

CHARLES RIVER LABORATORIES INTERNATIONAL INC
Form 10-K
February 12, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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 26, 2015

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. 001-15943

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)

(Registrant's telephone number, including area code): (781) 222-6000

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

Title of each class	Name of each exchange on which registered
Common Stock, \$0.01 par value	New York Stock Exchange

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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.) 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.

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

Large accelerated filer <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/> (Do not check if smaller reporting company)	Smaller reporting company <input type="checkbox"/>
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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

On June 27, 2015, the aggregate market value of the Registrant’s voting common stock held by non-affiliates of the Registrant was approximately \$3,300,699,578. As of January 29, 2016, there were 46,718,000 shares of the Registrant’s common stock outstanding, \$0.01 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2016 Annual Meeting of Shareholders scheduled to be held on May 11, 2016, which will be filed with the Securities and Exchange Commission (SEC) not later than 120 days after December 26, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the 2016 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.

CHARLES RIVER LABORATORIES INTERNATIONAL, INC.
 ANNUAL REPORT ON FORM 10-K
 FOR THE FISCAL YEAR 2015

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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 our current expectations, estimates, forecasts and projections about the industries in which we operate and the beliefs and assumptions of our management. Words such as “expect,” “anticipate,” “target,” “goal,” “project,” “intend,” “plan,” “believe,” “seek,” “estimate,” “will,” “likely,” “may,” “future,” “can,” “could” and other similar expressions that are predictions, indicate future events and trends or which do not relate to historical matters are intended to identify such forward-looking statements. These statements are based on our current expectations and beliefs 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: goodwill and asset impairments still under review; future demand for drug discovery and development products and services, including the outsourcing of these services; our expectations regarding stock repurchases, including the number of shares to be repurchased, expected timing and duration, the amount of capital that may be expended and the treatment of repurchased shares; present spending trends and other cost reduction activities by our clients; future actions by our management; the outcome of contingencies; changes in our business strategy, 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; our strategic relationships with leading pharmaceutical companies and venture capital limited partnerships, and opportunities for future similar arrangements; our cost structure; the impact of completed and in-process acquisitions (including Argenta, BioFocus, VivoPath, ChanTest, Sunrise, Celsis, Oncotest and WIL Research) and the timing of closing of in-process acquisitions; our expectations with respect to revenue growth and operating synergies (including the impact of specific actions intended to cause related improvements); the impact of specific actions intended to improve overall operating efficiencies and profitability (and our ability to accommodate future demand with our infrastructure), including gains and losses attributable to businesses we plan to close, consolidate or divest; changes in our expectations regarding future stock option, restricted stock, performance share units and other equity grants to employees and directors; expectations with respect to foreign currency exchange; assessing (or changing our assessment of) our tax positions for financial statement purposes; and our liquidity. In addition, these statements include the impact of economic and market conditions on us and our clients; the effects of our cost-saving actions and the steps to optimize returns to shareholders on an effective and timely basis.

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 sections entitled “Our Strategy,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” in our press releases and other financial filings with the SEC. 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

We began operating in 1947 and since then, we have undergone several changes to our business structure. Charles River Laboratories International, Inc. was incorporated in 1994 and in 2000 we completed our initial public offering. Our stock is traded on the New York Stock Exchange under the symbol “CRL” and is included in the Standard & Poor’s MidCap 400 and Composite 1500 indices, the Dow Jones U.S. Biotechnology Index, the NYSE Arca Biotechnology Index, the NYSE Composite and Healthcare Sector indices, and many of the Russell indices, among others. 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 (781) 222-6000. Our Internet site is

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” “the Company” 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 SEC, 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 full service, early-stage contract research organization (CRO). We have built upon our core competency of laboratory animal medicine and science (research model technologies) to develop a diverse portfolio of discovery and safety assessment services, both Good Laboratory Practice (GLP) and non-GLP, which is able to support our clients from target identification through preclinical development. We also provide a suite of products and services to support our clients' manufacturing activities. Utilizing our broad portfolio of products and services enables our clients to create a more flexible drug development model, which reduces their costs, enhances their productivity and effectiveness and increases speed to market.

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

Development activities, which follow, and which can take up to 7-10 years, 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 (non-animal, typically on a cellular or sub-cellular level in a test tube or multi-well petri plate) and in vivo (in research models) to support planned or on-going human trials.

The development of new drugs requires the steadily increasing investment of time and money. Various studies and reports estimate that it takes between 10-15 years, up to \$2.0 billion, and exploration of between 5,000 and 10,000 drug molecules to produce a single Food and Drug Administration (FDA)-approved drug. We are positioned to leverage our leading portfolio in early-stage drug research in an efficient and cost-effective way to aid our clients in bringing their drugs to market faster. Our clients reduce their costs, increase their speed and improve their productivity and effectiveness in early-stage discovery and development by using our broad portfolio of products and services.

For nearly 70 years, we have been in the business of providing the research models required in research and development of new drugs, devices and therapies. Over this time, we have built upon our core competency of in vivo biology to develop a diverse and expanding portfolio of products and services, which now encompasses the broader early-stage drug research process. Our client base includes global pharmaceutical companies, biotechnology companies, government agencies and hospitals and academic institutions around the world. We currently operate 64 facilities in 18 countries worldwide, which numbers exclude our Insourcing Solutions (IS) sites. Our products and services, supported by our global infrastructure and deep scientific expertise, enable our clients to overcome many of the challenges of early-stage life sciences research. In 2015, our total revenue was \$1.4 billion and our operating income from continuing operations, before income taxes, was \$195.4 million.

We have three reporting segments: Research Models and Services (RMS), Discovery and Safety Assessment (DSA), and Manufacturing Support (Manufacturing).

Through our RMS segment, we have been supplying research models to the drug development industry since 1947. With over 150 different strains, we continue to maintain our position as the global leader in the production and sale of the most widely used rodent research model strains, principally genetically and microbiologically defined purpose-bred rats and mice. We also provide a variety of related services that are designed to assist our clients in supporting the use of research models in drug discovery and development. With multiple facilities located on three continents (North America, Europe and Asia), we maintain production centers, including barrier rooms and/or isolator facilities. In 2015, RMS accounted for 34.7% of our total revenue and approximately 3,100 of our employees, including approximately 75 science professionals with advanced degrees.

Our DSA business segment provides services that enable our clients to outsource their innovative drug discovery research, their critical, regulatory-required safety assessment testing and related drug discovery and development activities to us. The demand for these services has historically been driven by the needs of large global pharmaceutical companies that exceeded their internal capacity and by the needs of biotechnology companies and non-profits who traditionally outsourced most of their discovery and development programs. Global pharmaceutical and biotechnology

companies choose to outsource their discovery and development activities because outsourcing reduces the significant investment in personnel, facilities and other capital resources necessary to efficiently and effectively conduct required scientific studies.

We are one of the two largest providers of drug discovery and preclinical development services worldwide and offer a comprehensive portfolio of target discovery through safety assessment studies required for regulatory submission. We have extensive expertise in the discovery of small molecule clinical candidates and in the design, execution and reporting of safety

assessment studies for both small and large molecules. We currently provide discovery and safety assessment services at multiple facilities located in the United States (U.S.), Canada and Europe. Our DSA segment represented 44.9% of our total revenue in 2015 and employed approximately 3,900 of our employees including approximately 630 science professionals with advanced degrees.

Through our Manufacturing segment, we help ensure the safe production and release of products manufactured by our clients. Our Microbial Solutions (formerly known as Endotoxin and Microbial Detection or EMD) business provides in vitro methods for conventional and rapid quality control testing of sterile and non-sterile biopharmaceuticals and consumer products. Our Avian Vaccine Services business provides specific-pathogen-free (SPF) fertile chicken eggs and chickens used in the manufacture of live viruses. Our Biologics Testing Solutions business provides specialized testing of biologics and devices frequently outsourced by global pharmaceutical and biotechnology companies.

In 2015, Manufacturing accounted for 20.4% of our total revenue from continuing operations and approximately 1,200 of our employees, including approximately 65 science professionals with advanced degrees.

In recent years, we have focused our efforts on unifying our businesses and improving the efficiency of our global operations to enhance our ability to support our key clients. Our key pharmaceutical and biotechnology clients are increasingly seeking full service, “one-stop” global partners to whom they can outsource more of their drug discovery and development efforts. It is estimated that the market for regulated safety assessment services is at least 50% outsourced, while emerging growth areas such as in vivo discovery and certain research model services are currently believed to be less outsourced.

Research Models and Services (RMS). Our RMS segment is comprised of (1) Research Models and (2) Research Model Services.

Research Models. Our Research Models business is comprised of the production and sale of research models.

Research Models. A significant portion of this business is comprised of the commercial production and sale of research models, principally purpose-bred rats and mice for use by researchers. We provide our rodent models to numerous clients around the world, including most pharmaceutical companies, a broad range of biotechnology companies and many government agencies, hospitals and academic institutions. We have a global footprint with production facilities strategically located in eight countries, in close proximity to our clients. Our research models include standard stocks and strains and disease models such as those with compromised immune systems, which are in demand as early-stage research tools. The FDA and foreign regulatory bodies typically require that 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. Our research models are bred and maintained in controlled environments, which are designed to ensure that the models are free of specific viral and bacterial agents and other contaminants that can disrupt research operations and distort results. With our production capabilities, we are able to deliver consistently high-quality research models worldwide.

Our research models include:

- outbred, which are purposefully bred for heterogeneity;
- inbred, which are bred to be homogeneous;
- spontaneous mutant, which contain a naturally occurring genetic mutation (such as immune deficiency);
- hybrid, which are the offspring of two different inbred parents; and
- other genetically modified research models, such as knock-out models with one or more disabled genes and transgenic models.

Certain of our research models are proprietary, disease-specific rodent models used to find new treatments for diseases such as diabetes, obesity, cardiovascular and kidney disease.

We are also a premier provider of high quality, purpose bred, SPF large research models to the biomedical research community.

Research Model Services. RMS also offers a variety of services designed to support our clients' use of research models in basic research and screening preclinical drug candidates. These services address the need among

pharmaceutical and biotechnology companies to outsource the non-core aspects of their drug discovery activities. Our services include those which are related to the maintenance and monitoring of research models, and managing research operations for government entities, academic

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organizations and commercial clients. We currently have three service offerings in research models services: Genetically Engineered Models and Services, Insourcing Solutions and Research Animal Diagnostic Services. Genetically Engineered Models and Services (GEMS). We breed and maintain research models purchased or purposefully created by our clients for biomedical research activities. The creation of a genetically engineered model (GEM) is a critical scientific event, but it is only the first step in the discovery process. Productive utilization of GEMs requires significant additional technical expertise in order to properly support basic and early discovery research. We provide breeding expertise and colony development, quarantine, health and genetic testing and monitoring, germplasm cryopreservation, and rederivation including assisted reproduction. Our team of project managers is supported by a technologically advanced system Internet Colony Management (ICM™) that allows for real-time data exchange. We provide these services to clients around the world, including pharmaceutical and biotechnology companies, hospitals, universities and government agencies.

Insourcing Solutions (IS). We manage research operations (including recruitment, training, staffing and management services) for government entities, academic organizations and commercial clients. Research institutions prefer to outsource staffing and management while retaining certain elements of their research in-house thus driving demand for our services. We believe that our expertise in early-stage drug research, and in particular research model care, scientific and technical support, facility operations, and discovery and development services, enhances the productivity and quality of our clients' research programs.

Research Animal Diagnostic Services (RADS). We monitor and analyze the health profiles of research models and cell lines used by our clients. We developed this capability internally in order to address the diagnostic needs of our own research model business. We are able to serve as their sole-source testing laboratory, or as an alternative source supporting our clients' internal laboratory capabilities. We believe we are the reference laboratory of choice for health testing of laboratory research models and an industry leader in the field of animal diagnostics.

Discovery and Safety Assessment (DSA)

We currently offer discovery and safety assessment services, both regulated and non-regulated, in which we include both in vivo and in vitro studies, supporting laboratory services, and strategic preclinical consulting and program management to support product development.

Discovery Services. We offer a full spectrum of discovery services from identification of a novel druggable target, followed by high-throughput screening and medical chemistry, through delivery of preclinical drug and therapeutic candidates ready for safety assessment. In 2014, we integrated our Early Discovery and In Vivo Discovery businesses into a single business line - Discovery Services - as part of our continued efforts to streamline and enhance the support we can provide for clients' integrated drug discovery programs. One seamless discovery organization allows us to better engage with clients at the earliest stages of drug discovery and support their complex scientific needs. We support a variety of therapeutic areas including oncology, central nervous system, bone and musculoskeletal, inflammation, metabolic diseases, respiratory and fibrotic diseases, cardiovascular, gastrointestinal, genito-urinary and ophthalmology. We also provide expertise in the growing area of rare and orphan diseases, which are typically diseases of high unmet medical need in smaller patient populations, such as cystic fibrosis and Huntington's Disease. We believe there are emerging opportunities to assist our clients in a variety of drug discovery applications and platforms from target discovery to candidate selection.

Early Discovery. We are a global leader in integrated drug discovery services, with a predominant focus on in vitro biology capabilities and medicinal chemistry. Our knowledge and expertise allow us to support our clients as they drive their programs forward through design and implementation of clear program plans. Our full suite of service offerings allows us to support our clients at the earliest stages of their research, and to stay with them through the entire early-stage process. Our Early Discovery service capabilities include: target discovery and validation, hit identification, medicinal chemistry and testing how a drug is absorbed, distributed in the body, metabolized and excreted (ADME). We also offer ion channel testing and in vitro cardiac safety assessment services, for both discovery and preclinical purposes. These services extend from the early discovery screening process through to in vitro GLP safety assessment testing.

