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ICON PLC /ADR/
Form 6-K
October 26, 2004

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer
Pursuant to Rule 13a - 16 under
the Securities Exchange Act of 1934

For the quarterly period ended August 31, 2004

ICON plc
(Registrant's name)

0-29714
(Commission file number)

South County Business Park, Leopardstown, Dublin 18, Ireland.
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Yes No

Indicate by check mark whether the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (1):

Yes No

Indicate by check mark whether the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (7):

Yes No

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82 N/A

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ICON plc

Quarterly Period Ended August 31, 2004

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ICON plc

GENERAL

As used herein, "ICON", the "Company" and "we" refer to ICON plc and its consolidated subsidiaries, unless the context requires otherwise.

Business

We are a contract research organization, or CRO, providing clinical research and development services on a global basis to the pharmaceutical, biotechnology and medical device industries. Our focus is on supporting the conduct of clinical trials. We have historically done so by providing such services as Phase I - IV clinical trials management, study design, laboratory services and drug development support. We believe that we are one of a select group of CROs with the capability and expertise to conduct clinical trials in most major therapeutic areas on a global basis. We have approximately 2,550 employees worldwide, with operations in 35 locations in 21 countries including the United States and major markets in Europe and Rest of World and have managed clinical trials in over 55 countries. For the three months ended August 31, 2004, we derived approximately 58.4%, 35.6%, and 6.0% of our net revenue in the United States, Europe and Rest of World, respectively.

Headquartered in Dublin, Ireland, we began operations in 1990 and have expanded

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our business through internal growth and strategic acquisitions.

On July 1, 2004 we acquired 70% of the common stock of Beacon Biosciences, Inc., a leading specialist CRO, which provides a range of medical imaging services to the pharmaceutical, biotechnology and medical device industries.

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ICON plc

CONDENSED CONSOLIDATED BALANCE SHEETS AS AT AUGUST 31, 2004 AND MAY 31, 2004

| | (Unaudited) August 31, 2004 |
|--|--------------------------------|
| ASSETS | |
| Current Assets: | |
| Cash and cash equivalents..... | \$4 |
| Short term investments - available for sale | 2 |
| Accounts receivable..... | 7 |
| Unbilled revenue..... | 6 |
| Other receivables..... | |
| Deferred tax asset..... | |
| Prepayments and other current assets..... | |
| Total current assets..... | 22 |
| Other Assets: | |
| Property, plant and equipment, net..... | 4 |
| Goodwill..... | 7 |
| Total Assets..... | \$34 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | |
| Current Liabilities: | |
| Accounts payable..... | \$7 |
| Payments on account..... | 61 |
| Other liabilities..... | 31 |
| Income taxes payable..... | 6 |
| Bank creditlines and loan facilities..... | 7 |
| Total current liabilities..... | 113 |
| Other Liabilities: | |
| Long term government grants..... | 1 |
| Long term finance leases..... | |
| Non-current deferred tax liability..... | 2 |
| Minority interest..... | |
| Shareholders' Equity: | |
| Ordinary Shares, par value 6 euro cents per share; 20,000,000 shares | |

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authorized, 13,842,536 shares issued and outstanding at August 31, 2004
and
13,838,476 shares issued and outstanding at May 31, 2004

| | |
|---|-----------------------------|
| Additional paid-in capital..... | 113 |
| Accumulated other comprehensive income..... | 8 |
| Merger reserve..... | 100 |
| Retained earnings..... | ----- 100 |
| Total Shareholders' Equity..... | ----- 222 |
| Total Liabilities and Shareholders' Equity..... | ----- \$341 ===== |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICON plc

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED AUGUST 31, 2004 AND 2003
(UNAUDITED)

| | Three Months Ended August 31, ----- | |
|--|---|-----------|
| | 2004 | 2003 |
| | ---- | ---- |
| | (in thousands except share and per share data) | |
| Revenue: | | |
| Gross revenue..... | \$117,195 | \$106,177 |
| Subcontractor Costs..... | (38,856) | (37,242) |
| | ----- | ----- |
| Net revenue..... | 78,339 | 68,935 |
| Costs and expenses: | | |
| Direct costs..... | 42,453 | 37,699 |
| Selling, general and administrative expenses.. | 23,339 | 21,025 |
| Depreciation | 3,062 | 2,589 |
| | ----- | ----- |
| Total costs and expenses..... | 68,854 | 61,313 |
| Income from operations..... | 9,485 | 7,622 |
| Interest income..... | 197 | 73 |
| Interest expense..... | (33) | (26) |
| | ----- | ----- |
| Income before provision for income taxes..... | 9,649 | 7,669 |

