

INC Research Holdings, Inc.
Form 10-K
February 25, 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 31, 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 Number: 001-36730

INC RESEARCH HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

3201 Beechleaf Court, Suite 600

Raleigh, North Carolina

(Address of principal executive offices)

Registrant's telephone number, including area code: (919) 876-9300

27-3403111

(I.R.S. Employer Identification No.)

27604-1547

(Zip Code)

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

Title of each class

Class A Common Stock, par value \$0.01 per share

Name of each exchange on which registered

The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if 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 Exchange 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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 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.

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based on the closing sale price of on June 30, 2015 (based on the closing sale price of \$40.12 on that date), was approximately \$718,968,173. Common stock held by each officer and director and by each person known to the registrant who owned 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of February 18, 2016, there were approximately 53,976,093 shares of the registrant's common stock outstanding. Portions of the registrant's Proxy Statement for its 2016 Annual Meeting of Stockholders are incorporated by reference into Part III hereof.

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward-looking statements reflect, among other things, our current expectations and anticipated results of operations, all of which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, market trends, or industry results to differ materially from those expressed or implied by such forward-looking statements. Therefore, any statements contained herein that are not statements of historical fact may be forward-looking statements and should be evaluated as such. Without limiting the foregoing, the words “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intend,” “may,” “might,” “plans,” “projects,” “should,” “would,” “targets,” “will” and the negative thereof and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” in Part I, Item 1A of this report. Unless legally required, we assume no obligation to update any such forward-looking information to reflect actual results or changes in the factors affecting such forward-looking information.

As used in this report, the terms “INC Research Holdings, Inc.,” “Company,” “we,” “us,” and “our” mean INC Research Holdings, Inc. and its subsidiaries unless the context indicates otherwise.

Item 1. Business.

Overview

We are a leading global contract research organization (“CRO”) based on revenues and are exclusively focused on Phase I to Phase IV clinical development services for the biopharmaceutical and medical device industries. We provide our customers highly differentiated therapeutic alignment and expertise, with a particular strength in complex therapeutic areas, such as central nervous system (“CNS”), oncology and other complex diseases. We consistently and predictably deliver clinical development services in a complex environment and offer a proprietary, operational approach to clinical trials through our Trusted Process[®] methodology. Our service offerings focus on optimizing the development of, and therefore, the commercial potential for, our customers' new biopharmaceutical compounds, enhancing returns on their research and development (“R&D”) investments, and reducing their overhead by offering an attractive variable cost alternative to fixed cost, in-house resources.

Founded more than two decades ago as an academic central nervous system research organization, we have translated that expertise into a global organization with a number of therapeutic specialties, as well as full data services and regulatory capabilities. Over the past decade, we have built our scale and capabilities to become a leading global provider of Phase I to Phase IV clinical development services, with approximately 6,400 employees in over 50 countries across six continents as of December 31, 2015. Our broad global reach has enabled us to provide clinical development services in over 110 countries. Our global footprint provides our customers with broad access to diverse markets and patient populations, local regulatory expertise and local market knowledge.

We provide clinical development services through specialized therapeutic teams that have deep scientific expertise and are strategically aligned with the largest and fastest growing areas of our customers' R&D investments. We believe our therapeutic focus and proprietary methodology have set us apart within our industry. We were named the “Best Contract Research Organization” at the 11th Annual Scrip Awards ceremony in December 2015. The annual Scrip awards competition is organized by Scrip Intelligence to celebrate the contributions of the pharmaceutical, biotech and other allied industries to improving human health worldwide. The Company was selected from among several leading global CROs after being judged based on full range of services provided and quality of relationships built with clients by a distinguished panel of life science industry executives.

We have also developed industry-leading relationships with principal investigators and clinical research sites, as demonstrated by being named the "Top CRO to Work With" among large global CROs in the 2015 CenterWatch Global Investigative Site Relationship Survey (the "2015 CenterWatch Survey") conducted by CenterWatch, a third-party leading publisher in the clinical trials industry. The 2015 CenterWatch Survey covered responses from over 1,900 sites globally that evaluated 11 CROs, including the top five by revenue, across 38 specific relationship attributes. We ranked in the top 3 on 33 out of the 38 specific relationship attributes. We believe the Company's ranking as "Top CRO to Work With" for a second straight time demonstrates the effectiveness of our business model and our ability to deliver high-quality clinical trial results on time and on budget for our customers.

Our extensive range of services supports the entire drug development process from Phase I to Phase IV and allows us to offer our customers an integrated suite of investigative site support and clinical development services. We offer these services across a wide variety of therapeutic areas with deep clinical expertise, with a primary focus on Phase I to Phase IV clinical trials. We provide total biopharmaceutical program development while also providing discrete services for any part of a trial. Our combination of service area experts and depth of clinical capability allows for enhanced protocol design and actionable trial data.

We have two reportable segments: Clinical Development Services and Phase I Services. Clinical Development Services offers a variety of clinical development services, including full-service global studies, as well as ancillary services such as clinical monitoring, investigator recruitment, patient recruitment, data management, study reports to assist customers with their drug development process, quality assurance audits and specialized consulting services. Phase I Services focuses on clinical development services for Phase I trials, which include scientific exploratory medicine, first-in-human studies through proof-of-concept stages and support for Phase I studies in established compounds. For further information about the Company's reportable segments, please see "Note 12 - Segment Information" in our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. For financial information about geographic areas of our revenue and long-lived assets, please see "Note 13 - Operations by Geographic Location" in our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. International operations expose us to risks that differ from those applicable to operating in the United States, including foreign currency translation and transaction risks, risks of changes in tax laws and other risks described further in Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K.

For the year ended December 31, 2015, we had total net service revenue of \$914.7 million, net income of \$117.0 million, Adjusted Net Income of \$120.2 million, and Adjusted EBITDA of \$221.4 million. For important disclosures about our non-GAAP measures and a reconciliation of Adjusted Net Income and Adjusted EBITDA to our GAAP net income (loss), see Part II, Item 6, "Selected Financial Data" of this Annual Report on Form 10-K. For further information about our consolidated revenues and earnings, see our consolidated financial statements included in Part II, Item 8 "Financial Statements and Supplementary Data" and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K.

Our diversified customer base includes a mix of many of the world's largest biopharmaceutical companies as well as high-growth, small and mid-sized biopharmaceutical companies. We deliver high quality service through our internally developed, metrics-driven Trusted Process[®], which is our proprietary methodology designed to reduce operational risk and variability by standardizing clinical development services and implement quality controls throughout the clinical development process. We believe our Trusted Process[®] leads our customers to faster, better-informed drug development decisions.

We were originally founded in 1998 as INC Research, and our headquarters are located in Raleigh, North Carolina. As a result of a corporate reorganization in connection with a business combination transaction, INC Research Holdings, Inc., was incorporated in Delaware in August 2010.

Our Market

The market for our services includes biopharmaceutical companies that outsource clinical development services. We believe we are well-positioned to benefit from the following market trends:

Trends in late-stage clinical development outsourcing. Within the clinical development market, we primarily focus on Phase II to Phase IV clinical trials. Biopharmaceutical companies continue to prioritize the outsourcing of Phase II to Phase IV clinical trials, particularly in complex, high-growth therapeutic areas such as CNS, oncology and other complex diseases. Additionally, small and mid-sized biopharmaceutical companies typically have limited infrastructure and therefore have a particular proclivity to outsource their clinical development to CROs. We estimate, based on industry sources, including analyst reports, and management's knowledge, that the market for CRO services for Phase II to Phase IV clinical development services will grow at a rate of 7% to 8% annually through 2020, driven by a combination of increased development spend and further outsourcing penetration. In addition, we estimate that total biopharmaceutical spending on drug development in 2015 was approximately \$75.4 billion, of which the clinical development market, which is the market for drug development following pre-clinical research, was approximately \$65.1 billion. Of the \$65.1 billion, we estimate our total addressable market to be \$52.5 billion, after excluding \$12.6 billion of indirect fees paid to principal investigators and clinical research sites, which are not a part of the CRO market. We estimate that total biopharmaceutical spending on clinical development will grow at a rate of 3% to 4% annually through 2020. In 2015, we estimate biopharmaceutical companies outsourced approximately \$26.0 billion of clinical development spend to CROs, representing an 8% increase compared to 2014 and a penetration rate of 49% of our total addressable market. We estimate that this penetration rate will increase to approximately 59% of our total addressable market by 2020. We believe that CROs with deep therapeutic expertise, global reach and capabilities, the ability to conduct increasingly complex clinical trials and maintain strong principal investigator and clinical research site relationships will be well-positioned to benefit from these industry trends.

Optimization of biopharmaceutical R&D efficiency. Market forces and healthcare reform, including the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act") and other governmental initiatives, place significant pressure on biopharmaceutical companies to improve cost efficiency. Companies need to demonstrate the relative improvement in quality, safety, and effectiveness of new therapies as compared to existing approved therapies as early as possible in the development process. CROs can help biopharmaceutical companies deploy capital more efficiently, especially because many biopharmaceutical companies do not have adequate in-house development resources. In response to high clinical trial costs, particularly in therapeutic areas such as CNS and oncology, which we believe present the highest mean cost per patient across all clinical trials, biopharmaceutical companies are streamlining operations and shifting development to external providers in order to lower their fixed costs. Based on efficiencies gained through experience, we estimate that CROs have shortened clinical testing timelines by as much as 30%. Full service CROs can deliver operational efficiencies, provide high visibility into trial conduct, and allow biopharmaceutical companies to focus internal resources on their core competencies related to drug discovery and commercialization.