In Vivo Discovery Services. In Vivo Discovery Services represents the earliest in vivo stages of drug research, directed at the identification, screening and selection of a lead compound for drug development. In vivo activities typically extend anywhere from 4-6 years in conventional pharmaceutical research and development timelines. We offer research and development expertise, capabilities, and services globally to accelerate our clients' drug discovery pipelines from lead generation to candidate selection and on occasion, completing in vivo studies in support of clinical efforts or post-marketing work. We complement clients' capabilities and expertise to improve their decision-making, increase their flexibility, and reduce their internal costs and product development timelines. In addition, we provide in vitro and in vivo assays in support of lead optimization to candidate selection activities. Examples of this include early pharmacokinetic and pharmacodynamic studies and in vitro and in

vivo assays to assess mechanism, bioavailability, metabolism, efficacy, and safety pharmacology. Furthermore, our November 2015 acquisition of Oncotest, a Germany-based CRO providing discovery services for oncology, complements our existing business in the United States, Canada, United Kingdom (U.K.) and Finland. Safety Assessment. We offer a full range of discovery and safety assessment studies required for regulatory submission on a global basis.

Bioanalysis, Pharmacokinetics and Drug Metabolism. In support of preclinical drug safety testing, our clients are required to demonstrate appropriate exposure, stability in the collected sample, kinetics of their drug or compound in circulation, the presence of metabolites, and, with biologics, the presence or absence of anti-drug antibodies. We have scientific depth in the sophisticated bioanalytical techniques required to satisfy these requirements for a number of drug classes. After performing sample analysis in support of preclinical studies, we have the opportunity to capture the benefits of bridging the preclinical bioanalysis with subsequent clinical development. Once the analysis is complete, our scientists evaluate the data to provide information on the pharmacokinetics and/or toxicokinetics of the drug, and complete an evaluation of the distribution of the drug or metabolites. Pharmacokinetics refers to understanding what the body does to a drug or compound once administered, including the process by which the drug is absorbed, distributed in the body, metabolized and excreted (ADME); toxicokinetics refers to the same understanding as applied at higher doses that may result in adverse effects. These studies are required for the full preclinical assessment of the disposition of the drug and the results are used in the final preclinical safety evaluation of the compound.

In support of preclinical drug safety testing, our clients are required to demonstrate that the compound does not have the potential to prolong the cardiac QT interval. We have the assays and can perform the screening for this demonstration that is required for an investigational new drug submission.

Toxicology. Toxicology is one of our nonclinical competencies and a competitive strength. We have expertise in the design and execution of development programs in support of both chemically-derived (small molecule) and biotechnology-derived (large molecule) pharmaceuticals. Once a lead molecule is selected, toxicology studies are required to support clinical trials in humans and new drug registrations. These toxicology studies focus on assessing the safety of the molecule to determine if administration of the molecules to humans might cause any unintended harmful effects. These studies are typically performed in research models to identify any potential adverse effects that a compound has on an organism over a variety of doses and over various time periods.

Our toxicology services feature:

- a broad offering of in vitro and in vivo capabilities and study types designed to identify possible safety risks for potential therapeutics as they transition from discovery into regulated drug development toxicology and human clinical testing;

- all the standard in vitro and in vivo studies in support of general toxicology (acute, sub-acute and chronic studies), genetic toxicology, safety pharmacology and carcinogenicity bioassays that are required for regulatory submissions supporting “first-in-human” to “first-to-the-market” strategies;

- expertise in standard and specialty routes of administration (e.g., infusion, intravitreal, intrathecal, and inhalation) that are important not only for the testing of potential pharmaceuticals and biopharmaceuticals, but also for the safety testing of medical devices, industrial chemicals, food additives, agrochemicals, biocides, nutraceuticals, animal health products and other materials;

- expertise in the conduct and assessment of reproductive and developmental toxicology studies (in support of larger-scale and later-stage human clinical trials);

- services in important specialty areas such as ocular, bone, juvenile/neonatal, immune-toxicology, photobiology and dermal testing;

- expertise in all major therapeutic areas;

- study design and strategic advice to our clients based on our wealth of experience and scientific expertise in support of drug development; and

- a strong history of assisting our clients in achieving their regulatory and/or internal milestones for the safety testing of numerous therapy types including stem cells, vaccines, proteins, antibodies, drug conjugates, oligonucleotide biotherapeutics, small molecules and medical devices.

Our safety assessment facilities comply with GLP to the extent required by the FDA, as well as other international regulatory bodies. Furthermore, our early-stage discovery work, which is not subject to GLP standards, is typically carried out under a quality management system such as ISO 9100 or similarly constructed internally developed quality systems. Our facilities are regularly inspected by U.S. and other regulatory compliance monitoring authorities, our clients' quality assurance departments and our own internal quality assessment program.

Pathology Services. The ability to identify and characterize clinical and anatomic pathologic changes is critical in determining the safety and efficacy of potential new therapeutics. Key “go/no-go” decisions regarding continued product development are typically dependent on the identification, characterization and evaluation of fluid, tissue and cellular changes that our experts identify and interpret for our clients. We employ a large number of highly trained veterinary anatomic and clinical pathologists and other scientists who use state-of-the-art techniques to identify potential test article-related changes within tissues, fluids and cells. In addition to all standard anatomic and clinical pathology techniques, we provide specialized evaluations such as cytology, platelet function, assay development, immunohistochemistry, in situ hybridization and electron microscopy services.

Manufacturing Support (Manufacturing)

Microbial Solutions (formerly known as Endotoxin and Microbial Detection). Our Microbial Solutions business provides in vitro methods for conventional and rapid quality control testing of sterile and non-sterile biopharmaceutical and consumer products. Our legacy business provided lot release testing of medical devices and injectable drugs for endotoxin contamination. With our acquisition of Celsis in July 2015, we now provide rapid microbial detection systems for quality control testing in the pharmaceutical, biopharmaceutical and consumer products industries. Our Accugenix business provides state-of-the-art microbial identification and genetic sequencing services for manufacturing in the biopharmaceutical, medical device, nutraceutical and consumer care industries. Endotoxin testing is an in vitro process which uses a processed extract from the blood of the horseshoe crab, known as limulus amoebocyte lysate (LAL). The LAL test is the first and most successful FDA-validated alternative to an in vivo test to date. The extraction of blood does not harm the crabs, which are subsequently returned to their natural ocean environment. Our Microbial Solutions business produces and distributes a comprehensive portfolio of endotoxin testing, microbial detection and identification kits, reagents, software, accessories, instruments and associated microbial quality control laboratory services to a broad range of companies manufacturing and releasing products from the pharmaceutical, biotechnology, consumer products and dairy industries worldwide. We are a market leader in endotoxin testing products and services, which are used for FDA-required quality control testing of injectable drugs and medical devices, their components and the processes by which they are manufactured.

The growth in our Microbial Solutions business is driven by our FDA approved line of next-generation endotoxin testing products. This line is based on the Endosafe Portable Testing System (Endosafe®-PTS™) technology, which allows rapid endotoxin testing in the central laboratory or manufacturing environment. In recent years, we expanded the PTS product portfolio to include a multiple sample testing system known as the Endosafe®-MCS™ (multi-cartridge system) to satisfy the demand of our clients who require higher sample throughput. We anticipate our clients' demand for rapid testing methods will continue to increase as they respond to the FDA's Process Analytical Technology (PAT) Initiative as well as move to faster, simpler testing methods for their technicians. In 2013, we launched the first fully automated robotic system developed specifically for high-volume endotoxin testing: Endosafe®-Nexus™. We expect to see expanded use of this rapid endotoxin testing technology in non-traditional areas such as renal dialysis, nuclear and compounding pharmacies and cellular therapy.

Celsis' systems are principally used for product-release testing to help ensure the safe manufacture of pharmaceutical, biopharmaceutical and consumer products. The addition of Celsis, with its Advance II™, Accel™ and Innovate™ systems for non-sterile applications, complements our PTS-Micro™, a rapid bacterial (bioburden) detection system for sterile biopharmaceutical applications. We expect our comprehensive portfolio to drive increased adoption of our quality control testing solutions across both sterile and non-sterile applications.

Our Accugenix subsidiary is the premier global provider of current Good Manufacturing Practice (cGMP) compliant contract microbial identification and genetic sequencing testing. Accugenix is an acknowledged industry leader in species-level identification and strain typing of bacteria and fungi that are recovered from manufacturing facilities.

Utilizing state-of-the-art and proprietary in vitro technologies, coupled with scientific expertise and analysis, Accugenix excels in providing accurate, timely and cost-effective microbial identification services required to meet internal quality standards and government regulations.

Biologics Testing Solutions. We perform specialized testing of biologics frequently outsourced by global pharmaceutical and biotechnology companies. Our laboratories in the U.S., Germany, Scotland and Ireland provide timely and compliant molecular

biology, virology, bioanalysis, immunochemistry, microbiology and related services. We confirm that biological processes and the drug candidates and drugs produced are consistent, correctly defined, stable and essentially contaminant free. This testing is required by the FDA and other international regulatory authorities for our clients to obtain new drug approvals, to maintain government licensed manufacturing facilities and to release approved therapeutic products for patient treatment.

Our manufacturing services group grows and stores well-characterized early-stage client cell lines for later development or manufacture of therapeutic proteins and vaccines for clinical trials. We further design and provide viral clearance projects for Phase I, II and III studies in our German and U.S. facilities.

Avian Vaccine Services. We are the global leader for the supply of SPF fertile chicken eggs and chickens. 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 and veterinary vaccine applications. The production of SPF eggs is performed under biosecure conditions, similar in many ways to our research model production. We have a worldwide presence, with several SPF egg production facilities in the U.S., contracted production capabilities in Hungary, and franchise operations in India. We also operate a specialized avian laboratory in the U.S., which provides in-house quality control testing of the SPF flocks, offers testing services to vaccine companies and commercial poultry operations, and manufactures poultry diagnostics and bulk antigens for poultry vaccines.

Our Strategy

Our objective is to be the preferred strategic global partner for our clients. Our strategy is to deliver a comprehensive and integrated portfolio of drug discovery and non-clinical development products, services and solutions to support our clients' discovery and early-stage drug research, process development, scale up and manufacturing efforts, and enable them to bring new and improved therapies to market faster and more cost effectively. In addition, we believe we can improve and augment drug discovery and early-stage development effectiveness by coordinating the dialog between large pharmaceutical, biotechnology, academic and non-governmental organizations and venture capitalists. Separately, through our various Manufacturing segment businesses, we aim to be the premier provider of products and services that ensure our clients produce and release their products safely. As these groups increasingly rely and interact with one another in this field, we assist them in working together by developing deeper strategic relationships with each of these constituencies.

We believe we have certain competitive advantages in executing this strategy, as a result of our continuing focus on the following:

Integrated Early-Stage Portfolio. We are the only large, global CRO with a portfolio of products, services and solutions that focuses on drug discovery and early-stage development. We provide research models and associated services, discovery research studies and services, and comprehensive safety assessment studies in both regulated and non-regulated environments. As such, we are able to collaborate with clients from target discovery through candidate selection. When critical decisions are made regarding which therapeutics will progress from discovery to development, we continue to work alongside our clients as the drug candidates move downstream. Our recognized expertise in early-stage drug research and pharmacology provides us with a competitive advantage. We understand our clients' therapies, and the challenges they face during the discovery and development process, including mechanism of action, efficacy, drug metabolism, safety assessment and toxicological testing critical for making “go/no-go” decisions.

Pharmaceutical Manufacturing Support Portfolio. We also offer a portfolio of products, services, and solutions that supports the process development, scale up and quality control efforts of the biopharmaceutical industry. We provide products and services that support the development and release of commercialized biologics products. In particular, we are an industry leader in the areas of microbial detection and microbial identification to support process development and ongoing commercial production. Our portfolio spans a broad range of traditional and rapid methods, which provide the highest testing quality, enhance productivity and reduce cycle time.

Deep Scientific Expertise. We provide a breadth and depth of scientific expertise which may be too costly for our clients to build and/or maintain in-house. We provide essential capabilities, including biomarkers, biologics, medicinal chemistry, in vitro screening, in vivo pharmacology, immunology, pathology, biologics process development testing,

microbial detection and identification and other specialty service areas that have high infrastructure costs or are cost-prohibitive for clients to maintain in-house. We continue to expand our portfolio in key therapeutic and pharmacology areas to align with our clients' internal drug discovery and development areas of focus. These areas of disease focus and expertise include oncology, metabolism and obesity, immunology, respiratory, bone and musculoskeletal, diabetes, cardiovascular, infectious disease and central nervous system. In the areas of functional expertise, it includes synthetic and medicinal chemistry, library design, cell line development, in vitro and in vivo assay development screening,

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preclinical imaging, structural biology, process chemistry, toxicology, veterinary pathology, bioanalysis, scale up and formulation development. We also continue to enhance our small molecule and biologics manufacturing portfolio in areas of greatest industry need, where outsourcing provides major benefits for our clients and where we could provide significant benefits given our unique early development portfolio and global footprint.

Commitment to Animal Welfare. We are committed to being the worldwide leader in the humane care of laboratory animals and implementation of the “3Rs” (Replacement, Reduction and Refinement). As researchers, we are responsible to our clients and the public for the health and well-being of the animals in our care. We work hand-in-hand with the scientific community to understand how living conditions, handling procedures and reduction of stress play an important role in the quality and efficiency of research.

Superior Quality and Client Support. We maintain scientific rigor and high quality standards through management of key performance indicators and an intense focus on biosecurity. These standards allow clients to access our global portfolio of products and services with the confidence that they will obtain consistent results no matter where they choose to obtain their products or conduct their research.

Flexible and Customized Environment to Provide the Right Solutions. Each of our clients is different, with unique needs and specific requirements. We understand the importance of flexibility, and leverage the expertise embedded in our integrated early-stage portfolio to provide customized solutions tailored to the specific need or therapeutic area for a particular client. By utilizing our streamlined and efficient facilities, we help clients create a flexible infrastructure in order to improve their workload and staffing requirements. This allows our clients to reduce internal capacity and/or staff. We provide enhanced value to clients who use us as a full-service integrated partner over a longer period of time.