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| | | |
|---|------------|------------|
| Provision for income taxes..... | (2,322) | (2,065) |
| Minority Interest..... | (22) | - |
| | ----- | ----- |
| Net income..... | \$7,305 | \$5,604 |
| | ===== | ===== |
| Net income per Ordinary Share: | | |
| Basic | \$0.53 | \$0.46 |
| | ===== | ===== |
| Diluted..... | \$0.52 | \$0.44 |
| | ===== | ===== |
| Weighted average number of Ordinary Shares outstanding: | | |
| Basic..... | 13,837,986 | 12,153,772 |
| | ===== | ===== |
| Diluted..... | 14,105,288 | 12,606,971 |
| | ===== | ===== |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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ICON plc

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED AUGUST 31, 2004 AND 2003
(UNAUDITED)

| | Three Months August 31 |
|--|---------------------------|
| | ----- 2004 ---- |
| Cash flows from operating activities: | |
| Net income..... | \$7,305 |
| Adjustments to reconcile net income to net cash (used in)/provided by | |
| operating activities:..... | |
| Depreciation..... | 3,062 |
| Amortization of grants..... | (48) |
| Minority interest..... | 22 |
| Changes in assets and liabilities: | |
| Decrease in accounts receivable..... | 4,340 |
| Increase in unbilled revenue..... | (6,837) |
| Increase in other receivables..... | (555) |
| Decrease/(increase) in prepayments and other current assets | 669 |

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| | |
|--|----------|
| (Decrease)/increase in payments on account..... | (548) |
| (Decrease)/increase in other liabilities..... | (3,559) |
| Increase in income taxes payable..... | 1,785 |
| Decrease in accounts payable..... | (5,625) |
| | ----- |
| Net cash provided by/(used in) operating activities..... | 11 |
| Cash flows from investing activities: | |
| Purchase of property, plant and equipment..... | (4,546) |
| Purchase of subsidiary undertakings and acquisition costs..... | (9,913) |
| Net cash acquired with subsidiary undertakings..... | 1,658 |
| Deferred payments in respect of prior year acquisitions | (6) |
| | ----- |
| Net cash used in investing activities..... | (12,807) |
| Cash flows from financing activities: | |
| Proceeds from / (repayment of) bank overdraft..... | 7,000 |
| Proceeds from issuance of share capital..... | - |
| Proceeds from exercise of share options..... | 75 |
| Share issuance costs..... | - |
| Costs in relation to prior year share issuance..... | (104) |
| Repayment of other liabilities..... | (117) |
| | ----- |
| Net cash provided by financing activities..... | 6,854 |
| Effect of exchange rate movements on cash..... | (244) |
| | ----- |
| Net (decrease)/increase in cash and cash equivalents..... | (6,186) |
| Cash and cash equivalents at beginning of period..... | 55,678 |
| | ----- |
| Cash and cash equivalents at end of period..... | \$49,492 |
| | ===== |

The accompanying notes are an integral part of these condensed consolidated financial statements.

ICON plc

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE INCOME
(UNAUDITED)

| | Additional Paid-in | Accumulated Other Comprehensive | Ret |
|--|-----------------------|---------------------------------------|-----|
|--|-----------------------|---------------------------------------|-----|

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may be expected for the fiscal year ending May 31, 2005.

2. Acquisitions

Acquisition of Beacon

On July 1, 2004, the Company acquired 70% of the common stock of Beacon Biosciences, Inc. ("Beacon"), based in Pennsylvania, USA, for an initial cash consideration of U.S.\$9.9 million, excluding costs of acquisition.

The acquisition of Beacon has been accounted for as a purchase in accordance with SFAS No. 141, "Business Combinations". The following table summarizes the fair values of the assets acquired and the liabilities assumed at the date of acquisition.

| | At July 1, ----- 2004 ----- (in thousands) |
|-------------------------------|--|
| Property, Plant and Equipment | \$792 |
| Goodwill | 8,760 |
| Cash | 1,658 |
| Other Current Assets | 935 |
| Current liabilities | (1,350) |
| Long term liability | (352) |
| | ----- 10,443 |
| Minority Interest | (568) |
| | ----- Purchase Price |
| | \$9,875 ----- |

The results of Beacon have been included in the consolidated financial statements from July 1, 2004.