Globalization of clinical trials. Clinical trials have become increasingly global as biopharmaceutical companies seek to accelerate patient recruitment, particularly within protocol-eligible, treatment-naïve patient populations without co-morbidities that could skew clinical outcomes. Additionally, biopharmaceutical companies increasingly seek to expand the commercial potential of their products by applying for regulatory approvals in multiple countries, including in areas of the world with fast-growing economies and middle classes that are spending more on healthcare. As part of the approval process for biopharmaceutical products in newer markets, especially in certain Asian and emerging markets, regulators often require trials to include specific percentages or numbers of people from local populations. Thus, clinical studies to support marketing approval applications frequently include a combination of multinational and domestic trials. These trends emphasize the importance of global experience and geographic coverage, local market knowledge and coordination throughout the development process.

Management of increasingly complex trials. The biopharmaceutical industry operates in an increasingly sophisticated and highly regulated environment and has responded to the demands of novel therapeutics by adapting efficient drug development processes. Complex trial design expertise has emerged as a significant competitive advantage for select CROs that have a track record of successfully navigating country-specific regulatory, trial protocol and patient enrollment barriers, including sometimes subjective, evolving clinical endpoints. Measures of clinical trial complexity significantly increased over the last decade, as evidenced by total procedures per trial protocol increasing by 57% between 2000 and 2011. In addition, the therapeutic areas where we have a particular focus, including CNS, oncology and other complex diseases, often require more complicated testing protocols than other disease indications. For

example, studies related to complex

4

therapeutic areas often require treatment-naïve patients, and sometimes have subjective endpoints, which can be difficult to measure. In addition, many of these studies have longer periods of duration due to these factors and have been increasing in duration over the last 24 months. For example, our average study duration has increased from approximately 30 months as of December 31, 2013 to slightly over 40 months as of December 31, 2015. As a result of these factors, these therapeutic areas demand greater clinical trial proficiency and therapeutic expertise, particularly in light of new methods of testing, such as the use of biomarkers and gene therapy.

Our Competitive Strengths

We believe that we are well positioned to capitalize on positive trends in the CRO industry and provide differentiated solutions to our customers based on our key competitive strengths set forth below:

Deep and long-standing expertise in the largest and fastest growing therapeutic areas. Since our inception in 1998, we have focused on building world-class therapeutic expertise to better serve our customers. We provide a broad offering of therapeutic expertise, with our core focus in the largest and fastest growing therapeutic areas, including our complex therapeutic areas, which collectively constitute approximately 66% of our backlog as of December 31, 2015. Based on industry data, we estimate that these complex therapeutic areas together represent over 60% of total Phase III drugs under development. We believe we have been growing faster than the market, resulting in market share gains in our key therapeutic areas. In 2015, our net service revenue grew by 13% and our net service revenue for our complex therapeutic areas grew by 18%. Our therapeutic expertise is managed by our senior leadership and delivered by our senior scientific and medical staff and our clinical research associates ("CRAs") within our various therapeutic areas. Industry analysts have reported that therapeutic expertise is the most influential factor for small to mid-cap as well as large sponsors of clinical trials in selecting a CRO. We believe that our expertise in managing complex clinical trials differentiates us from our competitors and has played a key role in our revenue growth, our ability to win new clinical trials and our successful relationship development with principal investigators and clinical research sites.

Clinical development focus and innovative operating model. We derive approximately 98% of our net service revenue from clinical development services without distraction from lower growth, lower margin non-clinical business. Since 2006, we have conducted our clinical trials using our innovative Trusted Process[®] operating model, which standardizes methodologies, increases the predictability of the delivery of our services and reduces operational risk. Since initiation of the Trusted Process[®], we have reduced median study start-up time (defined as the period from finalized protocol to first patient enrolled) on new projects. Based on industry sources for the median study start-up time for the biopharmaceutical industry, we believe we achieve this milestone for our customers at a faster pace than industry medians, due in part to our proprietary Trusted Process[®] operating model. In addition to the absolute reduction of cycle times in critical path milestones, we provide greater operating efficiency, more predictable project schedules and a reduction in overall project timelines. We were named the "Best Contract Research Organization" at the 11th Annual Scrip Awards in December 2015, which we believe is directly attributable to our innovative business model.

Unmatched, industry-leading principal investigator and clinical research site relationships. We have extensive relationships with principal investigators and clinical research sites. We believe these quality relationships are critical for delivering clinical trial results on time and on budget for our customers. Motivated and engaged investigative sites can facilitate faster patient recruitment, increase retention, maintain safety, ensure compliance with protocols as well as with local and international regulations, and streamline reporting. The ability to recruit and retain principal investigators and patients is an integral part of the clinical trial process. We have dedicated personnel focused on enhancing clinical research site relationships; we work with these sites in collaborative partnerships to improve cycle times and standardize start-up activities to drive efficiency. Our focus on principal investigator and clinical research site relationships is unmatched in the industry, as demonstrated by being named "Best Contract Research Organization" in December 2015 by an independent panel for Scrip Intelligence and our ranking as the "Top CRO to Work With" among large global CROs in the 2015 CenterWatch Survey. In the 2015 CenterWatch Survey, we ranked in the top 3 on 33 out of 38 attributes and received an average of 83% of "excellent" or "good" ratings across all attributes, up from approximately 80% in 2013. In addition, we are a top-three ranked CRO on four of the five attributes rated by sites as most important to study conduct success and the number one-ranked CRO for providing professional

medical staff in clinical operations. We also participate at the highest level of membership within the Society for Clinical Research Sites ("SCRS") as a Global Impact Partner ("GIP").

Broad global reach with in-depth local market knowledge. We believe that we are one of a few CROs with the scale, expertise, systems and agility necessary to conduct global clinical trials. We offer our services through a highly skilled staff of approximately 6,400 employees in over 50 countries as of December 31, 2015 and have conducted work in over 110 countries. We continue to have a presence in high-growth international markets such as Asia-Pacific, Latin America, the Middle East and North Africa. Our comprehensive regulatory expertise and extensive local knowledge facilitate timely patient recruitment for complex clinical trials and improved access to treatment-naïve patients and to emerging markets, thereby reducing the time and cost of these trials for our customers while also optimizing the commercialization potential for new therapies.

Diversified, loyal and growing customer base. We have a well-diversified, loyal customer base of over 300 customers that includes many of the world's largest biopharmaceutical companies as well as high-growth, small and mid-sized biopharmaceutical companies. We have several customers with whom we have achieved "preferred provider" or strategic alliance relationships. We define these customer relationships to include ones where we have executed master service agreements in addition to regularly scheduled strategy meetings to discuss the status of our relationship, and for which we serve as a preferred supplier of services. We believe these relationships provide us enhanced opportunities for more business, although they are not a guarantee of future business. In addition, many of our customers are diversified across multiple projects and compounds. Our top five customers represented approximately 71 compounds in 47 indications across 200 active projects and accounted for approximately 34% of our net service revenue in 2015. Our customer base is geographically diverse with well-established relationships in the United States, Europe and Asia. We believe the breadth of our footprint reduces our exposure to potential U.S. and European biopharmaceutical industry consolidation. We believe that the tenure of our customer relationships as well as the depth of penetration of our services reflect our strong reputation and track record. While 86% of our new business awards in 2015 were from repeat customers and our top ten customers have worked with us for an average of more than 10 years, we were also awarded clinical trials from 72 new customers in 2015, with particularly strong growth among small to mid-sized biopharmaceutical companies. We have also increased our penetration in the large biopharmaceutical market, which we define as the top 50 biopharmaceutical companies measured by annual drug revenue, with 59% of our net service revenue in 2015 coming from large biopharmaceutical companies. We believe we have increased our market share in recent years and are well positioned to continue growing our customer base.

Outstanding financial performance. We have achieved significant revenue and EBITDA growth over the past several years. For example, during 2015, we increased our net service revenue, Adjusted EBITDA and Adjusted Net Income by 13%, 52%, and 169%, respectively, as compared to 2014, and ended the year with net income of \$117.0 million, compared to that of a net loss of \$23.5 million in 2014. The momentum in our business is also reflected in the growth in our backlog and new business awards (which is the value of future net service revenue supported by contracts or pre-contract written communications from customers for projects that have received appropriate internal funding approval, are not contingent upon completion of another trial or event and are expected to commence within the next 12 months, minus the value of cancellations in the same period). Backlog and new business awards are not necessarily predictive of future financial performance because they will likely be impacted by a number of factors, including the size and duration of projects (which can be performed over several years), project change orders resulting in increases or decreases in project scope, and cancellations. For the period from December 31, 2014 to December 31, 2015, our backlog increased by 14% and net new business awards grew by 24%. We believe our outstanding financial profile and strong momentum demonstrate the quality of the platform we have built to position ourselves for continued future growth.

Highly experienced management team with a deep-rooted culture of quality and innovation. We are led by a dedicated and experienced senior management team with significant industry experience and knowledge focused on clinical development. Each of the members of our senior management has 20 years or more of relevant experience, including significant experience across the CRO and biopharmaceutical industries. Our management team has successfully grown our company into a leading CRO through a combination of organic growth and acquisitions and believes we are well positioned to further capitalize on industry growth trends.

Business Strategy

The key elements of our business strategy include:

Focus on attractive, high-growth late-stage clinical development services market. We believe outsourcing late-stage clinical development services to CROs optimizes returns on invested R&D for biopharmaceutical companies. As development spend and outsourcing penetration rates continue to increase, we estimate that the late-stage clinical development services market will grow at a rate of 7% to 8% annually through 2020 and is poised to realize incremental growth relative to the overall CRO market. We believe that our core focus on the late-stage clinical development services market ideally positions us to benefit from this growth trend. Additionally, we believe that our differentiated approach of investing in highly experienced people, making better use of enabling technology and improving the process of clinical development, will allow our customers to generate superior returns.