Large, Global Partner. We believe there is a particular advantage in being a full service, high-quality provider of research models and associated services, discovery and preclinical in vivo and in vitro services and manufacturing support on a global scale. Many of our clients, especially large biopharmaceutical companies, have decided to limit the number of suppliers with which they work. Their preference is to partner with large Tier 1 CROs like Charles River, who can offer clients support across the earlier-stage drug research process as a result of broader portfolios and experience in project management. This includes extensive scientific, technical and therapeutic area expertise, real-time access to data through secure portals, a global footprint, and streamlined and simplified processes and communications including professional project and relationship management. We are focused on leveraging our competitive advantages to ensure we are recognized as the premier preferred provider thereby enabling us to build broader and deeper long-term strategic relationships with our clients.

Global biopharmaceutical companies are continuing to make the decision to outsource more significant tranches of their drug discovery, development and manufacturing processes. Over the past few years we have entered into strategic relationships with leading global biopharmaceutical companies and expanded existing preferred provider agreements with other leading global biopharmaceutical companies. For example, in 2015, we extended the term of our collaboration with AstraZeneca for outsourced regulated safety assessment and development drug metabolism and pharmacokinetics until 2020. For some of these partners, we provide a broad suite of our research models and discovery and safety assessment services and for others we provide a customized and select array of discovery and safety assessment services and/or research models. Offering flexibility enables our clients to utilize our products and services to deliver innovative health solutions in a manner which best suits their individual needs.

There have been fundamental changes in our clients' research and development needs, particularly with regard to the large pharmaceutical industry. First, these clients are increasingly emphasizing studies that have greater translation to the clinic so that they can make appropriate decisions regarding the progression of potential therapeutic entities earlier in the development process. The result is a greater focus on discovery services, including in vivo pharmacology studies consisting of efficacy and non-GLP DMPK (drug metabolism and pharmacokinetics) studies. Second, these clients are choosing to outsource additional discovery and safety assessment services in order to increase the efficiency and effectiveness of their drug selection processes.

There have been fundamental shifts in the manufacturing needs of our clients. Clients have significantly outsourced their small molecule manufacturing capacity by selling off assets as well as contracting with contract manufacturing

organizations (CMOs). There is now a very large, global and highly fragmented CMO industry supporting the industry. Biologic production has been slower to be outsourced, but this is accelerating. Furthermore, the industry is increasing reliance on venture capital funded and mid-tier companies for new small molecule and biologics drugs and they prefer an outsourced CMO model. This will continue to drive further manufacturing outsourcing. Higher standards for quality control testing during process

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development and ongoing manufacturing will drive enhanced need for CMO testing support services, particularly rapid methods and fast turnaround services, to minimize the impact on manufacturing timelines and costs.

We believe that this changing environment will provide enhanced outsourcing opportunities for us in the future. We remain optimistic that our clients are increasingly receptive to partnering with CROs and CMOs as a means of meeting their discovery and preclinical support needs. We believe that the successful launch of new therapies and outsourcing by the pharmaceutical industry will continue to be positive drivers of demand for our products and services.

We also believe that larger biopharmaceutical companies will increasingly focus on efficiencies and execution. They will continue to reassess what are core differentiators from research and development to commercialization. We expect they will also continue to be conservative in re-building infrastructure and expertise. This should lead to more opportunities for strategic outsourcing as clients choose to utilize external resources rather than invest in internal infrastructure. In the aggregate, we believe that the evolving large biopharmaceutical research and development business model will make our essential products and services even more relevant to our clients, and allow them to leverage our integrated offerings and expertise to drive their research, preclinical development and manufacturing efficiency and cost effectiveness.

We believe it is critical to participate in the strategic partnering process because these relationships are likely to extend for lengthy periods of time - three to five years. Furthermore, both the client and the CRO invest heavily in the initial phases of the relationship to successfully transfer work streams and establish governance processes. Given this investment, clients are less likely to change CROs at the conclusion of the initial relationship. Our goal is to prevail in the majority of these opportunities.

We also believe that our portfolio provides flexible solutions that meet the customized needs for virtual and small biotechnology companies, which have limited or no infrastructure. These clients also value our ability to provide a broad range of services and integrated services where we work hand in hand with our customers to design, plan and manage integrated projects and programs. This includes classically outsourced services, “insourced” services and hybrid offerings blending resources from both our clients and staff. Our clients have utilized this capability, which blends both resources inside and outside their walls.

We maintain an intense focus on initiatives designed to allow us to drive profitable growth and maximize value for shareholders, and better position ourselves to operate successfully in the current and future business environment. As a result, we believe that we are well positioned to exploit both existing and new outsourcing opportunities.

We intend to continue to broaden the scope of the products and services we provide across the drug discovery and early-stage development continuum primarily through internal development, and, as needed, through focused acquisitions and alliances. Acquisitions are an integral part of our growth strategy, but we are committed to a disciplined approach that seeks to target businesses that are a sound strategic fit and that offer the prospect of enhancing shareholder value, typically including the achievement of a hurdle rate for return on invested capital above our weighted cost of capital. For example, in each of 2014 and 2015, we completed significant strategic acquisitions. In 2014, we acquired Argenta and BioFocus, global leaders in integrated drug discovery services with a predominant focus on in vitro capabilities, and ChanTest, a premier provider of ion channel testing. In 2015, we acquired Celsis Group Limited., a leading provider of rapid bacterial detection systems for sterile and non-sterile quality control testing in the biopharmaceutical and consumer products industries.

Our acquisition strategy also takes into account geographic as well as strategic expansion of existing core services. For example, in 2015, we acquired Oncotest, a Germany-based CRO providing discovery services for oncology, which complements our existing In Vivo Discovery businesses in the U.S. and Finland, and Sunrise Farms, a producer of SPF fertile chicken eggs and chickens used in the manufacture of live viruses. In 2013, we acquired Microbial Solutions Singapore and 75% ownership of Vital River, the premier commercial provider of research models and related services in China. And, in 2014 and 2012, we acquired VivoPath and Accugenix, respectively.

We are also partnering with a number of venture capital firms primarily investing in life sciences, health care and technology companies with an emphasis on early-stage emerging growth companies. Through these partnerships we are able to promote contract research services for discovery and safety assessment to these companies. This offers us

the opportunity to establish ourselves as a provider of choice for a unique client group which has emerged as biopharmaceutical companies rationalize and prioritize their development pipelines.

Customers

We maintain a three-pronged sales organization with a focus on:

global biopharmaceutical companies;

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small and mid-sized pharmaceutical and biotechnology companies; and academic and government institutions.

We also maintain several sales specialists which either have specific technical expertise (often degreed scientists) or cover unique markets.

Our clients continue to consist primarily of all of the major biopharmaceutical companies; many biotechnology, agricultural and chemical, life science, veterinary medicine, medical device, diagnostic and consumer product companies; contract research and contract manufacturing organizations; and other commercial entities, as well as leading hospitals, academic institutions, and government agencies. We have stable, long-term relationships with many of our clients. During 2015, no single commercial client accounted for more than 5% of our total revenue and no single customer accounted for more than 10% of the revenue of any of our three business segments.

We continue to pursue a goal of expanding our relationships with our large biopharmaceutical clients, and with many of our larger mid-market clients. These relationships take different forms, from preferred provider arrangements to strategic partnerships. The structure of these relationships incentivizes clients to purchase more products and services across our early-stage portfolio, and in total, the strategic relationships in which we are now engaged represent over 30% of our total revenues. Because of the strength of these relationships, we have better insight into our clients' planning processes, and therefore, better visibility than in the past. For information regarding revenue attributable to each of our business segments for the last three fiscal years, please see Note 14 "Segment and Geographic Information" included in the Notes to Consolidated Financial Statements included elsewhere in this Form 10-K. For information regarding revenue and long-lived assets attributable to operations in the United States, Europe, Canada, Japan and other countries for each of the last three fiscal years, please review Note 14 "Segment and Geographic Information" included in the Notes to Consolidated Financial Statements included elsewhere in this Form 10-K.

Sales, Marketing and Customer Support

We have designated dedicated sales people for each of our three client segments (global biopharmaceutical, small and mid-sized pharmaceutical and biotechnology companies, and academic and government institutions). This enhances our ability to meet client needs by offering customized, tailored solutions across our entire portfolio. In addition, our mid-market pharmaceutical and biotechnology clients benefit by additional support from a combination of account managers with broad portfolio knowledge and specialists with specific scientific expertise. This allows us to provide comprehensive coverage of all of the market segments among our diverse client population. We also apply the use of dedicated sales specialists for certain technical product lines, such as in our Manufacturing business.

We sell our products and services principally through our direct sales force and account management teams who work in North America, Europe and the Asia-Pacific countries. In addition to interactions with our direct sales force, our primary promotional activities include organizing scientific symposia, publishing scientific papers and newsletters, webinars and making presentations at, and participating in, scientific conferences and trade shows in North America, Europe and Asia. We supplement these scientifically based marketing activities with internet-based marketing, advertising and direct mail. In certain areas, our direct sales force is supplemented by international distributors and agents.

Our internal marketing/product management teams support the field sales staff and account management teams while developing and implementing programs to create close working relationships with our clients in the biomedical research industry. We maintain customer service, technical assistance and consulting service departments (in addition to project managers for our service businesses), which address both our clients' routine and more specialized needs and generally serve as a scientific resource for them. We frequently assist our clients in solving problems related to animal husbandry, health and genetics, biosecurity, preclinical study design, regulatory consulting, protocol development and other areas in which our expertise is widely recognized as a valuable resource by our clients.

Our marketing efforts are focused on stimulating demand for further outsourcing across our entire services portfolio. We believe that our ability to provide solutions that address all aspects of early-stage drug research are increasingly attractive to our clients, and we continue to design and market our commercial activities to deliver flexible, customized programs designed by segment to meet our clients' global and site-specific needs.

Competition

Our goal is to be a leader in each of the markets in which we participate. We compete in the marketplace on the basis of our therapeutic and scientific expertise in early-stage drug research, quality, reputation, flexibility, responsiveness, pricing,

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innovation and global capabilities. We are able to offer a unique portfolio of early-stage products and services to support drug discovery and development.

We encounter a broad range of competitors of different sizes and capabilities in each of our three businesses segments, although the largest competitors within any segment vary. We also face competition from the internal discovery and development resources of our clients.

For RMS, we have five main competitors of which one is a government funded, not-for-profit entity; one is part of a large public company; two are privately held in Europe and one is privately held in the U.S. We believe that none of these competitors compare to us in global reach, financial strength, breadth of product and services offerings, technical expertise or pharmaceutical and biotechnology industry relationships.

For DSA, both our Discovery Services and Safety Assessment businesses have numerous competitors. Discovery has hundreds of competitors as in a highly competitive and fragmented market. Safety Assessment has seven main competitors; one is part of a large public company in the U.S.; one is a privately held company in the U.K.; one is a private company with operations in the U.S. and China; one is a privately held company with operations in the U.S. and the EU; and three are privately held companies in the U.S. Our DSA segment also competes with in-house departments of pharmaceutical and biotechnology companies, universities and teaching hospitals.

For Manufacturing, each of our underlying businesses has several competitors. In addition to many smaller competitors, Biologics has five main competitors, of which three are public companies in Europe, one is a private company in the U.S., and one is a public company in China. Avian has one main competitor to its SPF eggs business, which is privately held in the European Union, and numerous competitors for services provided through our specialized avian laboratory. Microbial Solutions has six main competitors, of which three are public companies in the European Union, two are public companies in the U.S. and one is privately held in the U.S.

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 aspect 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 and implementation of the 3Rs (Replacement, Reduction and Refinement). 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 a role in the quality and efficiency of research. As researchers, we are responsible to our clients and the public for the health and well-being of the animals in our care.

We are firmly committed to the 3Rs and to reducing the number of animals used by emphasizing health and genetic integrity to decrease study data variability. Whenever possible, we use technological advances such as new diagnostic tests for screening pathogens in laboratory rodents, microsampling and in vitro assays. We also partner with customers to develop study designs decreasing the number of animals needed and suggesting pilot studies where appropriate. We have recently instituted a quarterly award recognizing our employees' efforts to continually implement the 3Rs at our sites globally.

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 and the supporters of 3Rs.

Employees

As of December 26, 2015, we had approximately 8,600 employees (including approximately 770 science professionals with advanced degrees, including Ph.D.s, D.V.M.s and M.D.s). Our employees are not unionized in the U.S. Employees at some of our European facilities are represented by works councils and/or unions, which is consistent with local customs for our industry. We believe we have good relationships with our employees, based on a number of factors including employee retention and survey results.

Backlog

Our backlog for our RMS, DSA and Manufacturing reportable segments was \$106.6 million, \$327.8 million and \$36.2 million, respectively, as of December 26, 2015, as compared to \$115.7 million, \$310.5 million and \$27.5 million, respectively, as of

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December 27, 2014. Related 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 client's intention to proceed. Canceled 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 or projects that are included in 2015 backlog may be completed in 2016, while others may be completed in later years). Second, the scope of studies or projects may change, which may either increase or decrease their value. Third, studies or projects included in backlog may be subject to bonus or penalty payments. Fourth, studies or projects may be terminated or delayed at any time by the client or regulatory authorities for a number of reasons, including the failure of a drug to satisfy safety and efficacy requirements, or a sponsor making a strategic decision that a study or service is no longer necessary. 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 environments and in a variety of locations worldwide, we are subject to numerous, and sometimes overlapping, regulatory environments.

The Animal Welfare Act (AWA) governs the care and use of certain species of animals used for research in the U.S. other than laboratory rats, mice and chickens. As a result, most of our U.S. small animal research models activities and our avian vaccine services operations are not subject to regulation under the AWA. For regulated species, the AWA and the associated 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, for certain species, environmental enrichment to assure the welfare of these animals. Separately, facilities using live vertebrate animals in research funded by the U.S. Public Health Service (PHS) must also adhere to the PHS Policy on Humane Care and Use of Laboratory Animals and follow the Guide for the Care and Use of Laboratory Animals produced by the Institute for Laboratory Animal Research.