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Prior Period Acquisitions

On September 9, 2003, the Company acquired 100% of the outstanding shares of Globomax LLC ("Globomax"), based in Maryland, USA, for an initial cash consideration of U.S.\$10.9 million, excluding costs of acquisition. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of U.S.\$4.0 million depending on the performance of Globomax over the period from date of acquisition to May 31, 2006.

The pro forma effect of the Globomax and Beacon acquisitions if completed on June 1, 2003 would have resulted in net revenue, net income and earnings per share for the three months ended August 31, 2003 and 2004 as follows:

Three months ended

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| | August 31 ----- | |
|----------------------------|--------------------|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Net Revenue | \$78,721 | \$72,785 |
| Net Income | \$7,258 | \$5,750 |
| Basic Earnings per Share | \$0.52 | \$0.47 |
| Diluted Earnings Per Share | \$0.51 | \$0.46 |

An effective tax rate of 35.0% was imputed on the profits before tax of Globomax for the periods prior to acquisition.

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3. Goodwill

| | Three months ended August 31 2004 (in thousands) | Year ended May 31 2004 (in thousands) |
|---|---|--|
| Opening Balance | \$64,226 | \$45,029 |
| Arising during the year | 8,760 | 13,134 |
| Arising on earn-out (current and prior year acquisitions) | - | 3,215 |
| Foreign exchange movement | (709) | 2,848 |
| ----- | | |
| Closing Balance | \$72,277 | \$64,226 |
| ===== | | |

The distribution of goodwill by business segment was as follows:

| | Three months ended August 31 2004 (in thousands) ----- | Year ended May 31 2004 (in thousands) ----- |
|--------------------|--|---|
| Central laboratory | \$7,017 | \$7,017 |
| Clinical research | 65,260 | 57,209 |
| ----- | | |
| Total | \$72,277 | \$64,226 |
| ----- | | |

4. Net income per Ordinary Share

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Basic net income per Ordinary Share has been computed by dividing net income available to ordinary shareholders by the weighted average number of Ordinary Shares outstanding during the period. Diluted net income per Ordinary Share is computed by adjusting the weighted average number of Ordinary Shares outstanding during the period for all potentially dilutive Ordinary Shares outstanding during the period and adjusting net income for any changes in income or loss that would result from the conversion of such potential Ordinary Shares.

There is no difference in net income used for basic and diluted net income per Ordinary Share. The reconciliation of the number of shares used in the computation of basic and diluted net income per Ordinary Share is as follows:

| | Three Months Ended August 31, ----- | |
|--|---|--------------|
| | 2004 ---- | 2003 ---- |
| Weighted average number of Ordinary Shares outstanding for basic net income per Ordinary Share | 13,837,986 | 12,153,772 |
| Effect of dilutive share options outstanding | 267,302 | 453,199 |
| Weighted average number of Ordinary Shares for diluted net income per Ordinary Share | 14,105,288 | 12,606,971 |

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5. Business Segment Information

The Company's areas of operation outside of Ireland principally include the United Kingdom, United States, Germany, Australia, Argentina, France, Japan, Israel, Singapore, Canada, Sweden, The Netherlands, Latvia, Russia, Taiwan, Hong Kong, South Africa, Spain, Hungary and India. Segment information for the three month periods ended August 31, 2004 and 2003 are as follows:

a) The distribution of net revenue by geographical area was as follows:

| | Three months ended August 31, ----- | |
|-------------------|---|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Ireland* | \$10,638 | \$9,884 |
| Rest of Europe | 17,214 | 12,459 |
| U.S. | 45,784 | 44,464 |
| Rest of the World | 4,703 | 2,128 |

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| | | |
|-------|----------|----------|
| Total | \$78,339 | \$68,935 |
|-------|----------|----------|

* All sales shown for Ireland are export sales.