Leverage our expertise in complex clinical trials. We intend to continue to develop and leverage our therapeutic expertise in complex clinical trials. We believe that our focus on and deep expertise in complex therapeutic areas such as CNS, oncology and other complex diseases better position us to win new clinical trials in these fast growing and large therapeutic areas. This is enhanced by the use of our proprietary Trusted Process® methodology that reduces operational risk and variability by standardizing processes and minimizing delays, instills quality throughout the clinical development process and leads customers to more confident, better-informed drug development decisions. Capitalize on our geographic scale. We intend to leverage our global breadth and scale to drive continued growth. We have built our presence across key markets over time, developing strong relationships with principal investigators and clinical research sites around the world. We have expanded our patient recruitment capabilities, principal investigator relationships and local regulatory knowledge, which should continue to position us well for new customer wins in a wide array of markets. We have added geographic reach through both acquisitions and organic growth in areas such as Asia-Pacific, Latin America and the Middle East and North Africa, which we believe is critical to obtaining larger new business awards from large and mid-sized biopharmaceutical companies. Our long-term growth opportunities are enhanced by our strong reputation in emerging markets and our track record of efficiently managing trials in accordance with regional regulatory requirements.

Continue to enhance our Trusted Process® methodology to deliver superior outcomes. We intend to continue the development and enhancement of our Trusted Process® methodology, which has delivered measurable, beneficial results for our customers and improved drug development decisions. We believe our Trusted Process® will continue to lead to high levels of customer satisfaction. Our Trusted Process® is subject to continual refinement based on feedback from therapeutic leadership, staff and customers as well as the market factors of an evolving regulatory environment and technology innovation. Our Trusted Process® uses best-in-class and industry-leading third-party technology solutions. We expect that through continuous enhancement of our Trusted Process® methodology, we will achieve better alignment of best-in-class technology to enable increased visibility into critical processes, management and controls in the drug development process. We intend to continue to position ourselves to quickly adopt best-in-class technology through effective third-party collaborations without the need for high capital investments and maintenance costs, driving attractive returns on capital.

Continue proven track record of identifying and successfully integrating selective acquisitions to augment our organic growth. Over the past decade, we have developed a systematic approach for integrating acquisitions. We have successfully acquired and integrated ten companies. These strategic acquisitions have increased our size, scale and reach, complementing our organic growth profile as we have become a leading provider of CRO services. Our acquisitions have enabled us to expand our global service offerings across all four phases of biopharmaceutical clinical development while also allowing us to achieve significant synergies and cost reductions. For example, in March 2014 we completed the acquisition of MEK Consulting, which expanded our presence in the high-growth Middle East and North Africa market. We will continue to evaluate opportunities to acquire and integrate selective tuck-in acquisitions within the CRO sector in order to strengthen our competitive position and realize attractive returns on our investments.

Drive our human capital asset base to grow existing relationships. As a clinical service provider, our employees are critical to our ability to deliver our innovative operational model by engaging with customers,

delivering clinical development services in a complex environment, and supporting and executing our growth strategy. All employees undergo comprehensive initial orientation and ongoing training, including a focus on our Trusted Process® methodology. Our recruiting and retention efforts are geared toward maintaining and growing a stable work force focused on delivering results for customers. We have a successful track record of integrating talent from prior acquisitions and believe we have a best-in-class pool of highly experienced project management professionals and CRAs.

Our Services

Our extensive range of services supports the entire clinical development process from Phase I to Phase IV and allows us to offer our customers an integrated suite of investigative site support and clinical development services. We offer these services across a wide variety of therapeutic areas with deep clinical expertise with a primary focus on Phase II to Phase IV clinical trials. We provide total biopharmaceutical program development while also providing discrete services for any part of a trial. The combination of service area experts and the depth of clinical capability allows for enhanced protocol design and actionable trial data. Our comprehensive suite of clinical development services includes, but is not limited to:

Clinical Development Services

| Clinical Trial Management | Data Services | Strategic and Regulatory Services | Post-Approval Services |
|---|--|---|---|
| <ul style="list-style-type: none"> • Patient recruitment and retention • Project management • Clinical monitoring • Drug safety / pharmacovigilance • Medical affairs • Quality assurance • Regulatory and medical writing • Functional service | <ul style="list-style-type: none"> • Clinical data management • Electronic data capture • Biostatistics | <ul style="list-style-type: none"> • Strategic development services • Regulatory consulting and submissions • Clinical operations optimization • Pricing and reimbursement planning | <ul style="list-style-type: none"> • Specialized support for patient registries • Safety surveillance studies, prospective observational studies • Health outcome research • Patient-reported outcomes • Phase IV effectiveness trials • Health economics studies and retrospective chart reviews |

Clinical Trial Management

We offer a variety of select and stand-alone clinical trial services as well as full-service, global studies through our clinical development services. Our key clinical trial management services include the following:

Patient Recruitment and Retention. Our patient recruitment services group helps identify and manage appropriate vendors, focuses on patient recruitment and retention strategies and acts as a liaison to media outlets and other vendors that we have validated.

Project Management. Our project managers provide customer-focused leadership in managing clinical trials and are accountable for the successful execution of all assigned projects, where success includes on-time, on-budget, and high quality results that lead to satisfied customers. Project managers have the skills, education, experience and training to support the successful conduct of clinical studies.

Clinical Monitoring. Our clinical monitors oversee the conduct of a clinical trial by working with and monitoring clinical research sites to assure the quality of the data. The clinical monitor ensures the trial is conducted according to Good Clinical Practice ("GCP"), International Conference on Harmonisation ("ICH") guidelines and local regulations, to meet the customers' and regulatory authorities' requirements according to the study protocol. CRAs engage with clinical research sites in site initiation, training and patient recruitment. We deploy and manage clinical monitoring

staff in all

8

regions of the globe. By maintaining a therapeutic focus, we attract CRAs who have a strong desire to dedicate themselves to working within a specific therapeutic area, providing an environment where they can further develop their expertise in their chosen area of interest.

Drug Safety/Pharmacovigilance. Our drug safety teams are strategically located across the United States, Europe, Latin America and Asia-Pacific. We provide global drug safety expertise in all phases of clinical research for serious adverse event/adverse event collection, evaluation, classification, reporting, reconciliation, post-marketing safety and pharmacovigilance.

Medical Affairs. We have in-house physicians who provide 24/7 medical monitoring, scientific and medical support for project management teams and clinical research sites. These in-house physicians consist of senior clinicians and former clinical researchers with patient care and trial management expertise.

Quality Assurance. Quality control steps are built into all of our processes. We have an independent quality assurance department that, in addition to conducting independent audits of all ongoing projects and processes as part of our internal quality assurance program, offers contracted quality assurance services to customers, including audits of clinical research sites and of various vendors to the clinical research industry; 'mock' regulatory inspections and clinical research site inspection-readiness training; standard operating procedure development; and quality assurance program development/consultation. Our customers also engage us to conduct third-party audits on behalf of their studies.

Regulatory and Medical Writing. We also offer regulatory and medical writing expertise across the entire biopharmaceutical product lifecycle. Our team has hands-on regulatory and medical writing knowledge gained through experience from working in large biopharmaceutical companies, as well as high-growth, small and mid-sized biopharmaceutical companies, CROs and the United States Food and Drug Administration ("FDA"). Additionally, each member is trained in FDA regulations, including GCP/standard operating practice compliance guidelines and guidelines established by the ICH.

Functional Services. Our functional service provider ("FSP") offering is a tool to help sponsors review their approach to key functional areas of clinical research, specifically those areas not core to their clinical development business. The aim of implementing an FSP approach is greater predictability and more consistent delivery of services across all protocols. We currently operate FSP hubs in North America, South America, Europe and Asia.

Data Services

Our data services include the following:

Clinical Data Management. Our clinical data management services allow us to confirm that the clinical trial database is ready, accurately populated and locked in an expeditious manner, with verification and validation procedures throughout every phase of a clinical trial. This processing is done in synchronization with the clinical team, utilizing the information provided from the trial to help ensure efficient processes are employed, regardless of the data collection method used.

Electronic Data Capture. To compete in today's changing global drug and device development environment, companies must collect and distribute data faster than ever before. We have the ability to manage electronic data capture ("EDC") to help our customers take advantage of the efficiencies available through EDC, which include improved access to data, reduced cycle time, increased productivity and improved relationships with customers, vendors and other parties. We utilize three leading EDC platforms: Medidata Rave, Oracle Clinical Remote Data Capture and Oracle Health Sciences InForm products. Our ability to design, build and deliver high quality databases in all three platforms enables our team to deliver effective EDC solutions.

Biostatistics. Our biostatistics team has a depth of experience with the FDA and European Medicines Agency ("EMA") which allows our teams to provide customers with guidance on building a statistical plan to meet regulatory and safety requirements as well as a careful analysis of the resulting study data. In addition, we provide support for independent drug safety monitoring boards and a full range

of related services. Our biostatisticians are also heavily involved in our Trusted Process[®] methodology, so that protocol and project development can be grounded in advanced statistical methodology. As part of a project team, our biostatisticians can provide data oversight throughout a clinical trial and address any data or data handling issues that may arise.

Strategic and Regulatory Services

Strategic Services. Our strategic consulting group focuses on maximizing the value of scientific knowledge, intellectual property and portfolio content. The key areas of advisory services include strategic drug development, clinical development plans, registration strategies, exit strategies, transitional clarity, good clinical practice compliance strategies, clinical operations optimization, pricing and reimbursement, and due diligence. Strategic consultants include senior personnel from medical and regulatory affairs, clinical research, biostatistics and data management. These individuals provide expertise gained through hands-on experience as former executives from biopharmaceutical companies, CROs and regulatory agencies.

