

CHARLES RIVER LABORATORIES INTERNATIONAL INC  
Form 10-K  
February 27, 2007

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

**(Mark One)**

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 30, 2006**
- OR**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File No. 333-92383

**CHARLES RIVER LABORATORIES INTERNATIONAL, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)  
**251 Ballardvale Street**  
**Wilmington, Massachusetts**  
(Address of Principal Executive Offices)

**06-1397316**  
(I.R.S. Employer  
Identification No.)  
**01887**  
(Zip Code)

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(Registrant's telephone number, including area code)(978) 658-6000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Common Stock, \$0.01 par value	Name of each exchange on which registered New York Stock Exchange
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Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

## Edgar Filing: CHARLES RIVER LABORATORIES INTERNATIONAL INC - Form 10-K

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

On July 1, 2006, the aggregate market value of the Registrant's voting common stock held by non-affiliates of the Registrant was approximately \$2,481,388,083.

As of February 15, 2007, there were outstanding 66,932,738 shares of the Registrant's common stock, \$0.01 par value per share.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement for its 2007 Annual Meeting of Stockholders scheduled to be held on May 8, 2007, which will be filed with the Securities and Exchange Commission not later than 120 days after December 30, 2006, are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the 2007 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Form 10-K.

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**CHARLES RIVER LABORATORIES INTERNATIONAL, INC.**  
**ANNUAL REPORT ON FORM 10-K**

**TABLE OF CONTENTS**

Item		Page
	<b><u>PART I</u></b>	
<u>1</u>	<u>Business</u>	1
<u>1A</u>	<u>Risk Factors</u>	13
<u>1B</u>	<u>Unresolved Staff Comments</u>	22
<u>2</u>	<u>Properties</u>	22
<u>3</u>	<u>Legal Proceedings</u>	22
<u>4</u>	<u>Submission of Matters to a Vote of Security Holders</u>	22
	<u>Supplementary Item. Executive Officers of the Registrant pursuant to Instruction 3 to Item 401 (b) of Regulation S-K</u>	22
	<b><u>PART II</u></b>	
<u>5</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	24
<u>6</u>	<u>Selected Consolidated Financial Data</u>	26
<u>7</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
<u>7A</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	41
<u>8</u>	<u>Financial Statements and Supplementary Data</u>	42
<u>9</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	100
<u>9A</u>	<u>Controls and Procedures</u>	100
<u>9B</u>	<u>Other Information</u>	100
	<b><u>PART III</u></b>	
<u>10</u>	<u>Directors and Executive Officers of the Registrant</u>	101
<u>11</u>	<u>Executive Compensation</u>	101
<u>12</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters</u>	101
<u>13</u>	<u>Certain Relationships and Related Transactions</u>	102
<u>14</u>	<u>Principal Accountant Fees and Services</u>	102
	<b><u>PART IV</u></b>	
<u>15</u>	<u>Exhibits and Financial Statement Schedules</u>	102

## PART I

### Item 1. Business

#### General

This Annual Report on Form 10-K contains forward-looking statements regarding future events and the future results of Charles River Laboratories International, Inc. that are based on current expectations, estimates, forecasts, and projections about the industries in which Charles River operates and the beliefs and assumptions of our management. Words such as expect, anticipate, target, goal, project, intend, plan, seek, estimate, will, likely, may, designed, would, future, can, could and other similar expressions that are predictions of or in and trends or which do not relate to historical matters are intended to identify such forward-looking statements. These statements are based on current expectations and beliefs of Charles River and involve a number of risks, uncertainties, and assumptions that are difficult to predict. For example, we may use forward-looking statements when addressing topics such as: future demand for drug discovery and development products and services, including the outsourcing of these services; future actions by our management; the outcome of contingencies; changes in our business strategy; changes in our business practices and methods of generating revenue; the development and performance of our services and products; market and industry conditions, including competitive and pricing trends; changes in the composition or level of our revenues; our cost structure; the impact of acquisitions and dispositions; the timing of the opening of new and expanded facilities; our expectations with respect to sales growth, efficiency improvements and operating synergies; changes in our expectations regarding future stock option, restricted stock and other equity grants to employees and directors; changes in our expectations regarding our stock repurchases; and our cash flow and liquidity. You should not rely on forward-looking statements because they are predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document or in the case of statements incorporated by reference, on the date of the document incorporated by reference. Factors that might cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-K under the section entitled Risks Related to Our Business and Industry, the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and in our press releases and other financial filings with the Securities and Exchange Commission. We have no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or risks. New information, future events or risks may cause the forward-looking events we discuss in this report not to occur.

#### Corporate History

Charles River has been operating since 1947 and during that time, we have undergone several changes to our business structure. Charles River Laboratories International, Inc. was incorporated in 1994. In 2000, we completed the initial public offering of Charles River Laboratories International, Inc. Our stock is traded on the New York Stock Exchange under the symbol CRL and is included in the Standard & Poor's MidCap 400, 1000 and Composite 1500 Indices, the Dow Jones US Biotech Index, and the NYSE Healthcare Sector Index. We are headquartered in Wilmington, Massachusetts. Our headquarters mailing address is 251 Ballardvale Street, Wilmington, MA 01887, and the telephone number at that location is (978) 658-6000. Our Internet site is [www.criver.com](http://www.criver.com). Material contained on our Internet site is not incorporated by reference into this Form 10-K. Unless the context otherwise requires, references in this Form 10-K to Charles River, we, us or our refer to Charles River Laboratories International, Inc. and its subsidiaries.

This Form 10-K, as well as all other reports filed with the Securities and Exchange Commission are available free of charge through the Investor Relations section of our Internet site as soon as practicable after we electronically file such material with, or furnish it to, the SEC. You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. In addition, you may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

## Overview

We are a leading global provider of solutions that advance the drug discovery and development process, including research models and associated services, and outsourced preclinical services (including Phase I clinical services). We provide the animal research models required in research and development for new drugs, devices and therapies and have been in this business for 60 years. We have built upon our core competency of laboratory animal medicine and science (research model technologies) to develop a diverse and growing portfolio of products and services. Our wide array of tools and services enables our customers to reduce costs, increase speed and enhance their productivity and effectiveness in drug discovery and development. Our customer base includes global pharmaceutical companies, a wide range of biotechnology companies, as well as government agencies, leading hospitals and academic institutions throughout the world. We currently operate over 80 facilities, including our production and warehousing facilities, in 15 countries worldwide. Our products and services, supported by our global infrastructure and deep scientific expertise, enable our customers to meet many of the challenges of early-stage life sciences research, a large and growing market. In 2006, our net sales from continuing operations were \$1.06 billion and our operating income from continuing operations was \$188.2 million.

In 2004, we acquired Inveresk Research Group, Inc, a leading provider of drug development services to companies in the pharmaceutical and biotechnology industries. That acquisition broadened our portfolio of high-end services including general toxicology, specialty toxicology and Phase I clinical services (in addition to the later-stage clinical services business of Inveresk). In addition, acquiring Inveresk:

- significantly expanded our overall corporate size;
- significantly increased the breadth of the products and services that we offer; and
- expanded and strengthened our global footprint in the growing market for pharmaceutical research and development services.

Acquiring Inveresk was a critical step in our continuing mission to support our key pharmaceutical and biotechnology customers, who are increasingly seeking full service, global partners to whom they can outsource more of their preclinical research and development efforts. Consistent with our philosophy to focus on our core competencies, in August 2006 we divested the Phase II-IV Clinical Services business that had previously been part of Inveresk, although we retained the Phase I Clinical Services business, which we believe serves as an integral part of our preclinical development processes and service offerings. To enhance our Phase I service offerings, we acquired a U.S. Phase I clinical services company, Northwest Kinetics, Inc. in October 2006.

As part of the divestiture of the Phase II-IV Clinical Service business in August 2006, we changed our business reporting segments to better reflect our results of operations and facilitate understanding of our business. We currently have two reporting segments: Research Models and Services (RMS) and Preclinical Services (PCS) which includes Phase I clinical services.