b) The distribution of net revenue by business segment was as follows:

| | Three months ended August 31, ----- | |
|--------------------|---|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Central laboratory | \$6,550 | \$5,723 |
| Clinical research | 71,789 | 63,212 |
| ----- | | |
| Total | \$78,339 | \$68,935 |

c) The distribution of income from operations by geographical area was as follows:

| | Three months ended August 31, ----- | |
|-------------------|---|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Ireland | \$2,811 | \$2,056 |
| Rest of Europe | 2,338 | 639 |
| U.S. | 2,699 | 4,835 |
| Rest of the World | 1,637 | 92 |
| ----- | | |
| Total | \$9,485 | \$7,622 |

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d) The distribution of income from operations by business segment was as follows:

| | Three months ended August 31, ----- | |
|--------------------|---|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Central laboratory | \$(861) | \$(1,231) |
| Clinical research | 10,346 | 8,853 |
| ----- | | |

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| | | |
|-------|---------|---------|
| Total | \$9,485 | \$7,622 |
| ----- | | |

e) The distribution of property, plant and equipment, net, by geographical area was as follows:

| | August 31, 2004 ---- | May 31, 2004 ---- |
|-------------------|----------------------------|-------------------------|
| | (in thousands) | |
| Ireland | \$19,447 | \$18,799 |
| Rest of Europe | 7,053 | 7,202 |
| U.S. | 17,245 | 15,935 |
| Rest of the World | 987 | 1,000 |
| ----- | | |
| Total | \$44,732 | \$42,936 |
| ----- | | |

f) The distribution of property, plant and equipment, net, by business segment was as follows:

| | August 31, 2004 ---- | May 31, 2004 ---- |
|--------------------|----------------------------|-------------------------|
| | (in thousands) | |
| Central laboratory | \$3,766 | \$3,989 |
| Clinical research | 40,966 | 38,947 |
| ----- | | |
| Total | \$44,732 | \$42,936 |
| ----- | | |

g) The distribution of depreciation by geographical area was as follows:

| | Three months ended August 31, ----- | |
|-------------------|---|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Ireland | \$1,119 | \$834 |
| Rest of Europe | 493 | 418 |
| U.S. | 1,361 | 1,249 |
| Rest of the World | 89 | 88 |
| ----- | | |
| Total | \$3,062 | \$2,589 |
| ----- | | |

h) The distribution of depreciation by business segment was as follows:

Three months ended

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| | August 31, ----- | |
|--------------------|---------------------|--------------|
| | 2004 ---- | 2003 ---- |
| | (in thousands) | |
| Central laboratory | \$236 | \$285 |
| Clinical research | 2,826 | 2,304 |
| ----- | | |
| Total | \$3,062 | \$2,589 |
| ----- | | |

i) The distribution of total assets by geographical area was as follows:

| | August 31, 2004 ---- | May 31, 2004 ---- |
|-------------------|----------------------------|-------------------------|
| | (in thousands) | |
| Ireland | \$73,144 | \$76,165 |
| Rest of Europe | 103,749 | 115,056 |
| U.S. | 160,998 | 141,104 |
| Rest of the World | 3,125 | 2,998 |
| ----- | | |
| Total | \$341,016 | \$335,323 |
| ----- | | |

j) The distribution of total assets by business segment was as follows:

| | August 31, 2004 ---- | May 31, 2004 ---- |
|--------------------|----------------------------|-------------------------|
| | (in thousands) | |
| Central laboratory | \$19,317 | \$20,343 |
| Clinical research | 321,699 | 314,980 |
| ----- | | |
| Total | \$341,016 | \$335,323 |
| ----- | | |

ICON plc

Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with the unaudited Consolidated Financial Statements and accompanying notes included elsewhere herein and the Consolidated Financial Statements and related notes thereto included in our Annual Report on Form 20-F for the fiscal year ended May 31, 2004. The Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States.

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Overview

We are a contract research organization, or CRO, providing clinical research and development services on a global basis to the pharmaceutical, biotechnology and medical device industries. Our focus is on supporting the conduct of clinical trials. We have historically done so by providing such services as Phase I - IV clinical trials management, study design, laboratory services and drug development support. We believe that we are one of a select group of CROs with the capability and expertise to conduct clinical trials in most major therapeutic areas on a global basis. We have approximately 2,550 employees worldwide, with operations in 35 locations in 21 countries including the United States and major markets in Europe and Rest of World and have managed clinical trials in over 55 countries. For the three months ended August 31, 2004, we derived approximately 58.4%, 35.6%, and 6.0% of our net revenue in the United States, Europe and Rest of World, respectively.