Regulatory Services. We offer regulatory expertise across the entire biopharmaceutical product lifecycle. Our regulatory affairs practice has a global presence with offices in North America, Europe and Asia-Pacific. In addition, subject matter experts are located worldwide to provide global regulatory coverage. Global regulatory services include worldwide regulatory submissions, regulatory strategy and agency meetings, early development consultancy, data safety monitoring board and data review committee management, chemistry manufacturing and controls, contemporary regulatory interpretation, investigational new drug ("IND"), applications and clinical trial authorizations.

Post-Approval Services

Our post-approval services are focused on efficient delivery of studies and support programs. These studies and programs include specialized support for patient registries, safety surveillance studies, prospective observational studies, health outcome research, patient reported outcomes, Phase IV effectiveness trials, health economics studies and retrospective chart reviews. Our proprietary post-approval study management system provides real-time support for sites and up-to-date status reports for sponsors.

Our Trusted Process[®] Methodology

We perform each of these service offerings through our proprietary, operational approach to clinical trials. Our Trusted Process[®] is a metrics-driven methodology that we employ to deliver superior results to our customers. We developed this process to improve reliability and predictability of clinical trial project management. Our Trusted Process[®] methodology has allowed us to reduce operational risk and variability as well as provide faster cycle times. This has resulted in greater operating efficiency, highly predictable project timelines and enhanced customer satisfaction and retention rates.

The Trusted Process[®] methodology is divided into four sub-processes which correlate with the key phases of a clinical project:

PlanActivation[®] — the design phase, where a project is analyzed and a strategy developed utilizing our therapeutic and clinical experience, forming the basis of a customized project proposal. The strategy continues to be refined based on discussions with the customer through new business award.

QuickStart[®] — the initiating phase, which serves to align the customer's and our project teams to a single set of objectives, create shared expectations and develop a joint plan for project implementation.

ProgramAccelerate[®] — the execution and control phase, which includes the processes of patient recruitment, clinical monitoring and data management. In this phase, we proactively process and review data to ensure quality and project timelines are actively managed, while maintaining strong relationships with investigative sites.

QualityFinish[®] — the closing phase, which is triggered by the first enrolled patient completing the clinical trial. This phase focuses on assuring high quality, actionable data is used to develop the final

deliverables which make up the basis of the documentation necessary for filing with regulatory agencies. Since 2006, we have conducted studies using the tools and discipline of the Trusted Process®. We accomplish standardized delivery through support from a company-wide Project Management Office, which defines, maintains and improves procedures relating to the Trusted Process® and ensures consistent application globally. Using this innovative operating model, we have reduced median study start-up time (defined as the period from finalized protocol to first patient enrolled) on new projects. Based on industry sources for the median study start-up time for the pharmaceutical industry, we believe we achieve this milestone for our customers at a faster pace than industry medians, as a result of our proprietary Trusted Process® operating model.

Customers

We have a well-diversified, loyal customer base that includes many of the world's largest biopharmaceutical companies, which we define as the top 50 biopharmaceutical companies measured by annual drug revenue. In addition, we have strong relationships with small and mid-sized biopharmaceutical customers that seek our services for our therapeutic expertise and full-service offering.

Since December 31, 2010, we have significantly increased our exposure to large biopharmaceutical customers through both acquisitions and organic growth, providing us the opportunity to compete for large, global late-stage clinical development trials, preferred provider lists and strategic multi-year relationships. For the year ended December 31, 2015, our net service revenue attributable to large biopharmaceutical companies represented approximately 59% of our total net service revenue and net service revenue attributable to small and mid-sized biopharmaceutical companies represented approximately 41%. Additionally, we serve customers in a variety of locations throughout the world, with approximately 48% of our workforce based in the United States and Canada, 34% in Europe, 11% in Asia-Pacific, 6% in Latin America and 1% in the Middle East and Africa as of December 31, 2015. This diversification allows us to grow our business in multiple customer segments and geographies.

For the year ended December 31, 2015, our top five customers accounted for approximately 34% of our net service revenue which was diversified across approximately 71 compounds in 47 indications across 200 active projects. No customer accounted for 10% or more of net service revenue for the year ended December 31, 2015.

Our top ten customers have worked with us for an average of more than 10 years as of December 31, 2015. We also have a growing list of "preferred provider" and/or strategic alliance relationships. Further, among the majority of our customers, revenue is diversified by multiple projects for a variety of compounds. For example, 36 of our customers have active projects in more than one therapeutic area, making up 54% of our net service revenue for the year ended December 31, 2015. We believe that the tenure of our customer relationships as well as the depth of penetration of our services reflects our strong reputation and track record.

New Business Awards and Backlog

We add new business awards to backlog when we enter into a contract or letter of intent or when we receive a written commitment from the customer selecting us as its service provider. Contracts generally have terms ranging from several months to several years. We recognize revenue on these awards as services are performed, provided we have entered into a contractual commitment with the customer. Our new business awards, net of cancellations of prior awards, for the years ended December 31, 2015, 2014 and 2013 were approximately \$1.18 billion, \$0.95 billion and \$0.81 billion, respectively.

Backlog consists of anticipated future net service revenue from contracts, letters of intent and other written forms of commitments that either have not started but are anticipated to begin in the near future, or are in process and have not been completed. The majority of our contracts can be terminated by our customers with 30 days' notice. Our backlog also reflects any related cancellation or adjustment activity. Our backlog as of December 31, 2015, 2014 and 2013 was approximately \$1.81 billion, \$1.59 billion and \$1.49 billion, respectively. Included within backlog at December 31, 2015 is approximately \$0.84 billion that we expect to

translate into revenue in 2016. Backlog is not necessarily indicative of future financial performance because it will likely be impacted by a number of factors, including the size and duration of projects (which can be performed over several years), project change orders resulting in increases or decreases in project scope and cancellations.

No assurance can be given that we will be able to realize the net service revenue that is included in the backlog. See Part I, Item 1A, "Risk Factors - Risk Relating to Our Business - Our backlog might not be indicative of our future revenues, and we might not realize all the anticipated future revenue reflected in our backlog," and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations - New Business Awards and Backlog" for more information.

Sales and Marketing

We employ a team of business development sales representatives and support staff that promote, market and sell our services to biopharmaceutical companies primarily in North America, Europe, Latin America and Asia-Pacific. In addition to significant selling experience, many of these individuals have technical and/or scientific backgrounds. Our business development team works with our senior executives, therapeutic leaders and project team leaders to maintain key customer relationships and engage in business development activities. For many of our largest customer relationships, we have dedicated strategic account management teams to provide customers with a single point of contact to support delivery, cultural and process integration and to facilitate cross-selling opportunities.

We use integrated and customer-focused business development teams to develop joint sales plans for key accounts. We also place our business development personnel with strong operational experience around the globe to help ensure project demands are fulfilled. Each business development employee is generally responsible for a specific group of customers and for strengthening and expanding an effective relationship with that customer. Each individual is responsible for developing his or her customer base on our behalf, responding to customer requests for information, developing and defending proposals, and making presentations to customers.

As part of each customer proposal, our business development personnel consult with potential biopharmaceutical customers early in the project consideration stage in order to determine their requirements. We involve our therapeutic, operational, technical and/or scientific personnel early in each proposal and, accordingly, these individuals along with our business development representatives invest significant time to determine the optimal means to design and execute the potential customer's program requirements. As an example, recommendations we make to a potential customer with respect to a drug development study design and implementation are an integral part of our bid proposal process and an important aspect of the integrated services we offer. Our preliminary efforts relating to the evaluation of a proposed clinical protocol and implementation plan, along with the therapeutic expertise and advice we provide during this process, enhance the opportunity for accelerated initiation and overall success of the trial.

Our marketing team supports our business development organization through various marketing activities to drive brand awareness and positioning, consisting primarily of market and competitive analysis, brand management, market information and collateral development, participation in industry conferences, advertising, e-marketing, publications, and website development and maintenance.

Competition

We compete primarily against other full-service CROs and services provided by in-house R&D departments of biopharmaceutical companies, universities and teaching hospitals. Although the CRO industry has experienced increased consolidation over the past three years, the landscape remains fragmented. Our major competitors include ICON plc, inVentiv Health, Inc., Laboratory Corporation of America Holdings (formerly Covance, Inc.), PAREXEL International Corporation, Pharmaceutical Product Development, LLC, PRA Health Sciences, Inc., Quintiles Transnational Holdings Inc. and numerous specialty and regional players. We generally compete on the basis of the following factors:

- experience within specific therapeutic areas;

- the quality of staff and services;
- the range of services provided;
- the ability to recruit principal investigators and patients into studies expeditiously;
- the ability to organize and manage large-scale, global clinical trials;
- an international presence with strategically located facilities;
- medical database management capabilities;
- the ability to deploy and integrate IT systems to improve the efficiency of contract research;
- experience with a particular customer;
- the ability to form strategic partnerships;
- speed to completion;
- financial strength and stability;
- price; and
- overall value.

Notwithstanding these competitive factors, we believe that our deep therapeutic expertise, global reach and operational strength differentiate us from our competitors.

Government Regulation

Regardless of the country or region in which approval is being sought, before a marketing application for a drug is ready for submission to regulatory authorities, the candidate drug must undergo rigorous testing in clinical trials. The clinical trial process must be conducted in accordance with the Federal Food, Drug and Cosmetic Act in the United States and similar laws and regulations in the relevant foreign jurisdictions. These laws and regulations require the drug to be tested and studied in certain ways prior to submission for approval.