**Research Models and Services (RMS).** Charles River has been supplying research models to the drug development industry since 1947. With approximately 150 different strains we continue to maintain

our position as the global leader in the production and sale of research models, principally genetically and virally defined purpose-bred rats and mice. We also provide a variety of related services that are designed to assist our customers in supporting the use of research models in drug development. With multiple facilities located on three continents (North America, Europe and Asia (Japan)), we maintain production centers, including a total of approximately 160 barrier rooms or isolator facilities strategically located near our customers. In addition, we are in process of expanding our existing U.S. West Coast capacity with additional construction which is expected to partially open in the first half of 2007. In 2006, RMS accounted for 49% of our total net sales and approximately 42% of our employees, including approximately 60 science professionals with advanced degrees

Our RMS segment is comprised of (1) Research Models, (2) Research Model Services and (3) other related businesses.

**Research Models.** A significant portion of this business is comprised of the commercial production and sale of research models, principally purpose-bred rats, mice and other rodents for use by researchers. We provide our rodent models to numerous customers around the world, including most pharmaceutical companies, a broad range of biotechnology companies, many government agencies, and leading hospitals and academic institutions. Our research models include both standard strains and disease models such as those with compromised immune systems, which are increasingly in demand as early-stage research tools. The United States Food and Drug Administration (FDA) and foreign regulatory bodies typically require the safety and efficacy of new drug candidates be tested on research models like ours prior to testing in humans. As a result, our research models are an essential part of the drug discovery and development process.

Our rodent species have been and continue to be some of the most extensively used research models in the world, largely as a result of our continuous commitment to innovation and quality in the breeding process. Our research models are bred and maintained in controlled environments which are designed to ensure that the animals are free of specific viral and bacterial agents and other contaminants that can disrupt research operations and distort results. With our barrier room production capabilities, we are able to deliver consistently high-quality research models worldwide.

Our small research models include:

- outbred animals, which are genetically heterogeneous;
- inbred animals, which are genetically identical;
- hybrid animals, which are the offspring of two different inbred parents;
- spontaneous mutant animals, which contain a naturally occurring genetic mutation (such as immune deficiency); and
- other genetically modified research models, including knock-out models with one or more disabled genes and transgenic animals, which contain genetic material transferred from a different species.

Since 2001, we have been offering new and proprietary, disease-specific rat models used to find new treatments for diseases such as diabetes, obesity and cardiovascular and kidney disease. We are presently focusing our disease model program on four areas of research: cardiovascular, metabolic, renal and oncology, which, in addition to providing overlapping disease modalities that support multiple uses of certain models, also will permit us to concentrate on focused sales and marketing efforts.

We believe that over the next several years, many new research models will be developed and used in biomedical research, such as transgenic models with modified genetic material, knock-out models with one or more disabled genes, and transgenic models that incorporate or exclude a particular gene. These more highly defined and characterized models will allow researchers to further focus their investigations into

disease conditions and potential new therapies or interventions. We intend to build upon our position as a leader in this field to expand our presence in this market for higher-value research models.

In addition to our small research models, we also are a global leader in providing purpose-bred, high quality, specific pathogen-free (SPF) or disease free, large research models to the biomedical research community, principally for use in their drug development and testing studies.

**Research Model Services.** RMS also offers a variety of services, described below, designed to assist our customers in screening drug candidates faster, including those which are related to genetically defined research models for in-house research, as well as those services designed to implement efficacy screening protocols to improve the customer's drug evaluation process. These services address the growing need among pharmaceutical and biotechnology companies to outsource the non-core aspects of their drug discovery activities. These services capitalize on the technologies and relationships developed through our research model business. We currently offer four major categories of research models services: transgenic services, laboratory services, consulting and staffing services, and preconditioning services.

**Transgenic Services.** In this area of our business, we assist our customers in validating, maintaining, improving, breeding and testing research models purchased or created by them for biomedical research activities. While the creation of a transgenic model can be a critical scientific event, it is only the first step in the discovery process. Productive utilization of genetically engineered research models requires significant additional technical expertise. We provide transgenic breeding expertise, model characterization (including genotyping and phenotyping) and colony development, quarantine, embryo cryopreservation, embryo transfer and health and genetic monitoring. We provide these services to over 200 laboratories around the world from pharmaceutical and biotechnology companies to hospitals and universities, and maintain more than 1,000 different types of naturally occurring or experimentally manipulated research models for our customers.

**Laboratory Services.** We assist our customers in monitoring and analyzing the health and genetics of the research models used in their research protocols. We developed this capability internally by building upon the scientific foundation created by the diagnostic laboratory needs of our research model business. Depending upon a customer's needs, we may serve as its sole-source testing laboratory, or as an alternative source supporting its internal laboratory capabilities. We believe that the continued growth in model development and characterization and utilization of specific disease models and genetically engineered models will drive our future growth as the reference laboratory of choice for health and genetic testing of laboratory animals.

**Preconditioning Services.** Augmenting our traditional model production and transgenic services described above, we believe there are emerging opportunities to provide customers with preconditioning services, which center upon speeding the development process by providing study-ready research models. As a result of our veterinary medicine expertise, we are well positioned to provide preconditioning services, such as those required for development of drugs for obesity or hypertension. Additionally, models of subclinical disease can be created through surgical approaches, thereby providing a model for study that otherwise may not be commercially available. In furtherance of our preconditioning services, we offer related surgical services in the United States, Europe and Asia. This value-added service offering enhances the basic research model by preparing models to be used in studies immediately upon arrival at the customer's facility, rather than requiring time and effort on the part of the customer to prepare the models.

**Consulting and Staffing Services.** Building upon our core capability as the leading provider of high-quality research models, we manage animal care operations (including recruitment, training, staffing and management services) on behalf of government and academic organizations, as well as commercial customers. Demand for our services results from the growing trend by these large institutions to outsource internal functions or activities that are not critical to the core scientific innovation process, or for which they do not maintain the necessary resources in-house. In addition, we believe that our expertise in animal



care and facility operations enhances the productivity and quality of our customers' animal care and use programs.

**Other Related Research Model Businesses.** We also offer two other categories of products and services within RMS: vaccine support and *in vitro* technology products.

**Vaccine Support.** We are the global leader for the supply of specific pathogen-free, or SPF, chickens and fertile chicken eggs. SPF chicken embryos are used by animal health companies as self-contained bioreactors for the manufacture of live viruses. These viruses are used as a raw material primarily in poultry, as well as human vaccine, applications. The production of SPF eggs is done under biosecure conditions, similar in many ways to our research model production. We have a worldwide presence that includes several SPF egg production facilities in the United States, a joint venture in Mexico and production capabilities in Hungary. We also operate a specialized avian laboratory in the United States, which provides in-house testing and support services to our customers and produces poultry diagnostics.

**In Vitro Technology.** Our *in vitro* business provides non-animal, or *in vitro*, methods for lot release testing of medical devices and injectable drugs. We are committed to being the leader in providing our customers with *in vitro* alternatives as these methods become scientifically validated and commercially feasible, and toward that goal we work with and support the European Center for Validation of Alternative Methods in these efforts. Endotoxin testing uses a processed extract from the blood of the horseshoe crab, known as limulus amoebocyte lysate (LAL). The LAL test is the first and only major FDA-validated *in vitro* alternative to an animal model test for endotoxin detection in pharmaceutical and medical device manufacturing. The process of extracting blood is generally not harmful to the crabs, which are subsequently returned to their natural ocean environment. Our *in vitro* technology business produces and distributes endotoxin testing kits, reagents, software, accessories, instruments and associated services to pharmaceutical and biotechnology companies worldwide. We are a market leader in endotoxin testing, which is used for FDA-required quality control testing of injectable drugs and medical devices, their components and the processes by which they are manufactured.

We have developed the next generation of the endotoxin testing platform, known as the Endosafe Portable Testing System (Endosafe®-PTS). The PTS is a portable endotoxin testing platform which allows endotoxin testing in the field, affording researchers accurate and timely results. In July 2006, we received FDA approval for the sale and marketing of the PTS system for FDA-required lot release testing. The PTS can also be used for non-regulated applications, ranging from drug research and development to environmental monitoring. As an example, a modified version of the PTS was launched into space in December 2006 aboard the space shuttle Discovery and reached the International Space Station as part of NASA's ongoing efforts to conduct biological research in space. We are also investigating expanding the use of the PTS system for endotoxin testing into other markets such as nuclear pharmacies, cell transplant, dialysis clinics, testing for sterile water, other contaminants such as pesticides, and clinical diagnostics.

