laboratory Services  
Clinical Trials Management/Monitoring  
Contract Staffing  
Data Management  
Health Economics

IVRS  
Medical Affairs  
Medical Imaging  
Medical Writing and Publishing  
Product Development Consulting  
Regulatory Affairs



## Phase III

**Most Phase III studies are randomised, blinded trials where a drug is tested in several hundred to several thousand patients. This large scale testing provides the pharmaceutical company and the FDA with a more thorough understanding of the drug's effectiveness, benefits and the range of possible adverse reactions.**

Phase III studies typically last several years and between seventy to ninety percent of drugs that enter Phase III studies successfully complete this phase of testing. Once a Phase III study is successfully completed, a pharmaceutical company can request FDA approval to allow the drug to be marketed.

Phase IIIb studies are commonly conducted while awaiting, or after, regulatory approval to attempt to find additional uses for the drug or to prove that prolonged use enhances mortality and/or quality of life.

As clients reach Phase III and later development phases, they frequently find that as the patient numbers increase, patient costs also increase. Recognising this, ICON has developed many innovative approaches to help reduce these costs while still delivering service excellence and reliable data.

**Excellence in Action**

Over 90% of ICON Central Laboratories business comes from repeat customers.

ICON Development Solutions has designed the product development plans for over 40 products; managing and executing over 70% of these programmes.

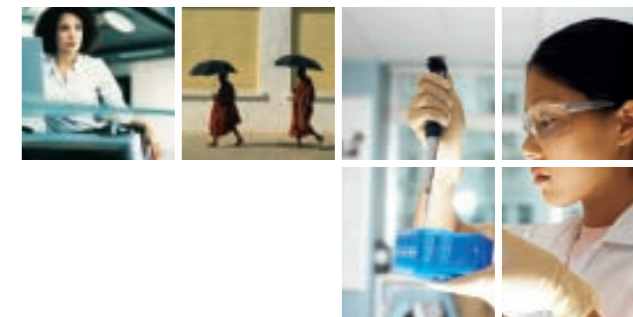
ICON Clinical Research has conducted over 1,000 clinical studies involving more than 250,000 patients in 12,000 centres across 50 countries in all therapeutic areas.



**ICON Services Include:**

- Health Economics
- IVRS
- Medical Affairs
- Medical Imaging
- Patient Outcomes Research

- Patient Registries
- Pharmacovigilance
- Phase IV Clinical Trials
- Regulatory Affairs
- Safety Services



## Phase IV

**Phase IV studies occur after the product receives regulatory approval. These studies are used to characterise the effectiveness and safety of a product in the general patient population under conditions of typical use. In some cases, the regulatory agencies may mandate post-marketing surveillance studies as part of the approval process. Typically, very large numbers of patients are involved in these studies, which may also be global in reach.**

**Recent trends have seen an increase in the number of late phase studies being used to compare a drug with other drugs already in the marketplace. There has also been a move to monitor a drugs overall impact on a patient’s quality of life. This type of “outcomes research” requires a distinct approach to data collection, storing and analysis over long periods of time.**

The recent high profile withdrawal of several drugs from the market is placing a greater spotlight on drug safety, which is leading to greater emphasis on post-marketing monitoring. ICON’s recent acquisition of Ovation Research has added additional capabilities to the organisation in the areas of health economics, patient registries and outcomes research.

Utilising the breadth of our resources and knowledge, ICON can offer a wide variety of research methodologies aimed at defining and communicating the safety and value of products to their marketplace so that good products can achieve their maximum potential.

**Excellence in Action**

ICON Clinical Research has conducted more than 30 very large late phase clinical trials with 1,000 or more patients.

Over 2 million patients have been enrolled in registries conducted by ICON Clinical Research.

ICON has generated over 300 publications based on findings from late phase research studies, many in the key pharmaceutical journals.

# 2006.

## A year in review



We continue to develop the business to enhance the services we provide to our clients and ensure that ICON remains an organisation that can attract the best market talent. To follow are some of the operational highlights of 2006:

#### ICON enhances its Italian operations

The opening of ICON's Milan office illustrates the company's commitment to a lasting presence in Italy and supports ICON's growth strategy in Western Europe.

#### Construction begins on major extension to HQ

Work began on the new corporate headquarters in Dublin. Phase I of this project is expected to be completed in July 07 enabling all Dublin staff to be based out of the same location.

#### ICON launches The Oncology Solution

The Oncology Solution is an integrated package of clinical services delivering tumor imaging, central laboratory, IVRS and CRF data, designed to meet the endpoints pharmaceutical organisations need to understand their oncology compounds.

#### ICON launches new branding initiative

During 2006 we embarked on a major branding initiative to drive consistency in the way we present ICON's services to our external customers. Our aim is to promote our image as a global organisation that offers a broad range of services that can be sold either standalone or as part of a "full service" integrated solution.