In the United States, the FDA regulates the conduct of clinical trials of drug products in human subjects, the form and content of regulatory applications. The FDA also regulates the development, approval, manufacture, safety, labeling, storage, record keeping, and marketing of drug products. The FDA has similar authority and similar requirements with respect to the clinical testing of biological products and medical devices. In the European Union ("EU") and other jurisdictions where our customers intend to apply for marketing authorization, similar laws and regulations apply. Within the EU, these requirements are enforced by the EMA, and requirements vary slightly from one member state to another. In Canada, clinical trials are regulated by the Health Products Food Branch of Health Canada as well as provincial regulations. Similar requirements also apply in other jurisdictions, including Australia, Japan, and other Asian countries, where we operate or where our customers intend to apply for marketing authorization. Sponsors of clinical trials also follow ICH E6 guidelines.

Our services are subject to various regulatory requirements designed to ensure the quality and integrity of the clinical trial process. In the United States, we must perform our clinical development services in compliance with applicable laws, rules and regulations, including GCP, which govern, among other things, the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Before a human clinical trial may begin, the manufacturer or sponsor of the clinical product candidate must file an IND with the FDA, which contains, among other things, the results of preclinical tests, manufacturer information, and other analytical data. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Each clinical trial must be conducted pursuant to, and in accordance with, an effective IND. In addition, under GCP, each human clinical trial we conduct is subject to the oversight of an independent institutional review board ("IRB") which is an independent committee that has the regulatory authority to review, approve and monitor a clinical trial. The FDA, the IRB, or the sponsor may

suspend or terminate a clinical trial at any time on various grounds, including a finding that the study subjects are being exposed to an unacceptable health risk.

Clinical trials conducted outside the United States are subject to the laws and regulations of the country where the trials are conducted. These laws and regulations might not be similar to the laws and regulations administered by the FDA and other laws and regulations regarding the protection of patient safety and privacy and the control of study pharmaceuticals, medical devices or other study materials. Studies conducted outside the United States can also be subject to regulation by the FDA if the studies are conducted pursuant to an IND or an investigational device exemption for a product candidate that will seek FDA approval or clearance. It is the responsibility of the study sponsor or the parties conducting the studies to ensure that all applicable legal and regulatory requirements are fulfilled.

In order to comply with GCP and other regulations, we must, among other things:

- comply with specific requirements governing the selection of qualified principal investigators and clinical research sites;
- obtain specific written commitments from principal investigators;
- obtain review, approval and supervision of the clinical trials by an IRB or ethics committee;
- obtain favorable opinion from regulatory agencies to commence a clinical trial;
- verify that appropriate patient informed consents are obtained before the patient participates in a clinical trial;
- ensure that adverse drug reactions resulting from the administration of a drug or biologic during a clinical trial are medically evaluated and reported in a timely manner;
- monitor the validity and accuracy of data;
- monitor drug or biologic accountability at clinical research sites; and
- verify that principal investigators and study staff maintain records and reports and permit appropriate governmental authorities access to data for review.

Similar guidelines exist in various states and in other countries. We may be subject to regulatory action if we fail to comply with applicable rules and regulations. Failure to comply with certain regulations can also result in the termination of ongoing research and disqualification of data collected during the clinical trials. For example, violations of GCP could result, depending on the nature of the violation and the type of product involved, in the issuance of a warning letter, suspension or termination of a clinical study, refusal of the FDA to approve clinical trial or marketing applications or withdrawal of such applications, injunction, seizure of investigational products, civil penalties, criminal prosecutions, or debarment from assisting in the submission of new drug applications. See "Risk Factors—Risks Related to Our Business—If we fail to perform our services in accordance with contractual requirements, regulatory standards and ethical considerations, we could be subject to significant costs or liability and our reputation could be harmed."

We monitor our clinical trials to test for compliance with applicable laws and regulations in the United States and the foreign jurisdictions in which we operate. We have adopted standard operating procedures that are designed to satisfy regulatory requirements and serve as a mechanism for controlling and enhancing the quality of our clinical trials. In the United States, our procedures were developed to ensure compliance with GCP and associated guidelines.

In addition to its comprehensive regulation of safety in the workplace, the U.S. Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers whose workers might be exposed to blood-borne pathogens such as HIV and the hepatitis B virus. Furthermore, certain employees might have to receive initial and periodic training to ensure compliance with applicable hazardous materials regulations and health and safety guidelines. We are subject to similar regulations in Canada and Spain.

The U.S. Department of Health and Human Services has promulgated rules under the Health Information Technology for Economic and Clinical Health Act in connection with the application of security and privacy provisions under the Health Information Portability and Accountability Act (collectively, "HIPAA"). These regulations govern the use, handling and disclosure of personally identifiable medical information. Although we do not consider that our business activities generally cause us to be subject to HIPAA as a covered entity, we endeavor to embrace sound identity protection practices. These regulations also establish procedures for the exercise of an individual's rights and the methods permissible for de-identification of health information. We are also subject to privacy legislation in Canada under the federal Personal Information and Electronic Documents Act, the Act Respecting the Protection of Personal Information in the Private Sector and the Personal Health Information Protection Act, and privacy legislation in the EU under the 95/46/EC Privacy Directive on the protection and free movement of personal data.

Intellectual Property

We develop and use a number of proprietary methodologies, analytics, systems, technologies and other intellectual property in the conduct of our business. We rely upon a combination of confidentiality policies, nondisclosure agreements and other contractual arrangements to protect our trade secrets, and copyright and trademark laws to protect other intellectual property rights. We have obtained or applied for trademarks and copyright protection in the United States and in a number of foreign countries. Our material trademarks include Trusted Process[®], PlanActivation, QuickStart, ProgramAccelerate, QualityFinish, and INC Research and other corporate emblems. Although the duration of trademark registrations varies from country to country, trademarks generally may be renewed indefinitely so long as they are in use and/or their registrations are properly maintained, and so long as they have not been found to have become generic. Although we believe the ownership of trademarks is an important factor in our business and that our success does depend in part on the ownership thereof, we rely primarily on the innovative skills, technical competence and marketing abilities of our employees. We do not have any material licenses, franchises or concessions.

Employees

As of December 31, 2015 we had approximately 6,400 full-time equivalent employees worldwide, with approximately 48% in the United States and Canada, 34% in Europe, 11% in Asia-Pacific, 6% in Latin America and 1% in the Middle East and Africa. None of our employees are covered by a collective bargaining agreement and we believe our overall relations with our employees are good. Employees in certain of our non-U.S. locations are represented by workers' councils as required by local laws.

The level of competition among employers in the United States and overseas for skilled personnel is high. We believe that our brand recognition and our multinational presence are advantages in attracting qualified candidates. In addition, we believe that the wide range of clinical trials in which we participate allows us to offer broad experience to clinical researchers.

Indemnification and Insurance

In conjunction with our clinical development services, we employ or contract with research institutions and in some jurisdictions principal investigators and pharmacies on behalf of biopharmaceutical companies to serve as research centers and principal investigators in conducting clinical trials to test new drugs on human volunteers. Such testing creates the risk of liability for personal injury or death of volunteers, particularly to volunteers with life-threatening illnesses, resulting from adverse reactions to the drugs administered. It is possible that we could be held liable for claims and expenses arising from any professional malpractice of the principal investigators with whom we contract or employ, or in the event of personal injury to or death of persons participating in clinical trials. In addition, as a result of our operation of Phase I clinical trial facilities, we could be liable for the general risks associated with clinical trials including, but not limited to, adverse events resulting from the administration of drugs to clinical trial participants or the professional malpractice of medical care providers. We also could be held liable for errors or omissions in connection with the services we perform through each of our service groups. For example, we could be held liable for errors or omissions, or breach of contract, if monitoring obligations have been transferred to us and one of our CRA's inaccurately reports from source documents or fails to adequately monitor a human clinical trial resulting in inaccurately recorded results.

We have sought to reduce our risks by implementing the following where practicable:

- securing contractual assurances such as indemnification provisions and provisions seeking to limit or exclude liability contained in our contracts with customers, institutions, pharmacies, vendors and principal investigators;

- securing contractual and other assurances that adequate insurance will be maintained to the extent applicable by customers, institutions, pharmacies, vendors, principal investigators and by us; and

- complying with various regulatory requirements, including monitoring that the oversight of independent review boards and ethics committees are intact where obligations are transferred to us and monitoring the oversight of the procurement by the principal investigator of each participant's informed consent to participate in the study.

The contractual indemnifications we have generally do not fully protect us against certain of our own actions, such as negligence. Contractual arrangements are subject to negotiation with customers, and the terms and scope of any indemnification, limitation of liability or exclusion of liability varies from customer to customer and from trial to trial. Additionally, financial performance of these indemnities is not secured. Therefore, we bear the risk that any indemnifying party against which we have claims may not have the financial ability to fulfill its indemnification obligations to us.

While we maintain professional liability insurance that covers the locations in which we currently do business and that covers drug safety issues as well as data processing and other errors and omissions, it is possible that we could become subject to claims not covered by insurance or that exceed our coverage limits. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any claim that is outside the scope of, or in excess of, a contractual indemnification provision, beyond the level of insurance coverage or not covered by insurance, or in the event that an indemnifying party does not fulfill its indemnification obligations.