#### **Preclinical Services (PCS)**

Our PCS customers are principally engaged in the *discovery* and *development* of new drugs, devices and therapies.

*Discovery* represents the earliest stages of research in the life sciences, directed at the identification, screening and selection of a lead compound for future drug development. Discovery activities typically last anywhere from 4-6 years in conventional pharmaceutical research and development timelines.

*Development* activities, which follow, are directed at demonstrating the safety, tolerability and clinical efficacy of the selected drug candidates. During the preclinical stage of the development process, a drug candidate is tested *in vitro* (typically on a cellular or subcellular level in a test tube or multi-well petri plate) and *in vivo* (in research models) to support planned or on-going human trials. We view



early-stage clinical Phase I studies as an essential, strategic component of our preclinical service offerings.

The development services portion of our PCS segment enables our customers to outsource their critical regulatory required toxicology and drug disposition activities to us. The demand for these services is driven by preclinical development programs for the smaller biotechnology companies, which traditionally have been outsourced, and key safety studies by the larger global pharmaceutical companies. Because of the necessary investments in personnel, facilities and other capital resources required in order to efficiently conduct and perform these activities, we believe that participants in these industries will prefer to focus on their core competencies of innovation, early drug discovery, and in the case of the larger pharmaceutical companies, targeted sales and marketing, and thus we believe the demand for our preclinical service offerings will continue to increase.

We are one of the two largest providers of preclinical services worldwide and offer particular expertise in the design, execution and reporting of general and specialty toxicology studies, especially those dealing with innovative therapies and biologicals. We currently provide preclinical services at multiple facilities located in the United States, Canada and Europe. As a result of increasing demand for outsourced preclinical services, we are conducting significant facilities expansions at our Preclinical Services facilities one in Massachusetts which opened recently and one in Nevada at which we expect to begin phased-in occupancy in mid-Summer 2007, as well as expansions at our Ohio and Edinburgh PCS facilities. The Massachusetts and Nevada facilities will eventually replace our legacy operations in those venues, and when fully built out, will more than double the size of the legacy operations. Our PCS segment represented 51% of our total net sales in 2006 (including the reclassified Phase I clinical services business) and employed 55% of our employees.

We currently offer the following preclinical services, in which we include both *in vivo* and *in vitro* studies, supportive laboratory services, and strategic preclinical consulting and program management to support product development from inception to proof of concept.

**Toxicology.** Toxicology is one of our core preclinical competencies and a competitive strength. Once a lead molecule is selected, the stage of preclinical development begins where appropriate toxicology studies are conducted to support initial clinical trials. Our toxicology services feature:

- all the standard protocols for general toxicity testing required for regulatory submissions;
- expertise in specialty routes of administration and modes of administration (e.g., infusion, intravitreal administration, and inhalation), which are important not only for the testing of potential pharmaceuticals, but also for safety testing of medical devices, industrial chemicals, food additives, agrochemicals, nutraceuticals and other materials;
- other services to fully evaluate the genotoxicity, safety pharmacology, acute, subacute, chronic toxicity and carcinogenicity potential to support first in man to first on the market strategies;
- market-leading expertise in the conduct and assessment of reproductive and developmental toxicology studies (in support of larger scale, human clinical trials);
- services in important specialty areas such as developmental/reproductive, ocular, bone, juvenile/neonatal, and immuno toxicology as well as photobiology and dermal testing;
- work in all major therapeutic areas;
- study design and strategic advice to our clients based on our wealth of experience in support of drug development; and

- a strong history of aiding our sponsors in reaching their regulatory or internal milestones for safety testing, including studies addressing stem cell therapies, DNA vaccines, recombinant proteins, standard small molecules and medical devices.

Our toxicology facilities operate in compliance with Good Laboratory Practices (GLPs) as required by the FDA as well as other international regulatory bodies. Our facilities are regularly inspected by U.S. and other GLP compliance monitoring authorities, as well as our own and our customers' Quality Assurance departments.

**Pathology Services.** In the drug development process, the ability to identify and characterize clinical and anatomic pathologic changes (within tissues and cells) is critical in determining the safety of a new compound. We employ highly trained pathologists who use state-of-the-art techniques to identify potential compound-related changes within tissues and cells, as well as at the molecular level. Pathology support is critical for regulatory driven safety studies, but also for specialized investigative studies, discovery support, and stand-alone immunohistochemistry evaluations for monoclonal antibodies. Key go/no-go decisions regarding continued product development are typically dependent on the characterization and evaluation of gross and microscopic pathology findings we perform for our clients.

**Bioanalysis, Pharmacokinetics, and Drug Metabolism.** In support of preclinical drug safety testing, our customers are required to demonstrate ample drug exposure, stability in the collected sample, kinetics of their drug or compound in circulation, the presence of metabolites, and with recombinant proteins and peptides, the presence of anti-drug antibodies. We have scientific depth in the sophisticated analytical techniques required to satisfy these requirements for a number of drug classes (including oligonucleotide and inhibitory RNAs). In the event that the sample analysis for preclinical study support translates to opportunities to analyze clinical samples for the same drug once human testing begins, we have opportunities to capture the benefits of bridging preclinical bioanalysis with later clinical development. Once the analysis is complete, our scientists evaluate the data to provide information on the kinetics (pharmaco-/toxico-) of the exposure to the drug, as well as complete evaluation of the distribution of the drug or metabolites by radio-labeled techniques. Our clients require these studies for the full preclinical assessment of the disposition of the drug and are used in the final preclinical safety evaluation of the compound.

**Discovery Support.** At the earliest stages of lead compound identification, our scientists are engaged in evaluating the activity of drug candidates in several important therapeutic and support areas, including:

- oncology (through our tumor xenograft models);
- asthma (through our specialized disease model colonies);
- bone disease (using our state-of-the-art imaging and pathology capabilities);
- ophthalmology (using our models of neovascularization);
- general cardiovascular and device testing (using our surgical models); and
- early drug formulation and bioanalysis support and method development.

We also offer lead optimization strategies including early pharmacokinetic, metabolism, and toxicology support to help in early integrative drug selection criteria.

**Biopharmaceutical Services.** We provide specialized, non-clinical quality control testing that is frequently outsourced by both pharmaceutical and biotechnology companies. These services allow our customers to determine if their human protein drug candidates, or the processes for manufacturing those products, are essentially free of residual biological materials. The bulk of this testing is required by the FDA in order to obtain new drug approval, to maintain an FDA-licensed manufacturing facility or to release approved products for use in patients. Our scientific staff consults with customers in the areas of process development, validation, manufacturing scale-up and biological testing.

***Phase I Trials in Healthy Normal and Special Populations***

The Phase I clinical services business represents a growth opportunity for us that initially originated through our acquisition of the Clinical Services business of Inveresk, and which we have grown through our acquisition of Northwest Kinetics in October 2006. Combined, our capabilities encompass two premier, internationally recognized Phase I clinics – one in Europe (Edinburgh, Scotland) and the other in North America (Tacoma, Washington), with a combined capacity of over 300 beds. We focus our clinical services business on high-end clinical pharmacology studies in healthy participants and in therapeutic areas including: cardiovascular, oncology, ophthalmology, respiratory and infectious diseases. From a strategic perspective, we believe that our clinical services business is positioned to benefit from pull-through from our preclinical and laboratory services, particularly with our biotechnology customers.

We offer a wide range of Phase I clinical research services designed to move lead pharmaceutical candidates rapidly from preclinical development through Phase I pharmacokinetic tolerability and pharmacodynamic assessment to explore human pharmacology. We can conduct studies across a wide range of therapeutic areas, and have demonstrated experience in complex dose tolerance, radio-labeled, pharmacokinetics, pharmacodynamics and bioavailability studies. In addition, we provide customers with high-end first-in-man studies for novel compounds, and expertise in complex drug-drug interaction studies. Participants at both clinics are evaluated through an intensive screening process to ensure study suitability. We employ quality assurance units at these facilities to monitor the conduct and reporting of Phase I trials and to assure management that these trials are conducted in compliance with appropriate regulatory requirements.