We earn revenues by providing a number of different services to our clients. These services include clinical trials management, biometric activities, consulting and laboratory services. We recognize biometric, consulting and laboratory revenues on a fee-for-service basis. Our laboratory service contracts are multiple element arrangements, with laboratory kits and laboratory testing representing the contractual elements. We determine the fair values for these elements, each of which can be sold separately, based on objective and reliable evidence of their respective fair values. Our laboratory contracts entitle us to receive non-refundable set up fees and we allocate such fees as additional consideration to the contractual elements based on the proportionate fair values of the elements. We recognize revenues for the elements on the basis of the number of deliverable units completed in a period.

We recognize clinical trials revenue on the basis of the relationship between time incurred and the total estimated duration of the contract as this represents the most accurate pattern over which our contractual obligations are fulfilled. We invoice our customers upon achievement of specified contractual milestones. This mechanism, which allows us to receive payment from our customers throughout the duration of the contract, is not reflective of revenue earned. We recognize revenues over the period from the awarding of the customer's contract to study completion and acceptance. This requires us to estimate total expected revenue, time inputs, contract costs, profitability and expected duration of the clinical trial. These estimates are reviewed periodically and, if any of these estimates change or actual results differ from expected results, then an adjustment is recorded in the period in which they become readily estimable.

As is customary in the CRO industry, we subcontract with third party investigators in connection with clinical trials. All subcontractor costs, and certain other costs where reimbursed by clients, are, in accordance with industry practice, deducted from gross revenue to arrive at net revenue. As no profit is earned on these costs, which vary from contract to contract, we view net revenue as our primary measure of revenue growth.

Direct costs consist primarily of compensation and associated fringe benefits for project-related employees and other direct project driven costs. Selling, general and administrative expenses consist of compensation and related fringe benefits for selling and administrative employees, professional services, advertising costs and all costs related to facilities and information systems.

As the nature of our business involves the management of projects having a typical duration of one to three years, the commencement, completion, curtailment or early termination of projects in a fiscal year can have a material impact on revenues earned with the relevant clients in such years. In addition, as we typically work with some, but not all, divisions of a client, fluctuations in the number and status of available projects within such

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divisions can also have a material impact on revenues earned from such clients from year to year.

Although domiciled in Ireland, we report our results in U.S. dollars. As a consequence, the results of our non-United States based operations, when translated into U.S. dollars, could be materially affected by fluctuations in exchange rates between the U.S. dollar and the currency of those operations.

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In addition to translation exposures, we are also subject to transaction exposures because the currency in which contracts are priced can be different from the currencies in which costs relating to those contracts are incurred. We have fourteen operations operating in U.S. dollars, five trading in Euros, three in pounds Sterling, and one each in Australian dollars, Indian Rupee, Singapore dollars, Yen, Israeli New Shekels, Latvian Lats, Swedish Krona, Argentine Peso, South African Rand, Russian Rouble, Canadian dollar, Hungarian Forint, Taiwan dollar and Hong Kong dollar. Our operations in the United States are not materially exposed to such currency differences as the majority of our revenues and costs are in U.S. dollars. However, outside the United States the multinational nature of our activities means that contracts are usually priced in a single currency, most often pounds Sterling, U.S. dollars or Euros, while costs arise in a number of currencies, depending, among other things, on which of our offices provide staff for the contract, and the location of investigator sites. Although many such contracts benefit from some degree of natural hedging due to the matching of contract revenues and costs in the same currency, where costs are incurred in currencies other than those in which contracts are priced, fluctuations in the relative value of those currencies could have a material effect on our results of operations. We regularly review our currency exposures and hedge a portion of these, using forward exchange contracts, where natural hedges do not cover them.

We have received capital and revenue grants from Enterprise Ireland, an Irish government agency. We record capital grants as deferred income, which are credited to income on a basis consistent with the depreciation of the relevant asset. Grants relating to operating expenditures are credited to income in the period in which the related expenditure is charged. The capital grant agreements provide that in certain circumstances the grants received may be refundable in full. These circumstances include sale of the related asset, liquidation of the Company or failing to comply in other respects with the grant agreements. The operating expenditure grant agreements provide for repayment in the event of downsizing of the Company calculated by reference to any reduction in employee numbers. We have not recognized any loss contingency having assessed as remote the likelihood of these events arising. Up to August 31, 2004, we have received \$2,464,243 and \$1,831,592 under the capital grants and operating grants, respectively. Pursuant to the terms of the grant agreements we are restricted from distributing some of these amounts by way of dividend or otherwise.