We comply with licensing and registration requirement standards set by the United States Department of Agriculture (USDA) and similar agencies in other countries such as the European Union, China, Japan and Canada for the care and use of regulated species. Our animal production facilities in the U.S. - our DSA facilities in the U.S., and Canada - and most of our DSA sites in the European Union are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, a private, nonprofit, international organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

Our import and export of animals and our operations in foreign countries are subject to international agreements and conventions, as well as a variety of national, regional, and local laws and regulations, which establish the standards for the humane treatment, care, handling and transport of animals by dealers and research facilities.

We conduct nonclinical safety assessment studies to support the submissions for approval or licensing of our clients' products throughout the world. Many of these studies must comply with national statutory or regulatory requirements for Good Laboratory Practice (GLP). GLP regulations describe a quality system for the organizational process and the conditions under which nonclinical studies are planned, performed, monitored, recorded, reported and archived. GLP compliance is required by such regulatory agencies as the FDA, United States Environmental Protection Agency, European Medicines Agency, Medicines and Healthcare Products Regulatory Agency in the U.K., Health Products Regulatory Authority in Ireland, Health Canada and other similar monitoring authorities in the countries where we operate. GLP requirements are significantly harmonized throughout the world and our laboratories are capable of conducting studies in compliance with all necessary requirements.

Our Manufacturing businesses produce endotoxin test kits, reagents, cell banks used in research and biopharmaceutical production, clinical trial vaccines and vaccine support products. Additionally, several of our laboratories conduct identity, stability, sterility and potency testing in support of our clients' manufacturing programs

working with our clients to fulfill their validation requirements as applicable. These activities are subject to regulation by the FDA and other national regulatory agencies under their respective current Good Manufacturing Practice (cGMP) regulations. These regulations require that we manufacture our products or perform testing in a prescribed manner with respect to cGMP compliance, and maintain records of our manufacturing, testing and control activities. In addition, the specific activities of some of our businesses require us to hold specialized licenses for the manufacture, distribution and/or marketing of particular products.

All of our sites are subject to licensing and regulation under international treaties and conventions, including national, regional and local laws relating to:

- the surface and air transportation of chemicals, biological reagents and laboratory specimens;
- the handling, use, storage and disposal of chemicals (including narcotics and psychotropic drugs), biological reagents, laboratory specimens, hazardous waste and radioactive materials;
- the procurement, handling, use, storage and disposal of human cells, tissues and cellular and tissue based products for research purposes;
- the safety and health of employees and visitors to our facilities; and
- protection of the environment and general public.

Global compliance programs are centralized under a single group responsible for global quality programs and systems to ensure that all business sectors comply with applicable statutory and regulatory requirements and satisfy our clients' expectations for quality and regulatory compliance. To assure these compliance obligations, we established quality assurance units (QAUs) in each of our regulated businesses that require independent oversight. The QAUs operate independently from those individuals that direct and conduct studies, manufacturing or studies that support manufacturing.

Intellectual Property

We develop and implement computer software and technically derived procedures and products intended to maximize the quality and effectiveness of our services. Although our intellectual property rights are valuable to our success, we believe that such factors as the technical expertise, proprietary know-how, ability and experience of our professionals are more important, and that, overall, these technological capabilities provide significant benefits to our clients. Where we consider it appropriate, steps are taken to protect our know-how through confidentiality agreements and registrations. In addition, we in-license technology and products from other companies when it enhances our product and services businesses. In the future, in-licensing may become a larger initiative to enhance our offerings, particularly as we focus on therapeutic area expertise. With the exception of technology related to our Microbial Solutions testing business, we have no patents, trademarks, licenses, franchises or concessions which are material and upon which any of our products or services are dependent.

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 SEC, and the Federal government as implemented by the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Eight of the nine members of our Board of Directors are independent and have no significant financial, business or personal ties to us or management and all of our board committees (with the exception of our Executive Committee and our Strategic Planning and Capital Allocation Committee) are composed entirely of independent directors. The Board adheres to our Corporate Governance Guidelines and a Code of Business Conduct and Ethics which has been communicated to employees and posted on our website. We are diligent in complying with established accounting principles and are committed to providing financial information that is transparent, timely and accurate. We have a Related Person Transactions Policy designed to promote the timely identification of such transactions and to ensure we give appropriate consideration to any real or perceived conflicts in our commercial arrangements. We have a global process 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 under the "Investor Relations-Corporate Governance" caption.

Item 1A. Risk Factors

Set forth below, 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 preclinical (discovery and safety assessment) stages of drug discovery and development may decrease, which could impair our growth.

Over the past decade, pharmaceutical and biotechnology companies have generally increased their outsourcing of preclinical research support activities, such as discovery and safety assessment. While many industry analysts expect the outsourcing trend to continue to increase for the next several years (although with different growth rates for different phases of drug discovery and development), decreases in such outsourcing may result in a diminished growth rate in the sales of any one or more of our service lines and may adversely affect our financial condition and results of operations. For additional discussion of the factors that we believe have recently been influencing outsourcing demand from our clients, please see the section entitled "Our Strategy" included elsewhere in this Form 10-K.

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

Our clients 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 molecules in the preclinical phases of research and development (and in particular discovery and safety assessment) and to outsource the products and services we provide. Fluctuations in the expenditure amounts in each phase of 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 (including available resources of our biotechnology clients, particularly those that are cash-negative, who may be highly focused on rationing their liquid assets in a challenging funding environment), general economic conditions and institutional budgetary policies. Available funding for biotechnology clients in particular may be affected by the capital markets, investment objectives of venture capital investors, and priorities of biopharmaceutical industry sponsors.

Our business could be adversely affected by any significant decrease in drug research and development expenditures by pharmaceutical and biotechnology companies, as well as by academic institutions, government laboratories or private foundations. In particular, studies in recent years have indicated that a majority of academic researchers are anticipating reductions in their budgets. Similarly, economic factors and industry trends that affect our clients in these industries, also affect their research and development budgets and, consequentially, our business as well. Furthermore, our clients (particularly larger biopharmaceutical companies) continue to search for ways to maximize the return on their investments with a focus on leaner research and development costs per drug candidate. For additional discussion of the factors that we believe have recently been influencing research and development budgets at our clients, please see the sections entitled "Our Strategy" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K.

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

A portion of revenue in our RMS segment is derived from clients 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, which can be difficult to forecast. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Our sales may be adversely affected if our clients 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. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the U.S. government as a higher priority. These budgetary pressures may result in reduced allocations in the future to government agencies that fund research and development activities. Only since 2013 has funding for the NIH begun to increase. A reduction in government funding for the NIH or other government research agencies could adversely affect our business and our financial results. Also, there is no guarantee that NIH funding will be directed towards projects and studies that require use of our products and services.

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 for certain products, such as large research models. Disruptions to their continued supply may arise from health problems, export or import laws/restrictions or embargoes, international trade regulations, foreign government or economic instability, severe weather conditions, increased competition amongst suppliers for models, disruptions to the air travel system, commercial disputes, supplier insolvency, or other normal-course or

unanticipated events. 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.

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

Governmental agencies throughout the world, but particularly in the U.S., strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies, among others, navigate the regulatory drug approval process. Accordingly, many regulations, and often new regulations, are expected to result in higher regulatory standards and often additional revenues for companies that service these industries. However, some changes in regulations, such as a relaxation in regulatory requirements or the introduction of streamlined or expedited 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.

Although we believe we are currently in compliance in all material respects with national, regional and local laws as well as other accepted guidance used by oversight bodies (which include the USDA, the standards set by the International Air Transport Association, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, U.S. Fish and Wildlife Service, The Centers for Disease Control, the Department of Transportation, the office of Laboratory Animal Welfare of NIH, the Drug Enforcement Agency as well as numerous other Canadian, European and Asian oversight agencies), failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions. In addition, if regulatory authorities were to mandate a significant reduction in safety assessment procedures which utilize laboratory animals (as has been advocated by certain groups), certain segments of our business could be materially adversely affected.

In March 2010, the U.S. Congress enacted health care reform legislation intended over time to expand health insurance coverage and impose health industry cost containment measures. In June 2012, the U.S. Supreme Court upheld the constitutionality of this legislation. The Court's decision allows implementation of key provisions impacting drug manufacturers going forward including, but not limited to, (1) expansion of access to health insurance coverage, (2) expansion of the Medicaid program, (3) enactment of an industry fee on pharmaceutical companies, and (4) imposition of an excise tax on the sale of medical devices. Since the law and its implementation continue to face challenges in Congress and federal courts, and from certain state governments, opposition advocacy groups, and some small business organizations, we are uncertain as to the effects of this legislation on our business and are unable to predict what legislative proposals will be adopted in the future.

Implementation of health care reform legislation may have certain benefits but also may contain costs that 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 U.S. and abroad. In addition, new laws or regulations may create a risk of liability, increase our costs or limit our service offerings. Furthermore, if health insurers were to change their practices with respect to reimbursements for pharmaceutical products, our clients may spend less, or reduce their growth in spending on research and development.

The FDA is in the process of reviewing and modernizing the GLP regulations to reflect current industry standards. As this may change some of the GLP requirements, the regulatory impact will not be known until the final regulations are issued.

We are at risk that changes in U.S. Government practices may negatively affect our business since it is a significant customer of ours. For example, in 2014, the National Cancer Institute (NCI) canceled a 10-year, \$112.0 million contract that was originally initiated in 2006, which had two years remaining. Under the contract, we produced NCI research models for academic and government researchers. In an effort to mitigate the effect of the cancellation, we launched an outreach program to inform researchers that they could continue to obtain the NCI models from us, with no change in initial pricing or logistics. From a revenue standpoint, we received between \$10.0 and \$11.0 million annually to produce the models, and expect that we will retain approximately half of that amount from direct sales to researchers.

Contaminations in our animal populations can damage our inventory, harm our reputation for contaminant-free production, result in decreased sales and cause us to incur additional costs.

Our research models and fertile chicken eggs must be free of certain 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 GEMS, harm our reputation for contaminant-free production and result in decreased sales.

If they occur, contaminations typically require cleaning up, renovating, disinfecting, retesting and restarting production or services. Such clean-ups result in inventory loss, clean-up and start-up costs, and reduced sales as a result of lost client orders and potentially credits for prior shipments. In addition to microbiological contaminations, the potential for genetic mix-ups or mis-matings also exists and may require the restarting of the applicable colonies. While this does not require the complete clean-up, renovation and disinfection of the barrier room, it would likely result in inventory loss, additional start-up costs and possibly reduced sales. Contaminations also expose us to risks that clients will request compensation for damages in excess of our contractual indemnification requirements. There also exists a risk that contaminations from models that we produce may affect our client's facilities, with similar impact to them for which we could be liable for damages. In some cases, we may produce or import animals carrying infectious agents capable of causing disease in humans; and in the case of such a contamination or undiagnosed infection, there could be a possible risk of human exposure and infection.

We are also subject to similar contamination risks with respect to our large research models. While often we own these models, they may be maintained on our behalf at a site operated by the original provider. Accordingly, risk of contamination may be outside of our control, and we depend on the practices and protocols of third parties to ensure a contamination-free environment. A contamination may require extended CDC quarantine with subsequent reduced sales as a result of lost client orders as well as the potential for complete inventory loss and disinfection of the affected quarantine rooms. Furthermore, while we often negotiate for contractual risk indemnification, we may be exposed in the event of such contaminations if the third party does not fulfill its indemnification obligation or is unable to as a result of insolvency or other impediments.

All such contaminations described above are unanticipated and difficult to predict and could adversely impact our financial results. Many of our operations are comprised of complex mechanical systems which are subject to periodic failure, including aging fatigue. Such failures are unpredictable, and while we have made significant capital expenditures designed to create redundancy within these mechanical systems, strengthen our biosecurity, improve our operating procedures to protect against such contaminations, and replace impaired systems and equipment in advance of such events, failures and/or contaminations may still occur.

Any failure by us to comply with applicable regulations and related guidance could harm our reputation and operating results, and compliance with new regulations and guidance may result in additional costs.

Any failure on our part to comply with applicable 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, the issuance of a notice of objectionable observations or a warning from the FDA based on a finding of a material violation by us for GLP or cGMP requirements could materially and adversely affect us. If our operations are found to violate any applicable law or other governmental regulations, we might be subject to civil and criminal penalties, damages and fines. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

In addition, regulations and guidance worldwide concerning the production and use of laboratory animals for research purposes continues to be updated. Notably, the European Directive 2010/63/EU requires new standards for animal housing and accommodations that require implementation by 2017. Some of these new standards require additional operating and capital expenses that will impact not only us and our industry competitors, but clients in the biomedical research community through both changes in the pricing of goods and services and changes in their own operations. Similarly, guidance has been and continues to be developed for other areas that impact the biomedical research community on both a national and international basis including transportation, mandated contingency planning, euthanasia guidance, import and export requirements of biological materials, health monitoring requirements and the use of disinfectants.

Our revenue generating agreements contain termination and service reduction provisions or may otherwise terminate according to their term, which may result in less contract revenue than we anticipate.

Many of our agreements with both large and small clients, including those which underlie our strategic relationships with some of our more significant customers, provide for termination or reduction in scope with little or no notice. In

addition, we sell our products and services to our competitors, and similarly they sell products and services to us. For instance, we have historically entered into, and currently are party to, contracts with certain of our competitors to distribute specialty research models in locations where our competitors may not have distribution capabilities. Clients and/or competitors 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;
- a client's decision to forego or terminate a particular study;
- establishment of alternative distribution channels by our competitors;
- the loss of funding for the particular research study; or
- general convenience/counterparty preference.

If a client or competitor terminates a contract with us, we are typically entitled under the terms of the contract to receive revenue earned to date as well as certain other costs and, in some cases, termination fees. Cancellation of a large contract or proximate delay, cancellation or conclusion of multiple contracts could materially adversely affect our business 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, and often at the discretion of the client. 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 predetermined termination fee and irrevocably committed costs/expenses.