**Our Strategy**

Our objective is to be the premier global company advancing the search for drugs, devices and therapies from discovery through proof of concept. The products and services which we provide our customers are essential to the drug discovery and development process, and are almost universally mandated by law. Our business is primarily driven by the continued growth of research and development spending by pharmaceutical and biotechnology companies, the federal government and academic institutions and of outsourced services. According to a report by the Biomedical Industry Advisory Group, it takes 11 to 16 years and costs in the range of \$180 million to \$1.65 billion, with an average cost of approximately \$900 million, to bring a new drug to market. As the pressure to develop new drugs increases, so does the pressure to contain costs, to implement research in multiple countries simultaneously and to identify, hire and retain a breadth of scientific and technical experts. In order to facilitate and speed their research, our pharmaceutical and biotechnology customers are making strategic decisions to increasingly outsource services which can be provided by high-quality service providers like us. Outsourcing allows our customers to concentrate their internal resources on early drug discovery, while continuing to advance their most promising products through the development pipeline. This creates opportunities for companies such as ours that can help speed the drug discovery and development process. Our strategy is to capitalize on these opportunities by continuing to build our portfolio of high end, value-added products and services through internal development, augmented by strategic bolt-on transactions.

In today's business environment, we believe there is a particular advantage in being a large, global, high-quality provider of services throughout the drug discovery and development process. Many of our customers, especially large pharmaceutical companies, are attracted to Tier 1 contract research organizations with a full breadth of capabilities, and establish preferred provider relationships with only a small number. We are focused on being recognized as a premier preferred provider and maintaining long-term relationships and strategic partnerships with our customers. Accordingly, with many of our largest customers, we have entered into global provider agreements that span both segments of our business.

We intend to continue to broaden the scope of our products and services primarily through internal development, which will be augmented, as needed, through focused acquisitions and alliances. We believe our approach to acquisitions is a disciplined one that seeks to target businesses that are a sound strategic fit and that offer the prospect of enhancing stockholder value. This strategy may include geographic expansion of existing core services (particularly in Asia if the appropriate opportunities present themselves), strengthening of one of our core services or the addition of a new product or service in a related or adjacent business.

We believe that we are well positioned to exploit both existing and new outsourcing opportunities. We intend to focus our marketing efforts on, among other things, stimulating demand for further outsourcing to gain additional market share to take advantage of promising opportunities which are available to us as a result of continued growth of outsourced services. In 2006 we invested heavily in expanding our facilities capacity, and we intend to continue the capital expansion activity in 2007. Similarly, we are investing in our information technology systems and resources in order to better serve our customers, harmonize our data, and streamline our processes.

### **Customers**

Our customers continue to consist primarily of all of the major pharmaceutical companies, many biotechnology companies, animal health, medical device, diagnostic and other life sciences companies, and leading hospitals, academic institutions, and government agencies. We have stable, long-term relationships with many of our customers. During 2006, no single commercial customer accounted for more than 6% of our total net sales.

For information regarding net sales and long-lived assets attributable to both of our business segments for the last three fiscal years, please see Note 15 included in the Notes to Consolidated Financial Statements included elsewhere in this Form 10-K. For information regarding net sales and long-lived assets attributable to operations in the United States, Europe, Asia and other countries for each of the last three fiscal years, please review Note 15 included in the Notes to Consolidated Financial Statements included elsewhere in this Form 10-K.

### **Sales, Marketing and Customer Support**

We sell our products and services principally through our direct sales force, the majority of whom work in North America, with the balance working in Europe and Japan. Our primary promotional activities include organizing scientific symposia, publishing scientific papers, making presentations and participating at scientific conferences and trade shows in North America, Europe and Japan. We supplement these scientifically based marketing activities with trade advertising, direct mail, newsletters and our website. The direct sales force is supplemented by international distributors for our products.

Our internal marketing/product management teams support the field sales staff while developing and implementing programs to create close working relationships with customers in the biomedical research industry. We maintain client/customer service, technical assistance and consulting service departments, which address both our customers' routine and more specialized needs. We frequently assist our customers in solving problems related to animal husbandry, health and genetics, biosecurity, preclinical and clinical

study design, regulatory consulting, protocol development and other areas in which our expertise is recognized as a valuable customer resource.

### **Competition**

Our strategy is to be a leader in each of the markets in which we participate. We compete in the marketplace on the basis of quality, reputation, responsiveness, pricing, innovation, timeliness and availability, supported by our strategically located facilities worldwide.

The competitive landscape for our two business segments varies. For RMS, our main competitors include three smaller competitors in North America (two of whom have a global scope), and several smaller competitors in Europe and in Japan. Of our main U.S. competitors, two are privately held businesses and the third is a government funded, not-for-profit institution. We believe that none of our competitors in RMS has our comparable global reach, financial strength, breadth of product and services offerings, technical expertise or pharmaceutical and biotechnology industry relationships.

We believe we are one of the two largest providers of preclinical services in the world, based on net service revenue. Our commercial competitors for preclinical services consist of both publicly held and privately owned companies. The Phase I clinical services market is highly fragmented, with approximately ten participants, both public and private, representing the majority of the market and a number of smaller, limited-service providers also providing capacity. In addition, our PCS segment (including our Phase I business) competes with in-house departments of pharmaceutical companies and universities and teaching hospitals.

### **Industry Support and Animal Welfare**

One of our core values is a concern for and commitment to animal welfare. We have been in the forefront of animal welfare improvements in our industry, and continue to show our commitment with special recognition programs for employees who demonstrate an extraordinary commitment in this critical area of our business. We created our own Humane Care Initiative, which is directed by our Animal Welfare and Training Group. The goal of the initiative is to assure that we continue as a worldwide leader in the humane care of laboratory animals. Laboratory animals are an important resource that further our knowledge of living systems and contribute to the discovery of life-saving drugs and procedures. We work hand-in-hand with the scientific community to understand how living conditions, handling procedures and stress play an important role in the quality and efficiency of research. As animal caregivers and researchers, we are responsible to our clients and the public for the health and well being of the animals in our care.

We support a wide variety of organizations and individuals working to further animal welfare as well as the interests of the biomedical research community. We fund scholarships to laboratory animal training programs, provide financial support to non-profit institutions that educate the public about the benefits of animal research and provide awards and prizes to outstanding leaders in the laboratory animal medicine field.

### **Employees**

As of December 30, 2006, we had approximately 8,000 employees, including approximately 330 science professionals with advanced degrees including D.V.M.s, Ph.D.s and M.D.s. Our employees are not unionized in the United States, although employees are unionized at some of our European facilities, consistent with local customs for our industry. Our annual satisfaction surveys indicate that we have an excellent relationship with our employees.

## **Backlog**

Our backlog for our PCS business segment was approximately \$341 million at December 30, 2006. We do not report backlog for the RMS segment because turnaround time from order placement to fulfillment, both for products and services, is rapid. Our preclinical services (including Phase I clinical services) are performed over varying durations, from short to extended periods of time, which may be as long as several years. We maintain an order backlog to track anticipated revenue from studies and projects that either have not started, but are anticipated to begin in the near future, or are in process and have not been completed. We only recognize a study or project in backlog after we have received written evidence of a customer's intention to proceed. We do not recognize verbal orders. Cancelled studies or projects are removed from backlog.

We believe our aggregate backlog as of any date is not necessarily a meaningful indicator of our future results for a variety of reasons. First, studies vary in duration (i.e., some studies that are included in 2006 backlog may be completed in 2007, while others may be completed in later years). Second, the scope of studies may change, which may either increase or decrease their value. Third, studies included in backlog may be subject to bonus or penalty payments. Fourth, studies may be terminated or delayed at any time by the client or regulatory authorities for a number of reasons. Delayed contracts remain in our backlog until a determination of whether to continue, modify or cancel the study has been made. We cannot provide any assurance that we will be able to realize all or most of the net revenues included in backlog or estimate the portion to be filled in the current year.

## **Regulatory Matters**

As our business operates in a number of distinct operating segments and in a variety of locations worldwide, we are subject to numerous, and sometimes overlapping, regulatory environments, as described below.