Executive Officers

The following table sets forth information concerning our executive officers as of December 31, 2015:

| Name | Age | Position |
|------------------------|-----|---|
| D. Jamie Macdonald | 47 | Chief Executive Officer and Director |
| Gregory S. Rush | 48 | Executive Vice President and Chief Financial Officer |
| Alistair Macdonald | 45 | President and Chief Operating Officer |
| Christopher L. Gaenzle | 49 | Chief Administrative Officer, General Counsel and Secretary |
| Michael Gibertini, PhD | 58 | President, Clinical Development |

The following is a biographical summary of the experience of our executive officers:

D. Jamie Macdonald - Chief Executive Officer and Director

Jamie Macdonald has been our Chief Executive Officer ("CEO") and a member of our Board of Directors since January 2013. He joined our Company in July 2011 as Chief Operating Officer when we acquired Kendle International Inc., or Kendle, where he was the Chief Operating Officer from May 2011 to July 2011. Prior to joining Kendle, Mr. Macdonald served for 15 years in various senior operational and finance roles at Quintiles Transnational Holdings Inc., or Quintiles, where he most recently was Senior Vice President and Head of Global Project Management from December 2008 to January 2011. Prior to Quintiles, Mr. Macdonald began his career in the pharmaceutical sector while in the UK, where he worked with Syntex Corporation (acquired by Roche Holdings, Inc., in 1994), before joining Quintiles through a transfer of undertakings in 1995. Mr. Macdonald earned a B.A. in Economics from Heriot-Watt University in Edinburgh, Scotland, and is a UK qualified Chartered Management Accountant (ACMA).

Gregory S. Rush - Executive Vice President and Chief Financial Officer

Greg Rush joined our Company in August 2013 as Executive Vice President and Chief Financial Officer ("CFO"), and has continued to serve in that role. From April 2010 to August 2013, Mr. Rush served as Senior Vice President and Chief Financial Officer of Tekelec, Inc., which was acquired by Oracle Corporation in June 2013, after serving as Interim Chief Financial Officer in March 2010. Mr. Rush joined Tekelec as Vice President and Corporate Controller in May 2005 and served as Vice President, Corporate Controller and Chief Accounting Officer from May 2006 to March 2010. His previous experience also includes roles in various senior financial positions with Siebel Systems, Inc., Quintiles, PricewaterhouseCoopers and Ernst & Young. Mr. Rush received his Bachelor of Science in Business and Master of Accounting degrees from the University of North Carolina at Chapel Hill, graduating with honors, and is a Certified Public Accountant.

Alistair Macdonald - President and Chief Operating Officer

Alistair Macdonald has been our President since January 2015 and Chief Operating Officer since January 2013. He joined our Company in 2002 and has served in various senior leadership roles during that time. Prior to his current role, Mr. Macdonald most recently served as our President, Clinical Development Services from March 2012 to January 2013, where he oversaw Study Start-up, Regulatory Consulting and Submissions, Drug Safety, Phase I Services, Global Clinical Operations Management, Alliance Delivery and Functional Service Provision and our Latin America region. He also served as Executive Vice President of our Global Oncology Unit from February 2011 to March 2012, Executive Vice President, Strategic Development from October 2009 to February 2011, and Senior Vice President, Biometrics from May 2002 to September 2009. He received his Master of Science in Environmental Diagnostics from Cranfield University.

Christopher L. Gaenzle - Chief Administrative Officer, General Counsel and Secretary

Chris Gaenzle joined our Company in April 2012 as General Counsel and Secretary and has continued to serve in that role. Since August 2013, he has also served as our Chief Administrative Officer. Prior to joining our Company, Mr. Gaenzle served for five years in various senior legal positions at Pfizer Inc., where he was

most recently Assistant General Counsel from 2010 to 2012. Prior to Pfizer, Mr. Gaenzle was a partner at Hunton and Williams LLP, where he was a practicing attorney from 1998 to 2007. Mr. Gaenzle has 20 years of private practice and corporate legal experience, the majority of which is in the pharmaceutical, medical and clinical research industries. Mr. Gaenzle received his Bachelor of Arts from Colgate University and his J.D. from Syracuse University.

Michael Gibertini, PhD - President, Clinical Development

Michael Gibertini has been our President, Clinical Development, since January 2015. Dr. Gibertini joined the Company in 2005 as President and General Manager, CNS Clinical Development, providing global leadership for the Company's CNS clinical development programs. Prior to joining the Company, Dr. Gibertini led teams in antidepressant and antipsychotic drug development for a major CNS pharmaceutical company. Dr. Gibertini has over 30 years of experience in the pharmaceutical and CRO industries as well as academic and private/hospital practice settings. Dr. Gibertini received his PhD in clinical psychology from the University of Houston.

Available Information

Our website address is www.incresearch.com. Information on our website is not incorporated by reference herein. Copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and our proxy statements for our annual stockholders meetings, and any amendments to those reports, as well as Section 16 reports filed by our insiders, are available free of charge on our website as soon as reasonably practicable after we file the reports with, or furnish the reports to, the Securities and Exchange Commission (the "SEC"). Our SEC filings are also available for reading and copying at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (<http://www.sec.gov>) containing reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. In evaluating our company, you should consider carefully the risks and uncertainties described below together with the other information included in this Annual Report on Form 10-K, including our consolidated financial statements and related notes included in Part II, Item 8, in this Annual Report on Form 10-K. The occurrence of any of the following risks may materially and adversely affect our business, financial condition, results of operations and future prospects.

Risks Related to Our Business

If we do not generate a large number of new business awards, or if new business awards are delayed, terminated, reduced in scope or fail to go to contract, our business, financial condition, results of operations or cash flows may be materially adversely affected.

Our business is dependent on our ability to generate new business awards from new and existing customers and maintain existing customer contracts for clinical development services and other services. Our inability to generate new business awards on a timely basis and subsequently enter into contracts for such awards could have a material adverse effect on our business, financial condition, results of operations or cash flows.

The time between when a study is awarded and when it goes to contract is typically several months, and prior to a new business award going to contract, our customers can cancel the award without notice. Once an award goes to contract, the majority of our customers can terminate the contract with 30 days' notice. Our contracts may be delayed or terminated by our customers or reduced in scope for a variety of reasons beyond our control, including but not limited to:

- decisions to forego or terminate a particular trial;
- budgetary limits or changing priorities;
- actions by regulatory authorities;
- production problems resulting in shortages of the drug being tested;
- failure of products being tested to satisfy safety requirements or efficacy criteria;
- unexpected or undesired clinical results for products;
- insufficient patient enrollment in a trial;
- insufficient principal investigator recruitment;
- shift of business to a competitor or internal resources; or
- product withdrawal following market launch.

As a result, contract terminations, delays and modifications are a regular part of our business. In the event of termination, our contracts often provide for fees for winding down the project, which include both fees incurred and actual and non-cancellable expenditures and may include a fee to cover a percentage of the remaining professional fees on the project. These fees may not be sufficient for us to maintain our margins, and termination may result in lower resource utilization rates and therefore lower operating margins. In addition, cancellation of a clinical trial for the reasons noted above may result in the unwillingness or inability of our customer to satisfy certain associated accounts receivable, which may in turn result in a material impact to our results of operations and cash flow.

Historically, cancellations and delays have negatively impacted our operating results. In addition, we might not realize the full benefits of our backlog if our customers cancel, delay or reduce their commitments to us, which may occur if, among other things, a customer decides to shift its business to a competitor or revoke our status as a preferred provider. Thus, the loss or delay of a large business award or the loss or delay of multiple awards could adversely affect our service revenues and profitability. Additionally, a change in the timing of a new business award could affect the period over which we recognize revenue and reduce our revenue in any one quarter.

Our backlog might not be indicative of our future revenues, and we might not realize all of the anticipated future revenue reflected in our backlog.

Backlog consists of anticipated net service revenue awarded from contract and pre-contract commitments that are supported by written communications. Once work begins on a project, revenue is recognized over the duration of the project, provided the award has gone to contract. Projects may be canceled or delayed by the customer or delayed by regulatory authorities for reasons beyond our control. To the extent projects are delayed, the timing of our revenue could be adversely affected. In addition, if a customer terminates a contract, we typically would be entitled to receive payment for all services performed up to the termination date and subsequent customer-authorized services related to terminating the canceled project. Typically, however, we have no contractual right to the full amount of the future revenue reflected in our backlog in the event of a contract termination or subsequent changes in scope that reduce the value of the contract. The duration of the projects included in our backlog, and the related revenue recognition, typically range from a few months to several years. Our backlog might not be indicative of our future revenues, and we might not realize all the anticipated future revenue reflected in our backlog. A number of factors may affect backlog, including:

- the size, complexity and duration of projects or strategic relationships;
- the cancellation or delay of projects;
- the failure of one or more business awards to go to contract; and
- changes in the scope of work during the course of projects.

The rate at which our backlog converts to revenue may vary over time. The revenue recognition on larger, more global projects could be slower than on smaller, more regional projects for a variety of reasons, including, but not limited to, an extended period of negotiation between the time the project is awarded to us and the actual execution of the contract, as well as an increased time frame for obtaining the necessary regulatory approvals.

Our backlog at December 31, 2015 was \$1.81 billion. Although an increase in backlog will generally result in an increase in revenues over time, an increase in backlog at a particular point in time does not necessarily correspond directly to an increase in revenues during any particular period, or at all. The extent to which contracts in backlog will result in revenue depends on many factors, including, but not limited to, delivery against project schedules, scope changes, contract terminations and the nature, duration and complexity of the contracts, and can vary significantly over time.

Our operating results have historically fluctuated between fiscal quarters and may continue to fluctuate in the future, which may adversely affect the market price of our stock.

Our operating results have fluctuated in previous quarters and years and may continue to vary significantly from quarter to quarter and are influenced by a variety of factors, such as:

- timing of contract amendments for changes in scope that could affect the value of a contract and potentially impact the amount of net new business awards and net service revenues from quarter to quarter;
- commencement, completion, execution, postponement or termination of large contracts;
- contract terms for the recognition of revenue milestones;
- progress of ongoing contracts and retention of customers;
- timing of and charges associated with completion of acquisitions and other events;
- changes in the mix of services delivered, both in terms of geography and type of services;

potential customer disputes, penalties or other issues that may impact the revenue we are able to recognize or the collectability of our related accounts receivable; and
exchange rate fluctuations.