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 client data. As a routine element of our business, we collect, analyze and retain substantial amounts of data pertaining to the preclinical studies we conduct for our clients. 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 appropriate measures to protect them from intrusion, and we continue to improve and enhance our systems in this regard, but in the event that our efforts are unsuccessful we could suffer significant harm. Our contracts with our clients 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.

Impairment of goodwill or other intangible assets may adversely impact future results of operations.

We have intangible assets, including goodwill, on our balance sheet due to our acquisitions of businesses. The initial identification and valuation of these intangible assets and the determination of the estimated useful lives at the time of acquisition involve use of management judgments and estimates. These estimates are based on, among other factors, projections of cash flows that arise from identifiable intangible assets of acquired businesses and discount rates based on an analysis of our weighted average cost of capital, adjusted for specific risks associated with the assets.

Disruptions in global financial markets and deterioration of economic conditions could, among other things, impact the discount rate and other assumptions used in the valuations and actual cash flows arising from a particular intangible asset could vary from projected cash flows, which could imply different carrying values from those established at the dates of acquisition and which could result in impairment of such assets.

If the future growth and operating results of our business are not as strong as anticipated, overall macroeconomic or industry conditions deteriorate and/or our market capitalization declines, this could impact the assumptions used in calculating the carrying value of goodwill or other intangibles. To the extent goodwill or other intangibles are impaired, their carrying value will be written down to their implied fair value and a charge will be made to our income from continuing operations. Such an impairment charge could materially and adversely affect our operating results. As of December 26, 2015, the carrying amount of goodwill and other intangibles on our consolidated balance sheet was \$719.6 million.

Our business is subject to risks relating to operating internationally.

A significant part of our revenue is derived from operations outside the U.S. Our international revenues, which include revenues from our non-U.S. subsidiaries, have represented approximately one-half of our total revenue in recent years. We expect that

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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 and in which we record expenses outside the U.S. could be subject to unfavorable exchange rates with the U.S. dollar and reduce the amount of revenue and cash flow (and increase the amount of expenses) that we recognize and cause fluctuations in reported financial results;
- certain contracts, particularly in Canada, are frequently denominated in currencies other than the currency in which we incur expenses related to those contracts and 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;
- general economic and political conditions in the markets in which we operate;
- potential international conflicts, including terrorist acts;
- potential trade restrictions, exchange controls, adverse tax consequences, and legal restrictions on the repatriation of funds into the U.S.;
- difficulties and costs associated with staffing and managing foreign operations, including risks of work stoppages and/or strikes, as well as violations of local laws or anti-bribery laws such as the U.S. Foreign Corrupt Practices Act, the UK Bribery Act, and the Organization for Economic Co-operation and Development (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;
- potentially negative consequences from changes in or interpretations of U.S. and foreign tax laws;
- exposure to business disruption or property damage due to geographically unique natural disasters;
- longer accounts receivable cycles in certain foreign countries; and
- import and export licensing requirements.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. For example, as mentioned above, we are subject to compliance with the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. While our employees, distributors and agents are required to comply with these laws, we cannot be sure that our internal policies and procedures will always protect us from violations of these laws despite our commitment to legal compliance and corporate ethics. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

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

The scientific and research communities continue to explore methods to develop improved models and systems that would improve the translation of cellular and animal models to human studies and vice-versa and possibly replace or supplement the use of traditional living animals as test platforms in biomedical research. Some companies have developed techniques in these areas that may have scientific merit to improve translation between species. In addition, technological improvements to existing or new processes, such as imaging and other translational biomarker technologies, could result in the refinement and utility for the number of animal research models necessary to improve the translation from preclinical to human studies. There is an increasing push to focus on in vitro technologies such as human materials, stem cell technology and model creation technology. However, the increasing availability and utility of these in vitro models is partially offset by these technologies facilitating the creation of humanized, highly specialized and specific disease mimicking models we can produce.

It is our strategy to explore these in vitro technologies to refine and potentially reduce the utilization of animal models as these new methods become validated. For example, ChanTest has a well-developed program to evaluate the cardiac properties of induced pluripotent stem cell-derived cardiomyocytes. We may not be successful in commercializing these methods, and, furthermore, revenues from these new models and approaches if successfully developed may not

offset reduced sales or profits

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from research models. In addition, alternative research methods could decrease the need for future research models, and we may not be able to develop new products effectively or in a timely manner to replace any lost sales. Lastly, other companies or entities may develop research models with characteristics different than the ones that we produce, and which may be viewed as more desirable by some of our clients.

Negative attention from special interest groups may impair our business.

The products and services which we provide our clients are essential to the drug discovery, development and manufacturing processes, and are almost universally mandated by law. Notwithstanding, certain special interest 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, including shareholder proposals and attempts to disrupt air carriers from transporting research models, impacting the industry. This has included demonstrations near facilities operated by us and at our annual meetings, as well as shareholder proposals we received for some of our past Annual Meetings of Shareholders. Periodic demonstrations at our operating sites occur, particularly where large animals are situated. Any negative attention, threats or acts of vandalism directed against either our animal research activities or our third party service providers such as our airline carriers in the future could impair our ability to operate our business efficiently.

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

At December 26, 2015, we had \$829.4 million of debt and in connection with our plan to acquire WIL Research (See Note 16 “Subsequent Events”, included in the Notes to Consolidated Financial Statements elsewhere in this Form 10-K), we announced our intention to increase our borrowing by approximately \$350.0 million. Our 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. For additional information regarding our debt, please see Note 7 “Long-Term Debt and Capital Lease Obligations”, included in the Notes to Consolidated Financial Statements elsewhere in this Form 10-K.

The drug discovery, development services and manufacturing support industries are highly competitive.

The drug discovery, preclinical development and manufacturing support services industries are highly competitive.

We often compete for business not only with other CROs and CMOs, but also with internal discovery and development departments within our larger clients, who may have greater resources than ours. We also compete with universities and teaching hospitals for outsourced services. We compete on a variety of factors, including:

- reputation for on-time quality performance;
- reputation for regulatory compliance;
- expertise and experience in multiple specialized areas;
- scope and breadth of service and product offerings across the drug discovery and development spectrum;
- scope and breadth of service and product offerings across the manufacturing support spectrum;
- ability to provide flexible and customized solutions to support our clients' drug discovery, preclinical development and manufacturing support needs;
- broad geographic availability (with consistent quality);
- price/value;
- technological expertise and efficient drug development processes;
- quality of facilities;
- financial stability;
- size;
- ability to acquire, process, analyze and report data in an accurate manner; and
- accessibility of client data through secure portals.

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, who are targets for each other and for larger pharmaceutical companies. If this trend continues, it is likely to produce more competition among the larger companies and CROs and CMOs generally, with respect to both clients and acquisition candidates. In addition, small, specialized entities considering entering the CRO industries will continue to find lower barriers to entry, and private equity firms may determine that there are opportunities to acquire and consolidate these companies, thus further increasing possible competition. More generally, our competitors or others might develop technologies, services or products that are more effective or commercially attractive than our current or future technologies, services or products, or that render our technologies, services or products less competitive or obsolete. If competitors introduce superior technologies, services or products and we cannot make enhancements to ours to remain competitive, our competitive position, and in turn our business, revenue and financial condition, would be materially and adversely affected. In the aggregate, these competitive pressures may affect the attractiveness of our technologies, services or products and could adversely affect our financial results.

Potential Changes in U.S. and International Tax Law.

In the U.S., there are several proposals to reform corporate tax law that are currently under consideration. These proposals include reducing the corporate statutory tax rate, broadening the corporate tax base through the elimination or reduction of deductions, exclusions and credits, implementing a territorial regime of taxation, limiting the ability of U.S. corporations to deduct interest expense associated with offshore earnings, modifying the foreign tax credit rules, and reducing the ability to defer U.S. tax on offshore earnings. These or other changes in the U.S. tax laws could increase our effective tax rate which would affect our profitability.

We have substantial operations in Canada and the United Kingdom which currently benefit from favorable corporate tax arrangements. We receive substantial tax credits in Canada, from both the Canadian federal and Quebec governments, and the United Kingdom. Any reduction in the availability or amount of these tax credits due to tax law changes or outcomes of tax controversies could have a material adverse effect on our profits, cash flow and effective tax rate.

Currently, the OECD has developed an action plan to address concerns regarding base erosion and profit shifting (BEPS). This initiative has resulted in proposed and enacted changes to tax laws in various countries including France, Germany, and the United Kingdom. Future changes to tax laws or interpretation of tax laws resulting from the BEPS project could increase our effective tax rate which would affect our profitability.

Contract research services create a risk of liability.

As a CRO, we face a range of potential liabilities which may include:

errors or omissions in reporting of study detail in preclinical studies that may lead to inaccurate reports, which may undermine the usefulness of a study or data from the study, or which may potentially advance studies absent the necessary support or inhibit studies from proceeding to the next level of testing;

risks associated with our possible failure to properly care for our clients' property, such as research models and samples, study compounds, records, work in progress, other archived materials, or goods and materials in transit, while in our possession;

risks that models in our breeding facilities or in facilities that we manage may be infected with diseases that may be harmful and even lethal to themselves or humans despite preventive measures contained in our policies for the quarantine and handling of imported animals; and

risks that we may have errors and omissions and/or product liabilities related to our products designed to conduct lot release testing of medical devices, injectable drugs, food, beverages and home and beauty products (primarily through our Microbial Solutions business) or in the testing of biologics and other services performed by our Biologics business, which could result in us or our clients failing to identify unsafe or contaminated materials.

While we attempt to mitigate these risks through a variety of methods, it is impossible to completely eradicate such risks. In our RMS business, we mitigate these risks to the best of our abilities through our regimen of animal testing, quarantine procedures, and veterinary staff vigilance, through which we seek to control the exposure of animal related

disease or infections. In our DSA and Manufacturing businesses, we attempt to reduce these risks by contractual risk transfer provisions entitling us to be indemnified subject to a limitation of liability, by insurance maintained by our clients and/or by us, and by various regulatory requirements we must follow in connection with our business.

Contractual risk transfer 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 are required to pay damages or bear the costs of defending any claim that is outside any contractual indemnification provision, or if a party does not fulfill its indemnification obligations, or the damage is beyond the scope or level of insurance coverage. We also often contractually indemnify our clients (subject to a limitation of liability), similar to the way they indemnify us, and we may be materially adversely affected if we have to fulfill our indemnity obligations. Furthermore, there can be no assurance that we nor a party required to indemnify us will be able to maintain such insurance coverage (either at all or on terms acceptable to us).

If we are not successful in selecting and integrating the businesses and technologies we acquire, or in managing our current and future divestitures, our business may suffer.

During the past fifteen years, we have steadily expanded our business through numerous acquisitions. We plan to continue to acquire businesses and technologies and form strategic 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 transactions.

On January 6, 2016, we announced our plans to acquire WIL Research, a premier provider of safety assessment and contract development manufacturing services to biopharmaceutical, agricultural and industrial chemical companies worldwide. If consummated, this transaction will be the largest acquisition in over ten years. Refer to Item 8, "Financial Statements and Other Supplementary Data" in this Annual Report on Form 10-K for more details.

Even if completed, acquisitions and alliances involve numerous risks which may include:

- difficulties in achieving business and financial success;
- difficulties and expenses incurred in assimilating and integrating operations, services, products, technologies or pre-existing relationships with our customers, distributors and suppliers;
- challenges with developing and operating new businesses, including those which are materially different from our existing businesses and which may require the development or acquisition of new internal capabilities and expertise;
- potential losses resulting from undiscovered liabilities of acquired companies that are not covered by the indemnification we may obtain from the seller or the insurance we acquire in connection with the transaction;
- loss of key employees;
- the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;
- diversion of management's attention from other business concerns;
- acquisitions could be dilutive to earnings, or in the event of acquisitions made through the issuance of our common stock to the shareholders of the acquired company, dilutive to the percentage of ownership of our existing shareholders;
- risks of not being able to overcome differences in foreign business practices, customs and importation regulations, language and other cultural barriers in connection with the acquisition of foreign companies;
- new technologies and products may be developed which cause businesses or assets we acquire to become less valuable; and
- risks that disagreements or disputes with prior owners of an acquired business, technology, service or product may result in litigation expenses and distribution of our management's attention.

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

Some of the same risks exist when we decide to sell a business, site, or product line. In addition, divestitures could involve additional risks, including the following:

- difficulties in the separation of operations, services, products and personnel; and
- the need to agree to retain or assume certain current or future liabilities in order to complete the divestiture.

We continually evaluate the performance and strategic fit of our businesses. These and any divestitures may result in significant write-offs, including those related to goodwill and other intangible assets, which could have an adverse effect on our results of operations and financial condition. In addition, we may encounter difficulty in finding buyers, or, alternative exit strategies at acceptable prices, terms and in a timely manner. We may not be successful in managing these or any other significant risks that we encounter in divesting a business, site or product line, and as a result, we may not achieve some or all of the expected benefits of the divestiture.

Upgrading and integrating our business systems could result in implementation issues and business disruptions. In recent years we implemented a project to replace many of our numerous legacy business systems at certain sites worldwide with an enterprise wide, integrated enterprise resource planning (ERP) system. The expansion of the system to other international locations may occur at a future date based on value to the business. In general, the process of planning and preparing for these types of integrated, wide-scale implementations is extremely complex and we are required to address a number of challenges including data conversion, system cutover and user training. Problems in any of these areas could cause operational problems during implementation including delayed shipments, missed sales, billing and accounting errors and other operational issues. There have been numerous, well-publicized instances of companies experiencing difficulties with the implementation of ERP systems which resulted in negative business consequences.

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.

We may not be able to successfully develop and market new services and products.