The Animal Welfare Act (AWA) governs the care and use of certain species of animals used for research. The United States Congress has passed legislation which excludes rats, mice and chickens used for research from regulation under the AWA. As a result, most of our United States small animal research model activities and our vaccine support services operations are not subject to regulation under the AWA. For regulated species, the AWA and attendant Animal Care regulations require producers and users of regulated species to provide veterinary care and to utilize specific husbandry practices such as cage size, shipping conditions, sanitation and environmental enrichment to assure the welfare of these animals. We comply with licensing and registration requirement standards set by the United States Department of Agriculture (USDA) for the care and use of regulated species. Our animal production facilities and preclinical facilities in the U.S. are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), a private, nonprofit, international organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. Portions of our preclinical business are also generally regulated by the USDA.

Our import and export of animals in support of several of our business units as well as our operations in foreign countries are subject to a variety of national, regional, and local laws and regulations, which establish the standards for the humane treatment, care and handling of animals by dealers and research facilities. We maintain the necessary certificates, licenses, detailed standard operating procedures and other documentation required to comply with applicable regulations for the humane treatment of the animals in our custody at our locations.

Our PCS business conducts nonclinical laboratory safety studies intended to support the registration or licensing of our clients' products throughout the world. The conduct of these studies must comply with national statutory or regulatory requirements for Good Laboratory Practice (GLP). GLP regulations describe a quality system concerned with the organizational process and the conditions under which

nonclinical laboratory studies are planned, performed, monitored, recorded, archived and reported. GLP compliance is required by such regulatory agencies as the FDA, United States Environmental Protection Agency, European Agency for the Evaluation of Medicinal Products, Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, Health Canada, and the Japanese Ministry of Health and Welfare. GLP requirements are significantly harmonized throughout the world and our laboratories are capable of conducting studies in compliance with all appropriate requirements. To assure our compliance obligations, we have established quality assurance units (QAU) in each of our nonclinical laboratories. The QAUs operate independently from those individuals that direct and conduct studies and monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in compliance with GLP. Our laboratory managers use the results of QAU monitoring as part of a continuous process improvement program to assure our nonclinical studies meet client and regulatory expectations for quality and integrity.

Our PCS business also conducts human Phase I clinical trials and provides services in support of our clients' registration or licensing applications. Human clinical trials are conducted in a progressive fashion beginning with Phase I, and in the case of approved drugs, continued through Phase IV trials. Phase I studies are the initial human clinical trials and are conducted with a small number of subjects under highly controlled conditions. These clinical trials and services are performed in accordance with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice Consolidated Guidance and in compliance with regulations governing the conduct of clinical investigations and the protection of human clinical trial subjects. In the United States, these trials and services must comply with FDA regulations and in Europe our clinical trials and services must comply with the clinical trials directive of the European Union. Neither FDA regulations nor the clinical trials directive requires a quality assurance program; however, each of our Phase I facilities has an established quality assurance unit that monitors the conduct and reporting of Phase I trials to assure that these trials are conducted in compliance with appropriate regulatory requirements. Our manufacturing business produces endotoxin test kits and reagents and vaccine support products. Additionally, the analytical divisions of several of our nonclinical laboratories conduct stability and potency testing in support of our clients' manufacturing programs. These activities are subject to regulation by the FDA and MHRA under their respective Good Manufacturing Practice regulations or the FDA's Quality Systems Regulation (manufacturing of medical devices). We are required to register with the FDA as a device manufacturer and are subject to inspection on a routine basis for compliance with these regulations. These regulations require that we manufacture our products in a prescribed manner with respect to, and maintain records of, our manufacturing, testing and control activities.

All of our sites are also subject to licensing and regulation under national, regional and local laws relating to the surface and air transportation of laboratory specimens, the handling, storage and disposal of laboratory specimens, hazardous waste and radioactive materials, and the safety and health of laboratory employees. Although we believe we are currently in compliance in all material respects with such national, regional and local laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

To ensure that all business sectors comply with applicable statutory and regulatory requirements and satisfy our client expectations for quality, we have established a corporate regulatory affairs and compliance organization that oversees our corporate quality system and all quality assurance functions within the Company. This organization reports to our Corporate Vice President for Regulatory Affairs and Compliance.

## Corporate Governance

We are committed to operating our business with integrity and accountability. We strive to meet or exceed all of the corporate governance standards established by the New York Stock Exchange, the Securities and Exchange Commission, and the Federal government as implemented by the Sarbanes-Oxley Act of 2002. Seven of the eight members of our Board of Directors are independent and have no significant financial, business or personal ties to the Company or management and all of our Board committees are composed of independent directors. The Board adheres to Corporate Governance Guidelines and a Code of Business Conduct and Ethics which has been communicated to employees and posted on our website. We have always been diligent in complying with established accounting principles and are committed to providing financial information that is transparent, timely and accurate. We have implemented a Related Person Transactions Policy in order to promote the timely identification of such transactions and to ensure we give appropriate consideration to any real or perceived conflicts in our commercial arrangement. We have established global processes through which employees, either directly or anonymously, can notify management (and the Audit Committee of the Board of Directors) of alleged accounting and auditing concerns or violations including fraud. Our internal Disclosure Committee meets regularly and operates pursuant to formal disclosure procedures and guidelines which help to ensure that our public disclosures are accurate and timely. Copies of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and Related Person Transactions Policy are available on our website at [www.criver.com](http://www.criver.com) under the Investors Relations Corporate Governance caption.

## Item 1A. Risk Factors

### Risks Related to Our Business and Industry

*Set forth below and elsewhere in this Form 10-K and in other documents we file with the SEC are risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Form 10-K. We note that factors set forth below, individually or in the aggregate, may cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.*

***The outsourcing trend in the preclinical and clinical stages of drug discovery and development may decrease, which could slow our growth.***

Over the past several years, some areas of our businesses have grown significantly as a result of the increase in pharmaceutical and biotechnology companies outsourcing their preclinical and clinical research support activities. We believe that due to the significant investment in facilities and personnel required to support drug development, pharmaceutical and biotechnology companies look to outsource some or all of those services. By doing so, they can focus their resources on their core competency of drug discovery, while obtaining the outsourced services from a full-service provider like us. While industry analysts expect the outsourcing trend to continue for the next several years a decrease in preclinical and/or clinical outsourcing activity could result in a diminished growth rate in the sales of one or more of our expected higher-growth areas and adversely affect our financial condition and results of operations. Furthermore, our customer contracts are generally terminable on little or no notice. Termination of a large contract or multiple contracts could adversely affect our sales and profitability. Our operations and financial results could be significantly affected these risks.

***A reduction in research and development budgets at pharmaceutical and biotechnology companies may adversely affect our business.***

Our customers include researchers at pharmaceutical and biotechnology companies. Our ability to continue to grow and win new business is dependent in large part upon the ability and willingness of the pharmaceutical and biotechnology industries to continue to spend on research and development and to outsource the products and services we provide. Fluctuations in the research and development budgets of these researchers and their organizations could have a significant effect on the demand for our products and services. Research and development budgets fluctuate due to changes in available resources, mergers of pharmaceutical and biotechnology companies, spending priorities and institutional budgetary policies. Our business could be adversely affected by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, as well as by academic institutions, government laboratories or private foundations. Similarly, economic factors and industry trends that affect our clients in these industries also affect our business.

***A reduction or delay in government funding of research and development may adversely affect our business.***

A portion of net sales in our RMS segment is derived from customers at academic institutions and research laboratories whose funding is partially dependent on both the level and timing of funding from government sources, such as the U.S. National Institutes of Health (NIH) and similar domestic and international agencies. Government funding of research and development is subject to the political process, which is inherently unpredictable. Our sales may be adversely affected if our customers delay purchases as a result of uncertainties surrounding the approval of government budget proposals. Also, government proposals to reduce or eliminate budgetary deficits have sometimes included reduced allocations to the NIH and other government agencies that fund research and development activities. A reduction in government funding for the NIH or other government research agencies could adversely affect our business and our financial results.