#### ICON acquires Ovation Research

This acquisition of Ovation Research extends ICON's capabilities into the areas of pharmaco-economic and quality-of-life analysis, statistical analysis, disease and product registries and health outcomes research.

#### ICON makes impressive showing in European Site Survey

ICON recorded an impressive performance in the bi-annual Thomson CenterWatch 2006 Investigative European Site Survey.

#### ICON enhances its presence in Eastern Europe with the opening of new offices in Warsaw, Vilnius and Novosibirsk

Expansion in these strategic Eastern European locations complements our existing network of offices in Riga, Moscow and Budapest and strengthens our capabilities in what is an increasingly significant area for clinical research.

#### ICON creates new Development Solutions division

Medeval, GloboMax and ICON Consulting unite to form a new division, ICON Development Solutions, specialising in the management and execution of product development and early phase clinical development.

#### ICON opens new office in Salt Lake City, Utah

Recognising the ongoing importance of the US market to our sponsors, we opened an office in Salt Lake City to provide clients with local access to ICON services.

#### ICON Central Laboratories announces Dublin laboratory expansion

Our expanded facility will enable us to continue to meet the high demand for global laboratory services as well as offer improved workflow for the other safety and esoteric tests performed in our Dublin facility.

#### ICON Contracting Solutions grows by 65%

Our contract staffing business, ICON Contracting Solutions, continued to make headway during 2006. Revenue increased by over 65% compared to 2005 and its candidate database expanded to over 18,000 contacts.

#### ICON Central Laboratories launches new remote data access tool

ICON Central Laboratories released ICOLabs, an innovative, remote data access tool that enables users to readily access study indicators, custom reports and track test result trending with numeric or graphical displays.

#### ICON signs partnership agreement with Phase Forward

This new agreement with Phase Forward for the provision of Electronic Data Capture (EDC) solutions, will enable ICON to continue to grow and expand the range of EDC services we can offer clients.

#### ICON expands activities in India

India continues to develop as an important location for Clinical Research, both as a cost effective operational base for functions such as data management and as a location for the conduct of clinical trials. During 2006 we grew both our clinical and data management groups in India and at the end of 2006 had 138 staff across our Bangalore and Chennai offices. We will continue to look for opportunities to utilise these bases to support additional ICON services during 2007.

#### ICON continues to advance in the Japanese market

By the end of 2006 we had over 50 operational staff in Japan and were working on 7 projects for a variety of clients. Japan remains a strategic opportunity, both as a market in its own right and in terms of building relationships with Japanese companies who subsequently develop their compounds in other locations.

#### ICON supports technology adoption in clinical studies

The use of technology to support clinical studies continued to gain momentum in 2006. ICON is at the forefront of this change and our EDC and IVRS groups both saw significant growth during 2006. We now have over 50 ongoing EDC based studies and sales of our ICOPhone system increased by over 30% in 2006.

#### ICON Clinical Research experiences rapid growth in 2006

Our core Clinical Research division experienced significant growth during 2006. Staff numbers increased to nearly 3,200 as we developed our presence in new geographic markets in places like Latin America, China, Eastern Europe and India.

#### ICON Medical Imaging grows revenues by 30%

Beacon Bioscience re-branded to become ICON Medical Imaging during 2006 and continued its penetration of large pharmaceutical accounts. Revenues increased 30% year on year supported by increased business development activity in both the US and Europe.

#### ICON implements new key systems to support quality and growth - iDoc, iLearn, ICOTrial, iRecruit, Salesforce.com

Ongoing system and process improvements are critical if we are to continue to deliver service excellence as we grow our business. During 2006 we implemented a new document management system (iDoc), a global online training tool (iLearn), enhanced clinical trials management software (ICOTrial), new recruitment systems (iRecruit) and standardised our customer relationship management software across all ICON divisions.

# Our Directors

## From left to right

Ciaran Murray, Bruce Given, Edward R. Roberts, Peter Gray, Shuji Higuchi, John Climax, Ronan Lambe, Thomas G. Lynch

**Ciaran Murray** Chief Financial Officer, Company Secretary ~

**Bruce Given** Director \*§ x

**Edward R. Roberts** Director \*§ x

**Peter Gray** Chief Executive Officer, Director ~

**Shuji Higuchi** Director

**John Climax** Chairman ~

**Ronan Lambe** Director ~

**Thomas G. Lynch** Director \*§ x

\* Member of Audit Committee

§ Member of Compensation Committee

X Member of Nomination Committee

~ Member of Executive Committee

**ICON is a global company with leading positions in many of the world's most important and dynamic markets. Our collective experience, operational flexibility and in-depth customer understanding combine to create innovative solutions.**



# Other Information

## Headquarters

ICON plc  
South County Business Park  
Leopardstown  
Dublin 18  
Ireland

## Company Secretary

Ciaran Murray

## Solicitors

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IFSC  
25-28 North Wall Quay  
Dublin 1  
Ireland

Cahill Gordon & Reindel  
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New York, New York  
10005 USA

## Auditors

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

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.

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