Our operating results for any particular quarter are not necessarily a meaningful indicator of future results and fluctuations in our quarterly operating results could negatively affect the market price and liquidity of our shares. We have a history of net losses which may continue and which may negatively impact our ability to achieve or sustain profitability.

Prior to 2015, we had a history of net losses and cannot assure you that we will sustain profitability on a quarterly or annual basis in the future. For the year ended December 31, 2015, we had net income of \$117.0 million. However, for the years ended December 31, 2014 and 2013 we incurred net losses of \$23.5 million and \$41.5 million, respectively. If we cannot maintain profitability, the value of our stock price may be impacted.

If we underprice our contracts, overrun our cost estimates or fail to receive approval for or experience delays in documentation of change orders, our business, financial condition, results of operations or cash flows may be materially adversely affected.

We price our contracts based on assumptions regarding the scope of work required and cost to complete the work. We bear the financial risk if we initially underprice our contracts or otherwise overrun our cost estimates, which could adversely affect our cash flows and financial performance. In addition, contracts with our customers are subject to change orders, which occur when the scope of work we perform needs to be modified from that originally contemplated in our contract with the customers. This can occur, for example, when there is a change in a key study assumption or parameter or a significant change in timing. We may be unable to successfully negotiate changes in scope or change orders on a timely basis or at all, which could require us to incur cost outlays ahead of the receipt of any additional revenue. In addition, under generally accepted accounting principles in the United States of America ("GAAP") we cannot recognize additional revenue anticipated from change orders until appropriate documentation is received by us from the customer authorizing the change. However, if we incur additional expense in anticipation of receipt of that documentation, we must recognize the expense as incurred. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business depends on the continued effectiveness and availability of our information systems, including the information systems we use to provide services to our customers and to store employee data, and failures of these systems, including cyber-attacks, may materially limit our operations or have an adverse effect on our reputation. Our information systems are comprised of systems we have purchased or developed, legacy information systems from organizations we have acquired and, increasingly, web-enabled and other integrated information systems. In using these information systems, we frequently rely on third-party vendors to provide hosting services, where our infrastructure is dependent upon the reliability of their underlying platforms, facilities and communications systems. We also utilize integrated information systems that we provide customers access to or install for our customers in conjunction with our delivery of services.

As the breadth and complexity of our information systems continue to grow, we will increasingly be exposed to the risks inherent in maintaining the stability of our legacy systems due to prior customization, attrition of employees or vendors involved in their development, and obsolescence of the underlying technology as well as risks from the increasing number and scope of external data breaches on multi-national companies. Because certain customers and clinical trials may be dependent upon these legacy systems, we also face an increased level of embedded risk in maintaining the legacy systems and limited options to mitigate such risk. We are also exposed to risks associated with the availability of all our information systems, including:

disruption, impairment or failure of data centers, telecommunications facilities or other key infrastructure platforms, including those maintained by our third-party vendors;

security breaches of, cyber-attacks on and other failures or malfunctions in our internal systems, including our employee data and communications, critical application systems or their associated hardware; and excessive costs, excessive delays or other deficiencies in systems development and deployment.

The materialization of any of these risks may impede the processing of data, the delivery of databases and services, and the day-to-day management of our business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. While we have disaster recovery plans in place, they might not adequately protect us in the event of a system failure. Despite any precautions we take, damage from fire, floods, hurricanes, power loss, telecommunications failures, computer viruses, break-ins and similar events at our various computer facilities or those of our third-party vendors could result in interruptions in the flow of data to us and from us to our customers. Corruption or loss of data may result in the need to repeat a trial at no cost to the customer, but at significant cost to us, the termination of a contract or damage to our reputation. Additionally, significant delays in system enhancements or inadequate performance of new or upgraded systems once completed could damage our reputation and harm our business. Finally, long-term disruptions in the infrastructure caused by events such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism, particularly involving cities in which we have offices, and cyber-attacks such as those recently faced by other multi-national companies could adversely affect our businesses. As our business continues to expand globally, these types of risks may be further increased by instability in the geopolitical climate of certain regions, underdeveloped and less stable utilities and communications infrastructure, and other local and regional factors. Although we carry property and business interruption insurance which we believe is customary for our industry, our coverage might not be adequate to compensate us for all losses that may occur.

Unauthorized disclosure of sensitive or confidential data, whether through systems failure or employee negligence, cyber-attacks, fraud or misappropriation, could damage our reputation and cause us to lose customers. Similarly, we have been and expect that we will continue to be subject to attempts to gain unauthorized access to or through our information systems or those we internally or externally develop for our customers, including a cyber-attack by computer programmers and hackers who may develop and deploy viruses, worms or other malicious software programs, process breakdowns, denial-of-service attacks, malicious social engineering or other malicious activities, or any combination of the foregoing. In addition, we may be susceptible to physical or computer-based attacks by terrorists or hackers due to our role in the CRO industry. These concerns about security are increased when information is transmitted over the Internet. Threats include cyber-attacks such as computer viruses, worms or other destructive or disruptive software, and any of these could result in a degradation or disruption of our services or damage to our properties, equipment and data. They could also compromise data security. If such attacks are not detected immediately, their effect could be compounded. To date these attacks have not had a material impact on our operations or financial results. Nonetheless, successful attacks in the future could result in negative publicity, significant remediation and recovery costs, legal liability and damage to our reputation and could have a material adverse effect on our financial condition, results of operations and cash flows. In addition, our liability insurance might not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

Additionally, we rely on service providers for the timely transmission of information across our global data network. If a service provider fails to provide the communications capacity or services we require for similar reasons, the failure could interrupt our services. Because of the centrality of our processing systems to our business, any interruption or degradation could adversely affect the perception of our brands' reliability and harm our business. We are subject to regulation in the areas of consumer privacy and data use and security.

Privacy, data use and security continue to receive heightened legislative and regulatory focus in the United States, Europe and elsewhere. For example, in many jurisdictions victims must be notified in the event of a data breach and those jurisdictions that have these laws are continuing to increase the circumstances and the breadth of these notices. Our failure or the failure of our clients to comply with these laws and regulations could result in fines, sanctions, litigation and damage to our global reputation and our brands.

Our customer or therapeutic area concentration may have a material adverse effect on our business, financial condition, results of operations or cash flows.

If any large customer decreases or terminates its relationship with us, our business, financial condition, results of operations or cash flows could be materially adversely affected. For the year ended December 31, 2015, our top ten customers based on revenue accounted for approximately 47% of our net service revenue and our top ten customers based on backlog accounted for approximately 47% of our total backlog. Although no customer accounted for 10% or more of total net service revenue for the year ended December 31, 2015, various subsidiaries of Otsuka Holdings Co., Ltd., accounted for approximately 14% and 15% of our net service revenue in the years ended December 31, 2014 and 2013, respectively. Additionally, various subsidiaries of Astellas Pharma, Inc. accounted for 12% of net service revenue for the year ended December 31, 2014. It is possible that an even greater portion of our revenues will be attributable to a smaller number of customers in the future, including as a result of our entering into strategic provider relationships with customers. Also, consolidation in our potential customer base results in increased competition for important market segments and fewer available customer accounts.

Additionally, conducting multiple clinical trials for different sponsors in a single therapeutic class involving drugs with the same or similar chemical action may adversely affect our business if some or all of the trials are canceled because of new scientific information or regulatory judgments that affect the drugs as a class. Similarly, marketing and selling products for different sponsors with similar drug action subjects us to risk if new scientific information or regulatory judgment prejudices the products as a class, leading to compelled or voluntary prescription limitations or withdrawal of some or all of the products from the market.

Our business is subject to international economic, political and other risks that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation.

We have operations in many foreign countries, including, but not limited to, countries in the Asia-Pacific region, Europe, Latin America and the Middle East and Africa. As of December 31, 2015, approximately 56% of our workforce was located outside of the United States, and for the fiscal year ended December 31, 2015, approximately 29% of our net service revenue was billed to locations outside the United States. Our international operations are subject to risks and uncertainties inherent in operating in these regions, including:

- conducting a single trial across multiple countries is complex, and issues in one country, such as a failure to comply with or unanticipated changes to local regulations or restrictions such as restrictions on import or export of clinical trial material or availability of clinical trial data may affect the progress of the trial in the other countries, resulting in delays or potential termination of contracts, which in turn may result in loss of revenue;

- the United States or other countries could enact legislation or impose regulations or other restrictions, including unfavorable labor regulations, tax policies, data protection regulations or economic sanctions, which could have an adverse effect on our ability to conduct business in or expatriate profits from the countries in which we operate; foreign countries are expanding or may expand their banking regulations that govern international currency transactions, particularly cross-border transfers, which may inhibit our ability to transfer funds into or within a jurisdiction, impeding our ability to pay our principal investigators, vendors and employees, thereby impacting our ability to conduct trials in such jurisdictions;

- foreign countries are expanding or may expand their regulatory framework with respect to patient informed consent, protection and compensation in clinical trials, additional transparency reporting requirements (similar to the Physician Payment Sunshine Act in the United States), which could delay, inhibit or prohibit our ability to conduct trials in such jurisdictions;

- the regulatory or judicial authorities of foreign countries might not enforce legal rights and recognize business procedures in a manner in which we are accustomed or would reasonably expect;

- changes in political and economic conditions, including inflation, may lead to changes in the business environment in which we operate, as well as changes in foreign currency exchange rates;

potential violations of existing or newly adopted local laws or anti-bribery laws, such as the United States Foreign Corrupt Practices Act ("FCPA"), and the UK Bribery Act of 2010, may cause a material adverse effect on our business, financial condition, results of operations, cash flows or reputation;

- customers in foreign jurisdictions may have longer payment cycles, and it may be more difficult to collect receivables in those jurisdictions;
- natural disasters, pandemics or international conflict, including terrorist acts, could interrupt our services, endanger our personnel or cause project delays or loss of trial materials or results;
- political unrest, such as the current situations in Ukraine and the Middle East, could delay or disrupt the ability to conduct clinical trials; and
- foreign governments may enact currency exchange controls that may limit the ability to fund our operations or significantly increase the cost of maintaining operations.