***Changes in government regulation or in practices relating to the pharmaceutical or biotechnological industries, including potential health care reform, could decrease the need for the services we provide.***

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies, among others, navigate the regulatory drug approval process. Changes in regulations, such as a relaxation in regulatory requirements or the introduction of simplified drug approval procedures, or an increase in regulatory requirements that we have difficulty satisfying or that make our services less competitive, could eliminate or substantially reduce the demand for our services.

In recent years the U.S. Congress and state legislatures have considered various types of health care reform in order to control growing health care costs. We are unable to predict what legislative proposals will be adopted in the future, if any. Similar reform movements have occurred in Europe and Asia.

Implementation of health care reform legislation that contains costs could limit the profits that can be made from the development of new drugs. This could adversely affect research and development expenditures by pharmaceutical and biotechnology companies, which could in turn decrease the business opportunities available to us both in the United States and abroad. In addition, new laws or regulations may create a risk of liability, increase our costs or limit our service offerings.

***Our standard customer agreements contain liberal termination and service reduction provisions, which may result in less contract revenue than we anticipate.***

Generally, our agreements with our customers provide that the customers can terminate the agreements or reduce the scope of services under the agreements with little or no notice. Customers may

elect to terminate their agreements with us for various reasons, including: the products being tested fail to satisfy safety requirements; unexpected or undesired study results; production problems resulting in shortages of the drug being tested; the customer's decision to forego or terminate a particular study; or the loss of funding for the particular research study. If a customer terminates a contract with us, we are entitled under the terms of the contract to receive revenue earned to date as well as certain other costs and, in some cases, penalties. Cancellation of a large contract or proximate cancellation of multiple contracts could materially adversely affect our business (particularly our Preclinical Services segment) and, therefore, may adversely affect our operating results.

***Many of our contracts are fixed price and may be delayed or terminated or reduced in scope for reasons beyond our control, or we may under price or overrun cost estimates with these contracts, potentially resulting in financial losses.***

Many of our contracts provide for services on a fixed price or fee-for-service with a cap basis and, accordingly, we bear the financial risk if we initially under-price our contracts or otherwise overrun our cost estimates. In addition, these contracts may be terminated or reduced in scope either immediately or upon notice. Cancellations may occur for a variety of reasons, including often upon the discretion of the customer. The loss, reduction in scope or delay of a large contract or the loss or delay of multiple contracts could materially adversely affect our business, although our contracts frequently entitle us to receive the costs of winding down the terminated projects, as well as all fees earned by us up to the time of termination. Some contracts also entitle us to a termination fee.

***Contaminations in our animal populations can damage our inventory, harm our reputation for contaminant-free production and result in decreased sales.***

Our research models and fertile chicken eggs must be free of certain adventitious, infectious agents such as certain viruses and bacteria because the presence of these contaminants can distort or compromise the quality of research results and could adversely impact human or animal health. The presence of these infectious agents in our animal production facilities and certain service operations could disrupt our contaminant-free research model and fertile egg production as well as our animal services businesses including transgenic services, harm our reputation for contaminant-free production and result in decreased sales.

Contaminations typically require cleaning up, renovating, disinfecting, retesting and restarting. This clean-up results in inventory loss, clean-up and start-up costs, and reduced sales as a result of lost customer orders and credits for prior shipments. In addition, contaminations expose us to risks that customers will request compensation for damages in excess of our contractual indemnification requirements. These contaminations are unanticipated and difficult to predict and could adversely impact our financial results. We have made significant capital expenditures designed to strengthen our biosecurity and have significantly improved our operating procedures to protect against such contaminations, however, contaminations may still occur.

***Our business is subject to risks relating to operating internationally.***

A significant part of our net sales is derived from operations outside the United States. Our international revenues, which include revenues from our non-U.S. subsidiaries, represented 50.2% of our total net sales in 2006, 49.8% of our total net sales in 2005, and 31.6% in 2004. We expect that international revenues will continue to account for a significant percentage of our revenues for the foreseeable future. There are a number of risks associated with our international business, including:

- foreign currencies we receive for sales outside the United States could be subject to unfavorable exchange rates with the U.S. dollar and reduce the amount of revenue that we recognize;

- general economic and political conditions in the markets in which we operate;
- potential international conflicts, including terrorist acts;
- potential increased costs associated with overlapping tax structures;
- potential trade restrictions, exchange controls and legal restrictions on the repatriation of funds into the United States;
- difficulties and costs associated with staffing and managing foreign operations, including risks of violations of local laws or the U.S. Foreign Corrupt Practices Act by employees overseas or the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions;
- unexpected changes in regulatory requirements;
- the difficulties of compliance with a wide variety of foreign laws and regulations;
- unfavorable labor regulations in foreign jurisdictions;
- longer accounts receivable cycles in certain foreign countries; and
- import and export licensing requirements.

In particular with respect to our operations in Canada and the United Kingdom, significant amounts of revenues and expenses are recorded in local (non-U.S.) currency. Our financial statements are presented in U.S. dollars. Accordingly, changes in currency exchange rates, particularly between the pound sterling, the Canadian dollar, the European Euro and the U.S. dollar, will cause fluctuations in our reported financial results, which could be material. In addition, our contracts with foreign customers are frequently denominated in currencies other than the currency in which we incur expenses related to those contracts. This is particularly the case with respect to our Canadian operations, where contracts generally provide for invoicing clients in U.S. dollars but its expenses are generally incurred in Canadian dollars. Where expenses are incurred in currencies other than those in which contracts are priced, fluctuations in the relative value of those currencies could have a material adverse effect on our results of operations.

***Negative attention from special interest groups may impair our business.***

The products and services which we provide our customers are essential to the drug discovery and development process, and are almost universally mandated by law. Notwithstanding, certain special interests groups categorically object to the use of animals for valid research purposes. Historically, our core research model activities with rats, mice and other rodents have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, impacting the industry. This has included occasional, but infrequent, on-site demonstrations at facilities operated by us. Any negative attention or threats directed against our animal research activities in the future could impair our ability to operate our business efficiently. In addition, if regulatory authorities were to mandate a significant reduction in safety testing procedures which utilize laboratory animals (as has been advocated by certain groups), our business could be materially adversely affected.

***Several of our product and service offerings are dependent on a limited source of supply, which if interrupted could adversely affect our business.***

We depend on a limited international source of supply of large animal models required in our product and service offerings. Disruptions to their continued supply may arise from colony fertility and health problems, export or import restrictions or embargoes, foreign government or economic instability, severe weather conditions, disruptions to the air travel system or contract disputes or disruptions. Any disruption



of supply could harm our business if we cannot remove the disruption or are unable to secure an alternative or secondary supply source on comparable commercial terms.

***We may be unable to build out our facilities as anticipated.***

To support our customers' growing demand for drug discovery and development services, including increased strategic focus on outsourcing services and programs, we are engaged in a substantial capacity expansion program, with \$182 million spent on capital expenditures in 2006 and another \$200-\$225 million allocated for capital expenditures in 2007. Included in our 2007 capital plan are the following: our new U.S. Preclinical Services facility in Nevada at which we expect to begin phased-in occupancy in mid-Summer 2007, expansions at our Ohio and Edinburgh Preclinical facilities, and an expansion of our RMS California capabilities (approximately half of which is scheduled to open in the second quarter of 2007). We cannot assure you that any or all of these facilities, or any particular phase of such facilities, will be constructed on the anticipated timetable or on budget. Any material delay in bringing these facilities on-line, or substantial increase in costs to complete these facilities, could materially and adversely affect us.

***Any failure by us to comply with existing regulations could harm our reputation and operating results.***

Any failure on our part to comply with existing regulations could result in the termination of ongoing research or the disqualification of data for submission to regulatory authorities. This could harm our reputation, our prospects for future work and our operating results. For example, if we were to fail to verify that informed consent is obtained from participants in connection with a particular Phase I clinical trial, the data collected from that trial could be disqualified and we might be required to redo the trial at no further cost to our customer, but at substantial cost to us. Furthermore, the issuance of a notice of observations or a warning from the FDA based on a finding of a material violation by us of good clinical practice, good laboratory practice or good manufacturing practice requirements could materially and adversely affect us.