As we conduct operations on a global basis, our effective tax rate has depended and will depend on the geographic distribution of our revenue and earnings among locations with varying tax rates. Our results of operations therefore may be affected by changes in the tax rates of the various jurisdictions. In particular, as the geographic mix of our results of operations among various tax jurisdictions changes, our effective tax rate may vary significantly from period to period.

Results of Operations

Three Months Ended August 31, 2004 Compared with Three Months Ended August 31,

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2003

The following table sets forth for the periods indicated certain financial data as a percentage of net revenue and the percentage change in these items compared to the prior comparable period. The trends illustrated in the following table may not be indicative of future results.

| | August 31, ----- 2004 ---- | Three Months Ended ----- August 31, ----- 2003 ---- |
|---|-------------------------------------|--|
| | Percentage of Net Revenue ----- | |
| Net revenue..... | 100.0% | 100.0% |
| Costs and expenses: | | |
| Direct costs..... | 54.2% | 54.7% |
| Selling, general and administrative.... | 29.8% | 30.4% |
| Depreciation and amortization..... | 3.9% | 3.8% |
| Income from operations..... | 12.1% | 11.1% |

Net revenue increased by \$9.4 million or 13.6%, from \$68.9 million to \$78.3 million. This improvement arose through a combination of increased business from existing clients, business won from new clients and revenues from acquisitions not included in the comparative period. The additional revenues from these acquisitions (Globomax & Beacon) amounted to \$3.6 million for the three months ended August 31, 2004. Including the impact of acquisitions, revenues in the United States, and Europe and the Rest of World grew by 3.0% and 33.0% respectively. For the three months ended August 31, 2004, net revenue for our central laboratory business

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grew by 14.5% from \$5.7 million to \$6.6 million while our clinical research segment grew by 13.6% from \$63.2 million to \$71.8 million over the comparable period. The growth in net revenue in our clinical research segment and central laboratory is due to the expansion of our services to both existing and new clients, increased use of outsourcing by the Pharmaceutical, Biotechnology and Medical Device industries, an underlying increase in research and development spending and consolidation in the CRO industry.

Direct costs increased by \$4.8 million, or 12.6%, from \$37.7 million to \$42.5 million, primarily due to increased staff numbers needed to support increased project related activity and increased direct costs arising from the acquisitions amounting to \$1.5 million. Direct costs, as a percentage of net revenue decreased from 54.7% in the three months to August 31, 2003 to 54.2% for the quarter ended August 31, 2004.

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Selling, general and administrative expense increased by \$2.3 million, or 11.0%, from \$21.0 million to \$23.3 million. The increase in costs is due to the continued expansion of our operations and additional selling, general and administrative costs from acquisitions of \$0.7 million not included in the comparative period. As a percentage of net revenue, selling, general and administrative expenses, decreased from 30.4% in the three months ended August 31, 2003, to 29.8% for the quarter ended August 31, 2004.

Depreciation increased by \$0.5 million, or 18.3%, from \$2.6 million to \$3.1 million. This increase is due to the continued investment in facilities and information technology to support the growth in activity. As a percentage of net revenue, depreciation increased from 3.8% of net revenues in the three months to August 31, 2003, to 3.9% for the three months ended August 31, 2004.

Income from operations increased by \$1.9 million, or 24.4%, from \$7.6 million to \$9.5 million, including acquisitions. This improvement is due to increased levels of activity carried out across the Company together with the acquisition of Globomax and Beacon. As a percentage of net revenue, including the effect of acquisitions, income from operations increased from 11.1% in the three months to August 31, 2003, to 12.1% for the quarter ended August 31, 2004. For the quarter, income from operations, as a percentage of net revenue, for the central laboratory was (13.1%), an improvement from the reported (21.5%) in the same quarter in fiscal 2004. The central laboratory constitutes approximately 8% of our business. Operating margins for our clinical research segment increased from 14.0% in the three months ended August 31, 2003, to 14.4% for the three months ended August 31, 2004.