We may seek to develop and market new services and products that complement or expand our existing business or service offerings. We believe our ability to in-license new technologies from third-parties will be critical to our ability to offer new products and services to our customers. Our ability to gain access to technologies that we need for new products and services depends, in part, on our ability to convince inventors and their agents or assignees that we can successfully commercialize their inventions. We cannot guarantee that we will be able to identify new technologies of interest to our customers. Even if we are able to identify new technologies of interest, we may not be able to negotiate license agreements on acceptable terms, or at all. If we are unable to develop new services and products and/or create demand for those newly developed services and products, our future business, results of operations, financial condition, and cash flows could be adversely affected.

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 four decades. We have no employment agreement with Mr. Foster or other members of our non-European based senior management. If Mr. Foster or other members of senior 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 attracting and retaining qualified scientific, technical and managerial personnel. While we have a strong record of employee retention, there is still significant 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:

- changes in the general global economy;

- the number and scope of ongoing client engagements;
- the commencement, postponement, delay, progress, completion or cancellation of client contracts in the quarter;
- changes in the mix of our products and services;
- competitive pricing pressures;
- the extent of cost overruns;
- holiday buying patterns of our clients;
- budget cycles of our clients;
- changes in tax laws, rules, regulations and tax rates in the locations in which we operate;
- the timing and charges associated with completed acquisitions and other events;
- the financial performance of the limited partnerships in which we invest;
- the occasional extra “53rd week” that we recognize in a fiscal year (and 4th fiscal quarter thereof) due to our fiscal year ending on the last Saturday in December; 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.

Our industry has a history of patent and other intellectual property litigation, which can be costly.

Our industry has a history of intellectual property litigation. On July 31, 2015, IDEXX Laboratories, Inc. and IDEXX Distribution, Inc. filed a complaint in the United States District Court for the District of Delaware alleging we infringed three recently issued patents related to a dried blood spot sample collection method used in determining the presence or absence of an infectious disease in a population of rodents. Legal proceedings relating to intellectual property can be expensive, take significant time and divert management’s attention from other business concerns, regardless of the outcome of the litigation. While we intend to defend against this proceeding vigorously, if we do not prevail in this lawsuit, we might be ordered to pay damages, and we could be required to stop the infringing activity or obtain a license to use the technology on unfavorable terms.

Since we do not expect to pay any cash dividends for the foreseeable future, our shareholders will benefit from an investment in our common stock only if it appreciates in value.

We have never declared or paid any cash dividends on our common stock. We do not anticipate that we will pay any dividends to holders of our common stock for the foreseeable future. Any payment of cash dividends will be at the discretion of our Board of Directors and will depend on our financial condition, capital requirements, legal requirements, earnings and other factors. Consequently, our shareholders should not rely on dividends to receive a return on their investment.

Item 1B. Unresolved Staff Comments

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

Item 2. Properties

We own or lease the land and buildings where we have facilities. We own large facilities (facilities over 50,000 square feet) for our DSA businesses in Canada, Ireland, Scotland and the United States and lease large facilities in England and the United States. We own large RMS facilities in Canada, China, France, Germany, Japan, England and the United States. We own large Manufacturing segment facilities in the United States and China. None of our leases is individually material to our business operations. Many of our leases have an option to renew, and 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, “Long-Term Debt and Capital Lease Obligations” and Note 13, “Commitments and Contingencies” included in Item 8, “Financial Statements and Other Supplementary Data” in this Annual Report on Form 10-K.

Capacity at our Safety Assessment businesses within our DSA segment is primarily based on physical room infrastructure designed towards meeting specific scientific and regulatory requirements. We track room utilization on an ongoing basis and

depending on the needs of our clients at given times, we may need to execute on contingent plans for expansion, which average between six and fifteen months to complete.

We may also expand at specific sites in order to accommodate needs resulting from any consolidation strategy. We continue to employ a master site planning strategy to proactively evaluate our real estate needs. In certain circumstances, we dispose of or consolidate operations, which could result in impairment charges. In situations where the associated real estate is leased, and depending on the resolution of these situations, we may be encumbered with the remaining real estate lease obligations.

Item 3. Legal Proceedings

We are not 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.

In early May 2013, with the assistance of the law firm of Davis Polk & Wardwell LLP, we commenced an investigation of inaccurate billing with respect to certain government contracts. This issue had been reported to our senior management by a Charles River employee. We promptly reported these matters to the relevant government contracting officers, the Department of Health and Human Services' Office of the Inspector General, and the Department of Justice, and is cooperating with these agencies to ensure the proper repayment and resolution of this matter.

The investigation to date has confirmed that our RMS business segment billed the Department of Health and Human Services for certain work that had not been performed with respect to a small subset of our government contracts. It has been determined that when employees regularly assigned to work in research model barrier rooms associated with these contracts were absent, other employees' names would be substituted on time-keeping records associated with the relevant contracts. We billed the government for the hours associated with these substitute employees, despite the fact that, in many cases, these employees did not perform any services in connection with the relevant government contracts. Based on the findings of the investigation to date, we believe that this conduct was limited to our research model facilities in Raleigh, North Carolina, and Kingston, New York. We have identified approximately \$1.5 million in excess amounts billed on these contracts since January 1, 2007 and have recorded a liability for such amount as of December 26, 2015. Because of the ongoing discussions with the government and the complex nature of this matter, we believe it is reasonably possible that additional losses may be incurred but cannot at this time make a reasonable estimate of the potential range of loss beyond such estimated liability.

We have already taken appropriate steps to prevent this conduct from recurring, and will consider additional remedial measures following the conclusion of the investigation.

On July 31, 2015, IDEXX Laboratories, Inc. and IDEXX Distribution, Inc. (collectively, IDEXX) filed a complaint in the United States District Court for the District of Delaware alleging we infringed three recently issued patents related to a blood spot sample collection method used in determining the presence or absence of an infectious disease in a population of rodents. On September 21, 2015, we timely filed a motion to dismiss the complaint on the grounds that all of the claims are directed to unpatentable subject matter and therefore are invalid. On October 7, 2015, IDEXX filed an amended complaint which substantially asserts the same patents and infringement allegations as asserted in the original complaint and, on October 26, 2015, we timely filed a motion to dismiss this amended complaint. While no prediction may be made as to the outcome of litigation, we intend to defend against this proceeding vigorously and therefore an estimate of the possible loss or range of loss cannot be made.

Item 4. Mine Safety Disclosures

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 of each of 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.

James C. Foster, age 65, joined us in 1976 as General Counsel. During his tenure, 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 60, joined us in 1999 with the acquisition of Sierra Biomedical. Dr. Gillett has 29 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 DSA 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. Currently, Dr. Gillett serves as our Corporate Executive Vice President, Chief Scientific Officer.

David P. Johst, age 54, 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 our General Counsel and Chief Administrative Officer and is responsible for overseeing our corporate legal function, Human Resources department and several other corporate staff departments. Prior to joining us, Mr. Johst was in private practice at the law firm of Hale and Dorr (now WilmerHale). Mr. Johst currently serves as a trustee of Mt. Ida College.

Davide Molho, age 46, joined our Italian operations in 1999 and was promoted to Director of Operations for Research Models and Services (RMS) Italy in 2002. In 2005, his role was expanded to include French RMS operations and in 2007, he became Corporate Vice President, European Research Models and Services with responsibility for all European RMS operations. In July 2009, Dr. Molho was promoted to Corporate Senior Vice President, North American and European Research Models and Services. He was subsequently promoted to Corporate Executive Vice President and President, Global Research Models and Services in December 2010. In 2011, Dr. Molho was named Corporate Executive Vice President, North America Operations and in December 2013, he was named Corporate Executive Vice President and President, Global RMS and DSA Operations.

David R. Smith, age 50, has served as our Corporate Executive Vice President and Chief Financial Officer since August 2015. He joined us as Corporate Vice President, Discovery Services through our acquisition of Argenta and BioFocus from Galapagos NV in March 2014 and was promoted to Corporate Senior Vice President, Global Discovery Services in October 2014. At Galapagos, he served in various capacities, including as Chief Executive Officer of its Galapagos Services division and as Chief Financial Officer. Mr. Smith served as Chief Financial Officer for Cambridge University Hospitals from 2007 to 2013. Mr. Smith spent eight years at PricewaterhouseCoopers prior to joining AstraZeneca in 1997, where he spent the next nine years in various finance and business roles of increasingly greater responsibility.

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 shows the high and low sales prices for our common stock:

Fiscal 2016	High	Low
First quarter (through January 29, 2016)	\$81.61	\$71.95
Fiscal 2015	High	Low
First quarter	\$84.69	\$63.22
Second quarter	80.30	68.59
Third quarter	78.50	63.75
Fourth quarter	80.44	59.99
Fiscal 2014	High	Low
First quarter	\$62.50	\$52.41
Second quarter	61.92	49.60
Third quarter	61.49	52.02
Fourth quarter	66.11	55.47

There were no equity securities that were not registered under the Securities Act of 1933, as amended, sold during the fiscal year 2015.

Shareholders

As of January 29, 2016, there were approximately 419 registered shareholders of the outstanding shares of common stock.

Dividends

We have not declared or paid any cash dividends on shares of our common stock in the past two years and we do not intend to pay cash dividends in the foreseeable future. We currently intend to retain any earnings to finance future operations and expansion.

Issuer Purchases of Equity Securities

The following table provides information relating to our purchases of shares of our common stock during the fourth quarter of 2015:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (in thousands)
9/27/2015 to 10/24/2015	734	\$64.11	—	\$69,694
10/25/2015 to 11/21/2015	—	—	—	\$69,694
11/22/2015 to 12/26/2015	—	—	—	\$69,694
Total:	734	—	—	—

In July 2010, our Board of Directors authorized a \$500.0 million stock repurchase program, and subsequently approved increases to the stock repurchase program of \$250.0 million in the fiscal year 2010, \$250.0 million in the fiscal year 2013 and \$150.0 million in the fiscal year 2014, for an aggregate authorization of \$1,150.0 million. During the fourth quarter of the fiscal year 2015, we did not repurchase any shares of common stock under our Rule 10b5-1 Purchase Plan and in open market trading.

Additionally, our stock-based compensation plans permit the netting of common stock upon vesting of restricted stock, performance share units, and restricted stock units in order to satisfy individual minimum statutory tax withholding requirements.

Comparison of 5-Year Cumulative Total Return

The following stock performance graph compares the annual percentage change in the Company's cumulative total shareholder return on its common stock during a period commencing on December 25, 2010 and ending on December 26, 2015 (as measured by dividing (1) the sum of (A) the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and (B) the difference between the Company's share price at the end and the beginning of the measurement period; by (2) the share price at the beginning of the measurement period) with the cumulative total return of the S&P 500 Index, the S&P 500 Health Care Index, and the NASDAQ Pharmaceutical Index during such period. The Company has not paid any dividends on the common stock, and no dividends are included in the representation of the Company's performance. The stock price performance on the graph below is not necessarily indicative of future price performance. The graph is not "soliciting material," is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing. Information used in the graph was obtained from Standards & Poor's Institutional Market Services, a source believed to be reliable, but the Company is not responsible for any errors or omissions in such information.

In the fiscal year 2015, the Company changed from the NASDAQ Pharmaceutical to the S&P 500 Health Care index because the companies which comprise the S&P 500 Health Care index better reflect the Company's current size and businesses. For the fiscal year 2015, the Company has presented both the old and new indices for comparison purposes.

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN

Among Charles River Laboratories International, Inc., The S&P 500, The NASDAQ Pharmaceutical and The S&P 500 Health Care

	December 25, 2010	December 31, 2011	December 29, 2012	December 28, 2013	December 27, 2014	December 26, 2015
Charles River Laboratories, Inc.	100	77	103	149	180	224
S&P 500	100	102	118	157	178	181
NASDAQ Pharmaceutical	100	114	156	263	340	354
S&P 500 Health Care	100	113	133	188	236	252

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Item 6. Selected Consolidated Financial Data

The selected financial data presented below is derived from our audited consolidated financial statements and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in Item 7 and “Financial Statements and Supplementary Data” contained in Item 8 of this Annual Report on Form 10-K. Our fiscal quarters consists of the 3 months ending on the last Saturday on, or prior to, March 31, June 30, September 30 and December 31.

	Fiscal Year				
	2015	2014	2013	2012	2011
	(in thousands)				
Statement of Income Data:					
Total revenue	\$ 1,363,302	\$ 1,297,662	\$ 1,165,528	\$ 1,129,530	\$ 1,142,647
Income from continuing operations, net of income taxes ⁽¹⁾	152,037	129,924	105,416	102,118	115,522
Loss from discontinued operations, net of income taxes	(950)	(1,726)	(1,265)	(4,252)	(5,545)
Common Share Data:					
Earnings per common share from continuing operations:					
Basic	\$ 3.23	\$ 2.76	\$ 2.18	\$ 2.12	\$ 2.26
Diluted	\$ 3.15	\$ 2.70	\$ 2.15	\$ 2.10	\$ 2.24
Other Data:					
Depreciation and amortization	\$ 94,881	\$ 96,445	\$ 96,636	\$ 81,275	\$ 85,230
Capital expenditures	63,252	56,925	39,154	47,534	49,143
Balance Sheet Data (at end of period):					
Cash and cash equivalents	\$ 117,947	\$ 160,023	\$ 155,927	\$ 109,685	\$ 68,905
Total assets ⁽²⁾	2,068,497	1,870,578	1,623,438	1,577,111	1,546,215
Total debt and capital lease obligations ⁽²⁾	863,030	772,461	656,663	660,096	708,706
Redeemable noncontrolling interest	28,008	28,419	20,581	—	—

⁽¹⁾ In the fiscal year 2011, our income from continuing operations, net of income taxes, included an asset impairment charge of \$7.5 million.

⁽²⁾ During the second quarter of 2015, we elected early adoption of Accounting Standards Update (ASU) 2015-03, “Simplifying the Presentation of Debt Issuance Costs” and applied the changes retrospectively to all prior periods. During the fourth quarter of 2015, we elected early adoption of ASU 2015-17, “Balance Sheet Classification of Deferred Taxes” and applied the changes retrospectively to all prior periods. Refer to “Financial Statements and Supplementary Data” contained in Item 8 for more details. Prior years’ amounts have been updated to conform to current year presentation.