***The drug discovery and development services industry is highly competitive.***

The drug discovery and development services industry is highly competitive. We often compete for business not only with other drug discovery and development companies, but also with internal discovery and development departments within our clients, who are often large pharmaceutical and biotechnology companies with greater resources than ours. We also compete with universities and teaching hospitals. We compete on a variety of factors, including:

- reputation for on-time quality performance and regulatory compliance;
- expertise and experience in specific areas;
- scope of service and product offerings;
- strengths in various geographic markets;
- price;
- technological expertise and efficient drug development processes;
- quality of facilities;
- ability to acquire, process, analyze and report data in an accurate manner;
- ability to manage clinical trials both domestically and internationally; and
- size.



If we do not compete successfully, our business will suffer. Increased competition might lead to price and other concessions that might adversely affect our operating results. The drug discovery and development services industry has continued to see a trend towards consolidation, particularly among the biotechnology companies. If this trend continues, it is likely to produce more competition among the larger companies and contract research organizations generally for both clients and acquisition candidates. In addition, small, limited-service entities considering entering the contract research organization industry will continue to find few barriers to entry, thus further increasing possible competition. These competitive pressures may affect the attractiveness of our services and could adversely affect our financial results.

***We could be adversely affected by tax law changes in the United Kingdom or Canada.***

We have substantial operations in the United Kingdom and Canada which currently benefit from favorable corporate tax arrangements. We receive substantial tax credits in Canada from both the Canadian federal and Quebec governments and benefits from tax credits and accelerated tax depreciation allowances in the United Kingdom. Any reduction in the availability or amount of these tax credits or allowances would be likely to have a material adverse effect on profits and cash flow from either or both of our Canadian and United Kingdom operations, and on our effective tax rate.

***Impairment of goodwill may adversely impact future results of operations.***

We accounted for our acquisition of Inveresk as a purchase under accounting principles generally accepted in the United States. Under the purchase method of accounting, the assets and liabilities of Inveresk, including identifiable intangible assets, have been recorded at their respective fair values as of the date the acquisition was completed. The excess of the purchase price over the fair value of acquired net assets and liabilities was recorded as goodwill. As a result of our acquisitions, we have recorded \$1.1 billion of goodwill and other intangible assets.

During fiscal 2006, we sold our Phase II-IV Clinical Services business segment, which we had acquired in the Inveresk transaction, for approximately \$215 million in cash as part of a portfolio realignment which would allow us to capitalize on our core competencies. Accordingly, during 2006 we performed a goodwill impairment test for the Clinical Services business segment and determined that the book carrying value of goodwill assigned to our Clinical Services business segment exceeded its implied fair value. We therefore recorded a \$129.2 million charge to write-down the value of this goodwill.

The remaining goodwill will not be amortized, but will be reviewed for impairment by us at least annually. If the future growth and operating results of the acquired businesses are not as strong as anticipated, goodwill may be impaired. To the extent goodwill is impaired, its carrying value will be written down to its implied fair value and a charge will be made to our earnings. Such an impairment charge could materially and adversely affect our operating results and financial condition.

***Contract research services create a risk of liability.***

In contracting to work on drug development trials, as a contract research organization we face a range of potential liabilities which may include:

- errors or omissions in reporting of study detail in preclinical or Phase I clinical studies that may lead to inaccurate reports, which may potentially advance studies absent the necessary support;
- litigation risk, including resulting from our errors or omissions, associated with the possibility that the drugs of our clients that were included in drug development trials we participated in may cause illness, personal injury or have other negative side effects to clinical study participants or other persons (including death);

- general risks associated with operating a Phase I business, including negative consequences from the administration of drugs to clinical trial participants or the professional malpractice of Phase I medical care providers;
- risks associated with our possible failure to properly care for our customers' property, such as research models and samples, while in our possession;
- risks that models in our breeding facilities may be infected with diseases that may be harmful and even lethal to themselves or humans despite preventive measures contained in our company policies for the quarantine and handling of imported animals; and
- errors and omissions during a trial that may undermine the usefulness of a trial or data from the trial.

We attempt to mitigate these risks through a variety of methods. Nonetheless, it is impossible to completely eradicate such risks.

In our RMS business, we mitigate these risks to the best of our abilities through our regiment of animal testing, quarantine, and veterinary staff vigilance, through which we seek to control the exposure of animal related disease or infections.

In our Preclinical businesses, we attempt to reduce these risks by contract provisions entitling us to be indemnified or entitling us to a limitation of liability; insurance maintained by our clients, investigators, and by us; and various regulatory requirements we must follow in connection with our business.

In both our RMS and Preclinical Services businesses, contractual indemnifications generally do not protect us against liability arising from certain of our own actions, such as negligence or misconduct. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim which is not covered by a contractual indemnification provision or in the event that a party who must indemnify us does not fulfill its indemnification obligations or which is beyond the level of our insurance coverage. Furthermore, there can be no assurance that we will be able to maintain such insurance coverage on terms acceptable to us.

***If we are unable to attract suitable participants for our clinical trials, our business might suffer.***

The clinical research studies we run rely upon the ready accessibility and willing participation of subjects. Participants generally include people from the communities in which the studies are conducted, including our Phase I clinics in Edinburgh, Scotland and Tacoma, Washington, which to date has provided a substantial pool of potential subjects for research studies. Our Phase I clinical research activities could be adversely affected if we were unable to attract suitable and willing participants on a consistent basis.

***New technologies may be developed, validated and increasingly used in biomedical research that could reduce demand for some of our products and services.***

For many years, groups within the scientific and research communities have attempted to develop models, methods and systems that would replace or supplement the use of living animals as test subjects in biomedical research. Some companies have developed techniques in these areas, including vaccine development, that may have scientific merit. It is our strategy to participate in some fashion with any non-animal test method as it becomes validated as a research model alternative or adjunct in our markets. However, we may not be successful in commercializing these methods if developed, and sales or profits from these methods may not offset reduced sales or profits from research models. Alternative research methods could decrease the need for research models, and we may not be able to develop new products effectively or in a timely manner to replace any lost sales.

***The drug discovery and development industry has a history of patent and other intellectual property litigation, and we might be involved in costly intellectual property lawsuits.***

The drug discovery and development industry has a history of patent and other intellectual property litigation and these lawsuits will likely continue. Accordingly, we face potential patent infringement suits by companies that have patents for similar products and methods used in business or other suits alleging infringement of their intellectual property rights. Legal proceedings relating to intellectual property could be expensive, take significant time and divert management's attention from other business concerns, whether we win or lose. If we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use technology on unfavorable terms.

***Our debt level could adversely affect our business and growth prospects.***

At December 30, 2006, we had approximately \$572.1 million of debt. This debt could have significant adverse effects on our business, including making it more difficult for us to obtain additional financing on favorable terms; requiring us to dedicate a substantial portion of our cash flows from operations to the repayment of debt and the interest on this debt; limiting our ability to capitalize on significant business opportunities; and making us more vulnerable to rising interest rates.

***If we are not successful in selecting and integrating the businesses and technologies we acquire, our business may suffer.***

During the past six years, we have expanded our business through several acquisitions. We plan to continue to acquire businesses and technologies and form alliances. However, businesses and technologies may not be available on terms and conditions we find acceptable. We risk spending time and money investigating and negotiating with potential acquisition or alliance partners, but not completing the transaction. Even if completed, acquisitions and alliances involve numerous risks which may include:

- difficulties and expenses incurred in assimilating and integrating operations, services, products or technologies;

- difficulties in developing and operating new businesses, including diversion of management's attention from other business concerns;
- potential losses resulting from undiscovered liabilities of acquired companies that are not covered by the indemnification we may obtain from the seller;
- risks of not being able to overcome differences in foreign business practices, language and other cultural barriers in connection with the acquisition of foreign companies;
- the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies; and
- difficulties in achieving business and financial success.

In the event that an acquired business or technology or an alliance does not meet our expectations, our results of operations may be adversely affected.

***We could experience a breach of the confidentiality of the information we hold or of the security of our computer systems.***

We operate large and complex computer systems that contain significant amounts of customer data. As a routine element of our business, we collect, analyze and retain substantial amounts of data pertaining to the preclinical and the clinical studies we conduct for our customers. Unauthorized third parties could attempt to gain entry to such computer systems for the purpose of stealing data or disrupting the systems. We believe that we have taken adequate measures to protect them from intrusion, but in the event that our efforts are unsuccessful we could suffer significant harm. Our contracts with our customers typically contain provisions that require us to keep confidential the information generated from these studies. In the event the confidentiality of such information was compromised, we could suffer significant harm.