Net interest income for the three months ended August 31, 2004, was \$0.16 million compared to \$.01 million for the equivalent period last year. Higher average level of funds invested in the first quarter this year over last year contributed to the increased interest income.

Our effective tax rate for the three months ended August 31, 2004 was 24.1% compared to 26.9% for the comparable period last year. The decrease in the effective rate was due to a change in the geographic distribution of pre-tax earnings.

Liquidity and Capital Resources

The CRO industry generally is not capital intensive. Since our inception, we have financed our operations and growth primarily with cash flows from operations, net proceeds of \$49.1 million raised in our initial public offering in May 1998 and net proceeds of \$44.3 million, raised in our secondary offering in August 2003. Our principal cash needs are payment of salaries, office rents, travel expenditures and payments to subcontractors. The aggregate amount of employee compensation, excluding stock compensation expense, paid by us and our subsidiaries in the three months ended August 31, 2003 and August 31, 2004 amounted to \$40.3 million and \$46.5 million, respectively. Investing activities primarily reflect capital expenditures for facilities and for information systems enhancements, the sale and purchase of short-term investments and acquisitions.

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Our clinical research and development contracts are generally fixed price with some variable components and range in duration from a few months to several years. Revenue from contracts is generally recognized as income on a percentage of completion basis as the work is performed. The cash flow from contracts typically consists of a down payment of between 10% and 20% paid at the time the contract is entered into, with the balance paid in instalments over the contract's duration, in some cases on the achievement of certain milestones. Accordingly, cash receipts do not necessarily correspond to costs incurred and revenue recognized on contracts.

As of August 31, 2004, our working capital amounted to \$110.4 million, compared to \$113.8 million at May 31, 2004. The other significant influence on our operating cash flow is revenue outstanding, which comprises accounts receivable and unbilled revenue, less payments on account. The dollar values of these amounts and the related days revenue outstanding can vary due to the achievement of contractual milestones, including contract signing, and the timing of cash receipts. The number of days revenue outstanding, decreased from 60 days at May 31, 2004 to 59 days at August 31, 2004.

Net cash provided by operating activities was less than \$0.1 million in the three months ended August 31, 2004, compared to net cash used in operating activities of \$0.2 million in the three months ended August 31, 2003.

Net cash used in investing activities was \$12.8 million in the three months ended August 31, 2004, compared to \$3.5 million in the three months ended August 31, 2003. This increase is due primarily to the \$9.9 million paid in respect of the acquisition of 70% of the common stock of Beacon during the quarter ended August 31, 2003.

Net cash provided by financing activities was \$6.9 million in the three months ended August 31, 2004, compared with \$46.0 million in the three months ended August 31, 2003.

As a result of these cash flows, cash and cash equivalents decreased by \$6.2 million in the three months ended August 31, 2004, compared to an increase of \$39.1 million in the three months ended August 31, 2003.

Our U.S. subsidiary, ICON Clinical Research, Inc. (the "Borrower"), had a \$12 million secured line of credit (the "PNC Facility") with PNC Bank N.A. ("PNC"). The PNC Facility bore interest at an annual rate equal to PNC's Prime Rate less three-quarters of one percent. The full sum of the unpaid principal and interest was payable on demand. The PNC Facility was secured by a first priority security interest in certain assets of the Borrower. This facility was terminated on July 3, 2003.

On July 3, 2003, ICON entered into a facility agreement (the "Facility Agreement") for the provision of a term loan facility of U.S.\$40 million, multi-currency overdraft facility of \$5 million; and revolving credit facility of \$15 million (the "Facilities") with The Governor and Company of the Bank of Ireland and Ulster Bank Ireland Limited (the "Banks"). Our obligations under the Facilities are secured by certain composite guarantees and indemnities and pledges in favour of each of the banks. This facility bears interest at an annual rate equal to the Banks Prime Rate plus three quarters of one percent. ICON plc and its subsidiaries are entitled to make borrowings under a term loan facility of \$40 million and a multi currency overdraft facility of \$5 million. As at August 31, 2004, the full amount of these facilities were available to be drawn down. ICON Clinical Research, Inc. (a subsidiary of ICON plc) is entitled to make borrowings under a revolving credit facility of \$15 million. As at August 31, 2004, US\$8 million of this facility was available to be drawn down.