Refer to Item 8. “Financial Statements and Supplementary Data” for additional information concerning the impact of our recent acquisitions.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing in Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in Item 1A "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Certain percentage changes from period over period may not recalculate due to rounding.

Overview

We are a full service, early-stage contract research organization (CRO). For nearly 70 years, we have been in the business of providing the research models required in research and development of new drugs, devices, and therapies. Over this time, we have built upon our original core competency of laboratory animal medicine and science (research model technologies) to develop a diverse portfolio of discovery and safety assessment services, both Good Laboratory Practice (GLP) and non-GLP, which are able to support our clients from target identification through preclinical development. We also provide a suite of products and services to support our clients' manufacturing activities. Utilizing our broad portfolio of products and services enables our clients to create a more flexible drug development model, which reduces their costs, enhances their productivity and effectiveness, and increases speed to market. Our client base includes all of the major global pharmaceutical companies, many biotechnology companies, CROs, agricultural and industrial chemical companies, life science companies, veterinary medicine companies, contract manufacturing organizations, medical device companies, and diagnostic and other commercial entities, as well as leading hospitals, academic institutions and government agencies around the world. We currently operate approximately 64 facilities in 18 countries worldwide, which numbers exclude our Insourcing Solutions (IS) sites.

Business Trends

The demand for our outsourced services increased in the fiscal year 2015, as did demand for products and services to support our clients' manufacturing activities. Our pharmaceutical and biotechnology clients continued to intensify their use of strategic outsourcing to improve their operating efficiency and access capabilities that they do not maintain internally. Many of our large biopharmaceutical clients have refocused on their drug discovery and early-stage development efforts, after a period of greater emphasis on delivering late-stage programs to bring new drugs to market. In addition, small and mid-size biopharmaceutical clients benefited from the continued strength in the biotechnology funding environment in the fiscal year 2015, from capital markets partnering with large biopharmaceutical companies, and investment by venture capital. Academia has also benefited from partnering activities, as large biopharmaceutical companies have increasingly utilized academic research capabilities to broaden the scope of their research activities.

The primary result of these trends was improved demand for our discovery and safety assessment services in the fiscal year 2015, particularly from biotechnology clients. This improvement led to capacity continuing to fill in our safety assessment facilities which were open during 2015, and in which utilization approached optimal levels. Price also improved moderately in the fiscal year 2015, as industry capacity utilization continued to increase. We believe our scientific expertise, quality, and responsiveness remain key criteria when our clients make the decision to outsource to us. In order to accommodate this increased demand and maintain responsiveness to clients' needs, we opened small amounts of new capacity in the fiscal year 2015 at existing facilities and reopened our Charles River Massachusetts facility in the first quarter of 2016. Charles River Massachusetts will provide additional capacity for early-stage drug research services and is strategically located near the Boston/Cambridge biotechnology hub.

Demand for our products and services that support our clients' manufacturing activities was also robust in the fiscal year 2015. Our Biologics Testing Solutions (Biologics) business continued to benefit from increased demand for services associated with the growing proportion of biologic drugs in the pipeline and on the market. Demand for our Microbial Solutions (formerly Endotoxin and Microbial Detection, or EMD) business also remained strong as we addressed manufacturers' requirements for a comprehensive rapid microbial testing solution. To further enhance our rapid testing portfolio, we acquired Celsis in the fiscal year 2015 to expand in the non-sterile quality control testing

market.

Our clients' intensified focus on the earliest stages of their pipelines has been visible in increasing demand for discovery services, and the willingness to outsource new areas of their research programs. To address these emerging needs and move further upstream in the drug research and development continuum, we have significantly enhanced our Discovery Services capabilities over the past two years to enable us to work with clients at the earliest stages of the discovery process. We acquired

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the Discovery Services businesses of Argenta, BioFocus, ChanTest, and VivoPath in the fiscal year 2014, and Oncotest in the fiscal year 2015. Our full service, early-stage portfolio continued to lead to additional client discussions in the fiscal year 2015 regarding strategic relationships, where clients seek to outsource larger portions of their early-stage drug research programs to us.

Demand for research models and certain services began to stabilize in the fiscal year 2015, particularly in North America and Europe. Clients' efforts to consolidate infrastructure and seek greater pipeline productivity have begun to moderate as these initiatives generate the desired benefits. We remain confident in the long-term drivers of this business because research models and services remain essential tools for our clients' drug discovery and early-stage development efforts.

Acquisitions

During the fiscal year 2015, we continued to make a number of strategic acquisitions designed to expand our portfolio of services to support the drug discovery and early-stage development continuum and position us as a market leader in the outsourced discovery services market. The 2015 acquisitions include:

In May 2015, we acquired Sunrise Farms, Inc. (Sunrise), a producer of specific-pathogen-free fertile chicken eggs and chickens used in the manufacture of live viruses. The purpose of this business acquisition was to expand the capabilities of our existing Avian Vaccine Services (Avian) business. The purchase price of the acquisition was \$9.6 million.

In July 2015, we acquired Celsis Group Limited (Celsis), a leading provider of rapid testing systems for non-sterile bacterial contamination for the biopharmaceutical and consumer products industries. The purpose of this acquisition was to enhance our portfolio of rapid microbial detection products and services with the addition of a rapid bioburden testing product. The purchase price for Celsis was \$214.5 million.

In November 2015, we acquired Oncotest GmbH (Oncotest), a CRO providing discovery services for oncology, one of the largest therapeutic areas for biopharmaceutical research and development spending. The purpose of this acquisition was to expand our oncology services capabilities, enabling us to provide clients with access to a more comprehensive portfolio of technologies, including patient-derived xenograft (PDX) and syngeneic models. The preliminary purchase price for Oncotest was \$36.0 million.

On January 6, 2016, we entered into a definitive agreement to acquire WRH, Inc. (WIL Research), a premier provider of safety assessment and contract development and manufacturing services to biopharmaceutical and agricultural and industrial chemical companies worldwide. Acquiring WIL Research will enhance our position as a leading global early-stage CRO by strengthening our ability to partner with global clients across the drug discovery and development continuum. The transaction is expected to close early in the second quarter of 2016, subject to regulatory approvals and customary closing conditions. The preliminary purchase price will be approximately \$585.0 million in cash, subject to customary closing adjustments. The acquisition and associated fees are expected to be financed through an expansion of our credit facility and cash. In the event the agreement is terminated under specified circumstances, we may be required to pay WIL Research a termination fee of \$17.5 million.

Segment Reporting

In the second quarter of 2014, following our acquisition of Argenta and BioFocus, we revised our reportable segments to ensure alignment with our view of the business. We reviewed the new and existing markets addressed by the business, the recently revised go-to-market strategy, long-term operating margins, and the discrete financial information available to our Chief Operating Decision Maker, and considered how our businesses aggregated based on these qualitative and quantitative factors. Based on this review, we identified three reportable segments: Research Models and Services (RMS), Discovery and Safety Assessment (DSA), and Manufacturing Support (Manufacturing). We reported segment results on this basis for all periods presented in this Annual Report on Form 10-K.

The revised reportable segments are as follows:

Research Models and Services	Discovery and Safety Assessment	Manufacturing Support
Research Models	Discovery Services ⁽²⁾	Microbial Solutions
Research Model Services ⁽¹⁾	Safety Assessment	Avian Biologics

⁽¹⁾ Research Model Services includes Genetically Engineered Models and Services (GEMS), Research Animal Diagnostic Services (RADS), and IS.

⁽²⁾ Discovery Services includes both the In Vivo Discovery business and the Early Discovery business. Early Discovery includes Argenta and BioFocus, which were acquired in April 2014; ChanTest Corporation (ChanTest), which was acquired in October 2014; and Oncotest, which was acquired in November 2015.

Our RMS segment includes the Research Models and Research Model Services businesses. Research Models includes the commercial production and sale of small research models, as well as the supply of large research models. Research Model Services includes three business units: GEMS, which performs contract breeding and other services associated with genetically engineered research models; RADS, which provides health monitoring and diagnostics services related to research models; and IS, which provides management of our clients' research operations (including recruitment, training, staffing, and management services). Our DSA segment includes services required to take a drug through the early development process including discovery services, which are non-regulated services to assist clients with the identification, screening, and selection of a lead compound for drug development, and regulated and non-regulated safety assessment services. Our Manufacturing segment includes Microbial Solutions, which includes in vitro (non-animal) lot-release testing products and microbial detection, conventional and rapid quality control testing of sterile and non-sterile biopharmaceutical and consumer products and species identification services; Biologics, which performs specialized testing of biologics; and Avian, which supplies specific-pathogen-free fertile chicken eggs and chickens.

Prior to recasting the reportable segments, the businesses were reported in two segments as follows:

Research Models and Services	Preclinical Services
Research Models ⁽³⁾	Discovery Services
Research Model Services ⁽⁴⁾	Safety Assessment
Endotoxin and Microbial Detection	Biologics

⁽³⁾ Research Models included Avian.

⁽⁴⁾ Research Model Services included GEMS, RADS, IS and Discovery Research Services. As part of the segment revisions, the former Discovery Research Services was folded into the Company's Discovery Services business, previously located under the Preclinical Services segment.

Fiscal Quarters

Our fiscal quarters consists of the 3 months ending on the last Saturday on, or prior to, March 31, June 30, September 30 and December 31.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (U.S.). The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience, trends in the industry, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions.

We believe that our application of the following accounting policies, each of which require significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 1, "Description of Business and Summary of Significant Accounting Policies", to our consolidated financial statements appearing elsewhere in this

Annual Report on Form 10-K.

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We believe the following represent our critical accounting policies and estimates used in the preparation of our financial statements:

Revenue Recognition

We recognize revenue when all of the following conditions are satisfied: persuasive evidence of an arrangement exists, delivery has occurred or services have been provided, our price to the customer is fixed or determinable, and collectibility is reasonably assured.

Service revenue is generally evidenced by client contracts, which range in duration from a few weeks to a few years and typically take the form of an agreed upon rate per unit or fixed fee arrangements. Such contracts typically do not contain acceptance provisions based upon the achievement of certain study or laboratory testing results. Revenue of agreed upon rate per unit contracts is recognized as services are performed, based upon rates specified in the contract.

In cases where performance spans reporting periods, revenue of fixed fee contracts is recognized as services are performed, measured on the ratio of outputs or performance obligations completed to the total contractual outputs or performance obligations to be provided. Changes in estimated effort to complete the fixed fee contract are reflected in the period in which the change becomes known. Changes in scope of work are common, especially under long-term contracts, and generally result in a change in contract value. Once the parties have agreed to the changes in scope and renegotiated pricing terms, the contract value is amended and revenue is typically recognized as described above.

Most contracts are terminable by the client, either immediately or upon notice. These contracts often require payment to us of expenses to wind down the project, fees earned to date or, in some cases, a termination fee. Such payments are included in revenues when earned.

We recognize product revenue, net of allowances for estimated returns, rebates and discounts, when title and risk of loss pass to customers. When we sell equipment with specified acceptance criteria, we assess our ability to meet the acceptance criteria in order to determine the timing of revenue recognition. We would defer revenue until completion of customer acceptance testing if we are not able to demonstrate the ability to meet such acceptance criteria.

A portion of our revenue is from multiple-element arrangements that include multiple products and/or services as deliverables in a single arrangement, with each deliverable, or a combination of the deliverables, representing a separate unit of accounting. We allocate revenues to each element in a multiple-element arrangement based upon the relative selling price of each deliverable. Revenue allocated to each deliverable is then recognized when all revenue recognition criteria are met. Judgments as to the identification of deliverables, units of accounting, the allocation of consideration to the deliverable, and the appropriate timing of revenue recognition are critical with respect to these arrangements.

At the inception of each arrangement that includes milestone payments, we evaluate whether each milestone is substantive. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, clinical, regulatory and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. If a substantive milestone is achieved and collection of the related receivable is reasonably assured, we recognize revenue related to the milestone in its entirety in the period in which the milestone is achieved. If we were to achieve milestones that we consider substantive under any of our revenue arrangements, we may experience significant fluctuations in our revenue from quarter to quarter and year to year depending on the timing of achieving such substantive milestones. In those circumstances where a milestone is not substantive, we recognize as revenue, on the date the milestone is achieved, an amount equal to the applicable percentage of the performance period that had elapsed as of the date the milestone was achieved, with the balance being deferred and recognized over the remaining period of performance. As of December 26, 2015, we had no significant milestones that were deemed substantive.

Income Taxes

We prepare and file income tax returns based on our interpretation of each jurisdiction's tax laws and regulations. In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Significant management judgment is required in assessing the realizability of our deferred

tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income, and the effects of tax planning strategies. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors, that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the “more-likely-than-not” threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews; we have no plans to appeal or litigate any aspect of the tax position; and we believe that it is highly unlikely that the taxing authority would re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

As of December 26, 2015, our non-U.S. subsidiaries’ undistributed foreign earnings included in consolidated retained earnings were \$547.6 million. As of the end of fiscal year 2015, our policy with respect to the undistributed earnings of our non-U.S. subsidiaries is to maintain an indefinite reinvestment assertion as they are required to fund needs outside of the U.S. and cannot be repatriated in a manner that is substantially tax-free. This assertion is made on a jurisdiction by jurisdiction basis and takes into account the liquidity requirements in both the U.S. and within our foreign subsidiaries. If we decide to repatriate funds to the U.S. in the future to execute our growth initiatives or to fund any other liquidity needs, the resulting tax consequences could negatively impact our results of operations through a higher effective tax rate and dilution of our earnings. On December 18, 2015, the U.S. enacted the Consolidated Appropriations Act, which provides for a reinstatement and extension of the controlled foreign corporation look-through rules through the fiscal year 2019. This rule allows us to access Chinese and Canadian cash in a more tax-efficient manner and utilize the cash outside of the U.S. without triggering residual U.S. tax. As such, we will begin accruing foreign withholding taxes to reflect this change for the years in which the rules are reinstated.