***We depend on key personnel and may not be able to retain these employees or recruit additional qualified personnel, which would harm our business.***

Our success depends to a significant extent on the continued services of our senior management and other members of management. James C. Foster, our Chief Executive Officer since 1992 and Chairman since 2000, has held various positions with us for 30 years. We have no employment agreement with Mr. Foster or other members of our management. If Mr. Foster or other members of management do not continue in their present positions, our business may suffer.

Because of the specialized scientific nature of our business, we are highly dependent upon qualified scientific, technical and managerial personnel. While we have an excellent record of employee retention, there is still strong competition for qualified personnel in the veterinary, pharmaceutical and biotechnology fields. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, could harm our business.

***Our quarterly operating results may vary, which could negatively affect the market price of our common stock.***

Our results of operations in any quarter may vary from quarter to quarter and are influenced by such factors as the number and scope of ongoing customer engagements, the commencement, postponement, completion or cancellation of customer contracts in the quarter, changes in the mix of our products and services, the extent of cost overruns, holiday patterns of our customers, budget cycles of our customers, and exchange rate fluctuations. We believe that operating results for any particular quarter are not necessarily

a meaningful indication of future results. Nonetheless, fluctuations in our quarterly operating results could negatively affect the market price of our common stock

**Item 1B. Unresolved Staff Comments**

There are no unresolved comments to be reported in response to Item 1B.

**Item 2. Properties**

We own and lease our facilities. We own large facilities (over 50,000 square feet) for our PCS businesses in the United States, Canada, Scotland and Ireland, and lease large facilities in the United States and Canada. We have recently brought a new U.S. Preclinical Service facility online in Massachusetts and will bring another one in Nevada online in 2007. We own large RMS facilities in the United Kingdom, France, Germany, Japan, Mexico, Canada and the United States. None of our leases are individually material to our business operations and many have an option to renew. We believe that we will be able to successfully renew expiring leases on terms satisfactory to us. We believe that our facilities are adequate for our operations and that suitable additional space will be available when needed. For additional information see Note 7 to the Consolidated Financial Statements included elsewhere in this Form 10-K.

**Item 3. Legal Proceedings**

We are not a party to any material legal proceedings, other than ordinary routine litigation incidental to our business that is not material to our business or financial condition.

**Item 4. Submission of Matters to a Vote of Security Holders**

Not applicable.

**Supplementary Item. Executive Officers of the Registrant (pursuant to Instruction 3 to Item 401(b) of Regulation S-K).**

Below are the names, ages and principal occupations for the last five years of each our current executive officers. All such persons have been elected to serve until their successors are elected and qualified or until their earlier resignation or removal.

**Joanne P. Acford**, age 51, joined us in 2004 as Corporate Senior Vice President, General Counsel and Corporate Secretary. Prior to joining us, Ms. Acford held a number of positions over 20 years at John Hancock Financial Services, Inc., most recently as Senior Vice President and Deputy General Counsel. Previously, Ms. Acford was an associate in the Corporate Department at Hale and Dorr.

**Thomas F. Ackerman**, age 52, joined us in 1988 with over eleven years of combined public accounting and international finance experience. He was named Controller, North America in 1992 and became our Vice President and Chief Financial Officer in 1996. In 1999, he was named a Senior Vice President and in 2005 he was named a Corporate Executive Vice President. He is currently responsible for overseeing our Accounting and Finance Department and several other corporate staff departments. Prior to joining us, Mr. Ackerman was an accountant at Arthur Andersen & Co.

**Christophe Berthoux**, age 44, rejoined us in February 2005 as General Manager of our clinical services business. Following the sale of our Phase II-IV clinical services business in August 2006, Dr. Berthoux was named Corporate Senior Vice President, U.S. Research Models and Services and In Vitro Products and Services. Previously, from 1990 to early 2004, Dr. Berthoux held a variety of managerial positions with the Company, including Corporate Vice President and head of European Research Models and Services.



**David J. Elliott**, age 49, joined us in October 2005 as Corporate Vice President, Corporate Controller. Prior to joining us, Mr. Elliott was Corporate Controller for Cabot Corporation. Prior to Cabot, he had over twenty years of diverse, financial experience with large, multinational companies in the chemical industry. He is responsible for the corporate accounting and purchasing functions and oversees all accounting and control activities globally.

**John C. Ho**, age 47, joined us in January 2006 as Corporate Senior Vice President, Corporate Strategy. Dr. Ho has over 17 years experience serving pharmaceutical, biotech, medical device and provider organizations in a variety of capacities including corporate and M&A strategy formulation, product commercialization, investment decision-making, process reengineering and organizational redesign. Prior to joining us, Dr. Ho was a partner in Accenture's Health and Life Sciences Practice, where he led the Preclinical Development and the Medical Device Practices, and before that he was a member of the Life Science Industry Group of Pittiglio Rabin Todd & McGrath.

**James C. Foster**, age 56, joined us in 1976 as General Counsel. Over the past 30 years, Mr. Foster has held various staff and managerial positions, and was named our President in 1991, Chief Executive Officer in 1992 and our Chairman in 2000.

**Nancy A. Gillett**, age 51, joined us in 1999 with the acquisition of Sierra Biomedical. Dr. Gillett has 21 years of experience as an ACVP board certified pathologist and scientific manager. In 1999, she became Senior Vice President and General Manager of our Sierra Biomedical division, and subsequently held a variety of managerial positions, including President and General Manager of Sierra Biomedical and Corporate Vice President and General Manager of Drug Discovery and Development (the predecessor to our Preclinical Services business segment). In 2004, Dr. Gillett was named Corporate Senior Vice President and President, Global Preclinical Services, and in 2006 she became a Corporate Executive Vice President.

**David P. Johst**, age 45, joined us in 1991 as Corporate Counsel and was named Vice President, Human Resources in 1995. He became Vice President, Human Resources and Administration in 1996, a Senior Vice President in 1999, and a Corporate Executive Vice President in 2005. He currently serves as the Company's Chief Administrative Officer and is responsible for overseeing our Human Resources department, our Consulting and Staffing Services business unit and several other corporate staff departments. Prior to joining the Company, Mr. Johst was an attorney in the Corporate Department at Hale and Dorr.

**Real H. Renaud**, age 59, joined us in 1964 and has over 40 years of research models production and related management experience. In 1986, Mr. Renaud became Vice President of Production, with responsibility for overseeing the Company's North American small animal operations, and was named Vice President, Worldwide Production in 1990. Mr. Renaud became Vice President and General Manager, European and North American Animal Operations in 1996, following a two-year European assignment during which he provided direct oversight to our European operations. In 1999, he became a Senior Vice President and in 2003, Mr. Renaud became Executive Vice President and General Manager, Global Research Models and Services.

**Nicholas Ventresca**, age 46, joined us in March 2006 as Corporate Senior Vice President, Information Technology and Chief Information Officer. Prior to joining us, Mr. Ventresca was Vice President in Business Technology for Pfizer, Inc, and previously he served in a number of senior information technology positions for multi-international organizations, including Warner-Lambert's Schick & Wilkinson Sword group and Pepsi-Cola International. He is responsible for establishing our global information technology strategies, and developing and maintaining our information technology systems and operational plans.



**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases Of Equity Securities**

Our common stock began trading on the New York Stock Exchange on June 23, 2000 under the symbol CRL. The following table sets forth for the periods indicated below the high and low sales prices for our common stock.

<b>2007</b>	<b>High</b>	<b>Low</b>
First quarter (through February 15, 2007)	\$ 47.64	\$ 42.71
<b>2006</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 51.50	\$ 41.99
Second quarter	49.95	36.30
Third quarter	43.46	33.73
Fourth quarter	45.34	41.00
<b>2005</b>	<b>High</b>	<b>Low</b>
First quarter	\$ 51.64	\$ 43.99
Second quarter	49.52	45.16
Third quarter	53.09	42.80