On July 1, 2004, ICON acquired 70% of the common stock of Beacon Biosciences, Inc., for an initial cash consideration of \$9.9 million.

On September 9, 2003, ICON completed the acquisition of Globomax LLC, for an initial cash consideration of \$10.9 million. Earn-out provisions have been built into the acquisition contract requiring the potential payment of additional deferred consideration up to a maximum of U.S.\$4.0 million depending on the performance of Globomax over the period from date of acquisition to May 31, 2006.

The Company entered into an overdraft agreement with Allied Irish Banks, plc ("AIB") whereby the company guarantees any overdraft of the subsidiary ICON Clinical Research GmbH up to an amount (euro)120,000 (U.S.\$144,132). As of August 31, 2004, the full facility was available to be drawn down.

The Company also entered into an overdraft agreement with AIB, whereby the company guaranteed any overdraft of the subsidiary ICON Clinical Research Israel Ltd. up to an amount of U.S.\$250,000. This facility was terminated on April 20, 2004.

On November 17, 1998, we entered into an overdraft facility (the "AIB facility") for (euro)2,539,000 (\$3,049,593) with AIB. This facility bore an annual interest rate equal to AIB Bank's Prime Rate plus one-quarter of one percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

On July 29, 2002, we entered into an additional AIB facility for STG(pound)50,000 (\$89,442) This facility bore interest at an annual rate equal to AIB Bank's Prime Rate plus two percent. The full sum of the unpaid principal and interest was repayable on demand. This facility was terminated on July 3, 2003.

Inflation

We believe the effects of inflation generally do not have a material adverse impact on our operations or financial conditions.

New Accounting Pronouncements

In December 2003, the FASB issued Interpretation No. 46, revised--Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 ("FIN 46R"). FIN 46R addresses the consolidation of variable interest entities ("VIEs"), which include entities that have one or more of the following characteristics: (1) The equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support; (2) The equity investors lack essential characteristics of a controlling financial interest (as defined by FIN 46R); and (3) The equity investors have voting rights that are not proportionate to their economic interests, and the activities of the entity involve or are conducted on behalf of an investor with a disproportionately small voting interest. In addition, FIN 46R provides for certain scope exceptions to its application. Adoption of this Interpretation is required in financial statements that have interests in VIEs or potential VIEs, commonly referred to as special-purpose entities, for periods ending after 15 December 2003. Application for all other types of entities is required in financial statements for periods ending after 15 March 2004. The adoption of FIN 46R has not had a material impact on the Company's Consolidated Financial Statements.

On April 30, 2003, the FASB issued FASB Statement No. 149, Amendment of

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Statement 133 on Derivative Instruments and Hedging Activities, which amends FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities, to address (1) decisions reached by the Derivatives Implementation Group, (2) developments in other Board projects that address financial instruments, and (3) implementation issues related to the definition of a derivative. Statement 149 has multiple effective date provisions depending on the nature of the amendment to Statement 133. Under SFAS No. 133, the Company's foreign exchange contracts do not qualify for hedge accounting treatment. The impact of adopting Statement 149 did not have a significant impact on our financial statements.

On May 15, 2003, the FASB issued FASB Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, except for certain mandatorily redeemable financial instruments. It is to be implemented by reporting the cumulative effect of a change in an accounting principle for financial

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instruments created before the issuance date of the Statement and still existing at the beginning of the interim period of adoption. Restatement is not permitted. The adoption of SFAS No.150 did not have a significant impact on our financial statements.

The Emerging Issues Task Force (EITF) has reached a final consensus on EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. This Issue addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities, specifically how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. The Issue also addresses how arrangement consideration should be measured and allocated to the separate units of accounting in the arrangement. The guidance in this Issue is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003, with a possible alternative means of adoption by applying the new rules to existing contracts and recording the effect of adoption as a cumulative effect of a change in accounting principle. Early adoption is permitted. We adopted EITF Issue No. 00-21 on June 1, 2003. The adoptions of EITF Issue No. 00-21 did not have a significant impact on our financial statements.

Legal Proceedings

We are not party to any litigation or other legal proceedings that we believe could reasonably be expected to have a material adverse effect on our business, results of operations and financial condition.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ICON plc

September 24, 2004

/s/ Sean Leech

Date

Sean Leech
Chief Financial Officer