Goodwill and Intangible Assets

We use assumptions and estimates in determining the fair value of assets acquired and liabilities assumed in a business combination. The determination of the fair value of intangible assets, which represent a significant portion of the purchase price in many of our acquisitions, requires the use of significant judgment with regard to (i) the fair value; and (ii) whether such intangibles are amortizable or non-amortizable and, if the former, the period and the method by which the intangible asset will be amortized. We utilize commonly accepted valuation techniques, such as the income approach and the cost approach, as appropriate, in establishing the fair value of intangible assets. Typically, key assumptions include projections of cash flows that arise from identifiable intangible assets of acquired businesses as well as discount rates based on an analysis of our weighted average cost of capital, adjusted for specific risks associated with the assets.

We review definite-lived intangible assets for impairment when indication of potential impairment exists, such as a significant reduction in cash flows associated with the assets. Actual cash flows arising from a particular intangible asset could vary from projected cash flows which could imply different carrying values from those established at the dates of acquisition and which could result in impairment of such asset.

We evaluate goodwill for impairment annually, during the fourth quarter, and when events occur or circumstances change that may reduce the fair value of the asset below its carrying amount. Events or circumstances that might require an interim evaluation include unexpected adverse business conditions, economic factors, unanticipated technological changes or competitive activities, loss of key personnel and acts by governments and courts. Estimates of future cash flows require assumptions related to revenue and operating income growth, asset-related expenditures, working capital levels and other factors. Different assumptions from those made in our analysis could materially affect projected cash flows and our evaluation of goodwill for impairment.

We have the option to first assess qualitative factors to determine whether it is necessary to perform the two-step goodwill impairment test. If we elect this option and believe, as a result of the qualitative assessment, that it is more-likely-than-not that the carrying value of goodwill is not recoverable, the quantitative two-step impairment test is required; otherwise, no further testing is required. Alternatively, we may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test. In the first step, we compare the fair value of our reporting units to their carrying values. If the carrying values of the net assets assigned to the reporting units exceed the fair values of the reporting units, then the second step of the impairment test is performed in order to determine the implied fair value of our goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference.

In the fiscal years 2015, 2014 and 2013, we performed the first step of the two-step goodwill impairment test for our reporting units. Fair value was determined by using a weighted combination of a market-based approach and an income approach, as this combination was deemed to be the most indicative of our fair value in an orderly transaction between market participants. Under the market-based approach, we utilized information about our Company as well as publicly available industry information to determine earnings multiples and sales multiples that are used to value our reporting units. Under the income approach, we determined fair value based on the estimated future cash flows of each reporting unit, discounted by an estimated weighted-average cost of capital, which reflects the overall level of inherent risk of the reporting unit and the rate of return an outside investor would expect to earn.

Our 2015, 2014 and 2013 impairment test indicated that goodwill and other intangible assets were not impaired.

In 2014, we revised our reportable segments to align with our new view of the business following the Argenta and BioFocus acquisition. As a result of this reorganization, goodwill was allocated from our prior reportable segments to our new reportable segments based on the fair value of each business group within its original reporting unit relative to the fair value of that reporting unit. In addition, we completed an assessment of any potential goodwill impairment for all reporting units immediately prior to the reallocation and determined that no impairment existed.

Valuation and Impairment of Long-Lived Assets

Long-lived assets to be held and used, including property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable. Factors we consider important which could trigger an impairment review include, but are not limited to, the following:

- significant underperformance relative to expected historical or projected future operating results;
- significant negative industry or economic trends; or
- significant changes or developments in strategy or operations that negatively affect the utilization of our long-lived assets.

Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset, net of any sublease income, if applicable, and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values.

We measure any impairment based on a projected discounted cash flow method using a discount rate determined by management to be commensurate with the risk inherent in our current business model. Significant judgments are required to estimate future cash flows, including the selection of appropriate discount rates and other assumptions. We may also estimate fair value based on market prices for similar assets, as appropriate. Changes in these estimates and assumptions could materially affect the determination of fair value for these assets. During the fiscal year 2015, we did not record any significant impairment charges to long-lived assets.

Pension and Other Post-Retirement Benefit Plans

Several of our U.S. and non-U.S. subsidiaries sponsor defined benefit pension and other post-retirement benefit plans. We recognize the funded status of our defined benefit pension and other postretirement benefit plans as an asset or liability. This amount is defined as the difference between the fair value of plan assets and the benefit obligation. We measure plan assets and benefit obligations as of the date of our fiscal year end.

The cost and obligations of these arrangements are calculated using many assumptions to estimate the benefits that the employee earns while working, the amount of which cannot be completely determined until the benefit payments

cease. Major assumptions used in the accounting for these employee benefit plans include the expected return on plan assets, withdrawal and mortality rates, discount rate, and rate of increase in employee compensation levels. Assumptions are determined based on our

data and appropriate market indicators, and are evaluated each year as of the plans' measurement date. Should any of these assumptions change, they would have an effect on net periodic pension costs and the unfunded benefit obligation.

The expected long-term rate of return on plan assets reflects the average rate of earnings expected on the funds invested, or to be invested, to provide for the benefits included in the projected benefit obligations. In determining the expected long-term rate of return on plan assets, we consider the relative weighting of plan assets, the historical performance of total plan assets and individual asset classes and economic and other indicators of future performance. The discount rate reflects the rate we would have to pay to purchase high-quality investments that would provide cash sufficient to settle our current pension obligations. Beginning in the fiscal year 2014, we have employed the discount rate based on a cash-flow matching analysis using Towers Watson's proprietary Bond:Link tool. Prior to the fiscal year 2014, we employed a cash-flow matching methodology, which used the spot yield curve underlying the Citigroup Index. The refined estimation technique permits us to more closely match cash flows to the expected payments to participants than would be possible with the previously used yield curve model. We believe such a refinement results in an estimate of the discount rate that more accurately reflects the settlement value for plan obligations than the yield curve methodology used in prior years, as it provides the ability to review the quality and diversification of the portfolio to select the bond issues that would settle the obligation in an optimal manner. This refinement reduced our benefit obligations as of December 27, 2014 by \$5.5 million.

The rate of compensation increase reflects the expected annual salary increases for the plan participants based on historical experience and the current employee compensation strategy.

In the fiscal year 2014, for our U.K. and U.S. plans, we adopted newly released mortality tables and mortality improvement scales for measurement of retirement plan obligations, which increased our benefit obligations by \$7.9 million as of December 27, 2014. In the fiscal year 2015, new mortality improvement scales were issued in the U.S. and the U.K. reflecting a decline in longevity projection from the 2014 releases that we adopted, which decreased our benefit obligations by \$3.3 million as of December 26, 2015.

Stock-Based Compensation

We grant stock options, restricted stock, restricted stock units, and performance share units (PSUs) to employees, and stock options and restricted stock to non-employee directors under stock-based compensation plans. We make certain assumptions in order to value and record expense associated with awards made under our stock-based compensation arrangements. Changes in these assumptions may lead to variability with respect to the timing and amount of expense we recognize in connection with share-based payments.

Determining the appropriate valuation model and related assumptions requires judgment. The fair value of stock options granted is calculated using the Black-Scholes model and the fair value of PSUs is calculated using a lattice model with a Monte Carlo simulation, both of which require the use of subjective assumptions including volatility and expected term, among others.

Determining the appropriate amount to expense based on the anticipated achievement of PSU's performance targets requires judgment, including forecasting the achievement of future financial targets. The estimate of expense is revised periodically based on the probability of achieving the required performance targets. The cumulative impact of any changes to our estimates is reflected in the period of change.

We also estimate forfeitures over the requisite service period when recognizing share-based compensation expense based on historical rates and forward looking factors; these estimates are adjusted to the extent that actual forfeitures differ, or are expected to materially differ, from our estimates.

New Accounting Pronouncements

For a discussion of new accounting pronouncements, refer to Note 1, "Description of Business and Summary of Significant Accounting Policies" to our consolidated financial statements included in this Annual Report on Form 10-K.

Results of Operations

Fiscal Year 2015 Compared to Fiscal Year 2014

Revenue

	Fiscal Year		\$ Change	% Change	Impact of FX	
	2015	2014			(in millions, except percentages)	
RMS	\$473.2	\$507.4	\$(34.2)	(6.7)%	(6.3))%
DSA	612.2	538.2	74.0	13.7%	(3.4))%
Manufacturing	277.9	252.1	25.8	10.2%	(7.6))%
Total revenue	\$1,363.3	\$1,297.7	\$65.6	5.1%	(5.3))%

Revenue for the fiscal year 2015 increased \$65.6 million, or 5.1%, compared with the fiscal year 2014. The negative effect of changes in foreign currency exchange rates decreased revenue by \$69.4 million, or 5.3%, when compared to the prior year.

RMS revenue decreased \$34.2 million due primarily to the negative effect of changes in foreign currency exchange rates. Excluding the impact of foreign exchange rates, RMS revenue decreased slightly due to lower research model services revenue and lower research models revenue in Japan; partially offset by higher research models revenue in North America, China and Europe.

DSA revenue increased \$74.0 million due to higher revenue in the Safety Assessment business, as a result of increased study volume; higher revenue in the Discovery Services business, primarily as a result of the Argenta, BioFocus, ChanTest, and Oncotest acquisitions that contributed \$27.8 million to revenue growth; partially offset by the negative effect of changes in foreign currency exchange rates.

Manufacturing revenue increased \$25.8 million, as higher revenue for Microbial Solutions and Avian, which include the Celsis and Sunrise acquisitions, respectively, was partially offset by the negative effect of changes in foreign currency exchange rates.

Service revenue for the fiscal year 2015 was \$858.2 million, an increase of \$60.4 million, or 7.6%, compared to \$797.8 million for the fiscal year 2014. The increase in service revenue was due to higher revenue in the Safety Assessment business, as a result of increased study volume; and higher revenue in the Discovery Services business, which included the acquisitions of Argenta, BioFocus, ChanTest, and Oncotest that contributed \$27.3 million to service revenue growth; partially offset by lower revenue in our research model services and the negative effect of changes in foreign currency exchange rates. Product revenue for the fiscal year 2015 was \$505.1 million, an increase of \$5.2 million, or 1.0%, compared to \$499.9 million for the fiscal year 2014. The increase was due to higher revenue for Microbial Solutions and Avian, which include the acquisitions of Celsis and Sunrise, respectively that contributed \$16.7 million to product revenue growth; higher research models revenue in North America, China and Europe; partially offset by lower revenue in our research models and the negative effect of changes in foreign currency exchange rates.

Cost of Products Sold and Services Provided (Excluding Amortization of Intangible Assets)

	Fiscal Year		\$ Change	% Change		
	2015	2014			(in millions, except percentages)	
RMS	\$286.2	\$317.2	\$(31.0)	(9.8)%)%
DSA	407.0	387.3	19.7	5.1%)%
Manufacturing	139.0	120.5	18.5	15.4%)%
Total cost of products sold and services provided (excluding amortization of intangible assets)	\$832.2	\$825.0	\$7.2	0.9%)%

Cost of products sold and services provided (excluding amortization of intangible assets) (costs) for the fiscal year 2015 increased \$7.2 million, or 0.9%, compared with the fiscal year 2014. Costs as a percentage of revenue for the fiscal year 2015 were 61.0%, a decrease of 2.6%, from 63.6% for the fiscal year 2014.

RMS costs decreased \$31.0 million due primarily to favorable effect of changes in foreign currency exchange rates, cost savings achieved as a result of our efficiency initiatives, and reduced restructuring costs. RMS costs as a percentage of revenue for the fiscal year 2015 were 60.5%, a decrease of 2.0%, from 62.5% for the fiscal year 2014.

DSA costs increased \$19.7 million due primarily to an increase in Discovery Services costs, which included a higher cost base due to the acquisitions of Argenta, BioFocus, ChanTest, and Oncotest; partially offset by the favorable effect of changes in foreign currency exchange rates. Safety Assessment costs increased due to higher costs resulting from the growth of the business, partially offset by the favorable effect of changes in foreign currency exchange rates. DSA costs as a percentage of revenue for the fiscal year 2015 were 66.5%, a decrease of 5.5%, from 72.0% for the fiscal year 2014, primarily due to improved operating leverage as a result of increased study volume in our Safety Assessment business.

Manufacturing costs increased \$18.5 million due primarily to the Celsis and Sunrise acquisitions, partially offset by the favorable effect of changes in foreign currency exchange rates. Manufacturing costs as a percentage of revenue for the fiscal year 2015 were 50.0%, an increase of 2.2%, from 47.8% for the fiscal year 2014.

Costs of services provided for the fiscal year 2015 was \$568.2 million, an increase of \$9.6 million, or 1.7%, compared to \$558.6 million for the fiscal year 2014. The increase was due to a higher cost base, as a result of the acquisitions of Argenta, BioFocus, ChanTest, and Oncotest as well as increased Safety Assessment revenues; partially offset by the favorable effect of changes in foreign currency exchange rates and lower costs for our research model services as a result of lower revenue. Costs of products sold for the fiscal year 2015 was \$264.0 million, a decrease of \$2.4 million, or 0.9%, compared to \$266.4 million for the fiscal year 2014. The decrease was due to savings associated with global efficiency initiatives, reduced restructuring costs and the favorable effect of changes in foreign currency exchange rates, partially offset by increased costs as a result of the acquisitions of Sunrise and Celsis.

Selling, General and Administrative Expenses

	Fiscal Year		\$ Change	% Change	
	2015	2014			
	(in millions, except percentages)				
RMS	\$62.5	\$66.2	\$(3.7)	(5.6)	%
DSA	69.2	63.1	6.1	9.7	%
Manufacturing	57.5	47.6	9.9	20.8	%
Unallocated corporate	111.2				