These risks and uncertainties could negatively impact our ability to, among other things, perform large, global projects for our customers. Furthermore, our ability to deal with these issues could be affected by applicable U.S. laws. Any such risks could have an adverse impact on our business, financial condition, results of operations, cash flows or reputation.

Governmental authorities may question our intercompany transfer pricing policies or change their laws in a manner that could increase our effective tax rate or otherwise harm our business.

As a U.S. company doing business in international markets through subsidiaries, we are subject to foreign tax and intercompany pricing laws, including those relating to the flow of funds between the parent and subsidiaries.

Regulators in the United States and in foreign markets closely monitor our corporate structure and how we account for intercompany fund transfers. If regulators challenge our corporate structure, transfer pricing mechanisms or intercompany transfers, our operations may be negatively impacted and our effective tax rate may increase. Tax rates vary from country to country and if regulators determine that our profits in one jurisdiction should be increased, we might not be able to fully utilize all foreign tax credits that are generated, which would increase our effective tax rate. Additionally, the Organization for Economic Cooperation and Development ("OECD"), has issued certain proposed guidelines regarding base erosion and profit sharing. Once these guidelines are formally adopted by the OECD, it is possible that separate taxing jurisdictions may also adopt some form of these guidelines. In such case, we may need to change our approach to intercompany transfer pricing in order to maintain compliance under the new rules. Our effective tax rate may increase or decrease depending on the current location of global operations at the time of the change. Finally, we might not always be in compliance with all applicable customs, exchange control, Value Added Tax and transfer pricing laws despite our efforts to be aware of and to comply with such laws. If these laws change we may need to adjust our operating procedures and our business could be adversely affected.

If we are unable to successfully increase our market share, our ability to grow our business and execute our growth strategies could be materially adversely affected.

A key element of our growth strategy is increasing our market share both within the clinical development market and in the geographic markets in which we operate. As we grow our market share, we might not have or adequately build the competencies necessary to perform our services satisfactorily or may face increased competition. If we are unable to succeed in increasing our market share, we will be unable to implement this element of our growth strategy, and our ability to grow our business could be adversely affected.

Upgrading the information systems that support our operating processes and evolving the technology platform for our services pose risks to our business.

Continued efficient operation of our business requires that we implement standardized global business processes and evolve our information systems to enable this implementation. We have continued to undertake significant programs to optimize business processes with respect to our services. Our inability to effectively manage the implementation of new information systems or upgrades and adapt to new processes designed into these new or upgraded systems in a timely and cost-effective manner may result in disruption to our business and negatively affect our operations.

We have entered into agreements with certain vendors to provide systems development, integration and hosting services that develop or license to us the information technology ("IT") platforms and capacity for programs to optimize our business processes. If such vendors or their products fail to perform as required or if there are substantial delays in developing, implementing and updating our IT platforms, our customer delivery may be impaired, and we may have to make substantial further investments, internally or with third parties, to achieve our objectives. For example, we rely on an external vendor to provide the clinical trial management software used in managing the completion of our customer clinical trials. If that externally provided system is not properly maintained we might not be able to meet the obligations of our contracts or may need to incur significant costs to replace the system or capability. Additionally, our progress may be limited by parties with existing or claimed patents who seek to enjoin us from using preferred technology or seek license payments from us.

Meeting our objectives is dependent on a number of factors which might not take place as we anticipate, including obtaining adequate technology-enabled services, depending upon our third-party vendors to develop and enhance existing applications to adequately support our business, creating IT-enabled services that our customers will find desirable and implementing our business model with respect to these services. Also, increased IT-related expenditures and our potential inability to anticipate increases in service costs may negatively impact our business, financial condition, results of operations or cash flows.

If we fail to perform our services in accordance with contractual requirements, regulatory standards and ethical considerations, we could be subject to significant costs or liability and our reputation could be harmed.

We contract with biopharmaceutical companies to perform a wide range of services to assist them in bringing new drugs to market. Our services include monitoring clinical trials, data and laboratory analysis, EDC, patient recruitment and other related services. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. For example, we must adhere to applicable regulatory requirements such as the FDA, current GCP regulations, which govern, among other things, the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. If we fail to perform our services in accordance with these requirements, regulatory agencies may take action against us or our customers. Such actions may include sanctions such as injunctions or failure of such regulatory authorities to grant marketing approval of products, imposition of clinical holds or delays, suspension or withdrawal of approvals, rejection of data collected in our studies, license revocation, product seizures or recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Additionally, there is a risk that actions by regulatory authorities, if they result in significant inspectional observations or other measures, could harm our reputation and cause customers not to award us future contracts or to cancel existing contracts. Any such action could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation.

Such consequences could arise if, among other things, the following occur:

Improper performance of our services. The performance of clinical development services is complex and time-consuming. For example, we may make mistakes in conducting a clinical trial that could negatively impact or obviate the usefulness of the trial or cause the results of the trial to be reported improperly. If the trial results are compromised, we could be subject to significant costs or liability, which could have an adverse impact on our ability to perform our services and our reputation could be harmed. For example:

- non-compliance generally could result in the termination of ongoing clinical trials or the disqualification of data for submission to regulatory authorities;

- compromise of data from a particular trial, such as failure to verify that adequate informed consent was obtained from subjects or improper monitoring of data, could require us to repeat the trial under the terms of our contract at no further cost to our customer, but at a substantial cost to us; and

- breach of a contractual term could result in liability for damages or termination of the contract.

Large clinical trials can cost hundreds of millions of dollars and improper performance of our services could have a material adverse effect on our financial condition, damage our reputation and result in the termination of current contracts by or failure to obtain future contracts from the affected customer or other customers.

Interactive Voice/Web Response Technology malfunction. We develop, maintain and use third-party computer run interactive voice/web response systems to automatically manage the randomization of patients in a given clinical trial to different treatment arms and regulate the supply of investigational drugs, all by means of interactive voice/web response systems. An error in the design, programming or validation of these systems could lead to inappropriate assignment or dosing of patients which could give rise to patient safety issues, invalidation of the trial or liability claims against us. Furthermore, negative publicity associated with such a malfunction could have an adverse effect on our business and reputation. Additionally, errors in randomization may require us to repeat the trial at no further cost to our customer, but at a substantial cost to us.

Investigation of customers. From time to time, one or more of our customers are audited or investigated by regulatory authorities or enforcement agencies with respect to regulatory compliance of their clinical trials, programs or the marketing and sale of their drugs. In these situations, we have often provided services to our customers with respect to the clinical trials, programs or activities being audited or investigated, and we are called upon to respond to requests for information by the authorities and agencies. There is a risk that either our customers or regulatory authorities could claim that we performed our services improperly or that we are responsible for clinical trial or program compliance. If our customers or regulatory authorities make such claims against us and prove them, we could be subject to damages, fines or penalties. In addition, negative publicity regarding regulatory compliance of our customers' clinical trials, programs or drugs could have an adverse effect on our business and reputation.

Insufficient customer funding to complete a clinical trial. As noted above, clinical trials can cost hundreds of millions of dollars. There is a risk that we may initiate a clinical trial for a customer, and then the customer becomes unwilling or unable to fund the completion of the trial. In such a situation, notwithstanding the customer's ability or willingness to pay for or otherwise facilitate the completion of the trial, we may be ethically bound to complete or wind down the trial at our own expense.

In addition to the above U.S. laws and regulations, we must comply with the laws of all countries where we do business, including laws governing clinical trials in the jurisdiction where the trials are performed. Failure to comply with applicable requirements could subject us to regulatory risk, liability and potential costs associated with redoing the trials, which could damage our reputation and adversely affect our operating results.

Any future litigation against us could be costly and time-consuming to defend.

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. While we do not believe that the resolution of any currently pending lawsuits against us will, individually or in the aggregate, have a material adverse effect on our business, financial condition, results of operations or cash flows, litigation to which we subsequently become a party might result in substantial costs and divert management's attention and resources, which might seriously harm our business, financial condition, results of operations and cash flows. Insurance might not cover such claims, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in potential liability for us if the claim is outside the scope of the indemnification agreement we have with our customers, our customers do not abide by the indemnification agreement as required or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations, cash flows or reputation.

Our business exposes us to potential liability for personal injury or claims that could materially adversely affect our business, financial condition, results of operations, cash flows or reputation.

Our business involves clinical trial management, which is one of our clinical development service offerings and includes the testing of new drugs on human volunteers. This business exposes us to the risk of liability for personal injury or death to patients resulting from, among other things, possible unforeseen adverse side effects or improper administration of a drug or device. Many of these volunteers and patients are already seriously ill and are at risk of further illness or death. Although we attempt to negotiate indemnification arrangements with our customers or vendors, we might not be able to collect under these arrangements and

our exposure could exceed any contractual limits on indemnification. Any claim or liability could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation.

If our insurance does not cover all of our indemnification obligations and other liabilities associated with our operations, our business, financial condition, results of operations or cash flows may be materially adversely affected. We maintain insurance designed to provide coverage for ordinary risks associated with our operations and our ordinary indemnification obligations which we believe to be customary for our industry. The coverage provided by such insurance might not be adequate for all claims we may make or may be contested by our insurance carriers. If our insurance is not adequate or available to pay all claims or exposures associated with our operations, or if we are unable to purchase adequate insurance at reasonable rates in the future, our business, financial condition, results of operations or cash flows may be materially adversely affected.

If we are unable to attract suitable principal investigators and recruit and enroll patients for clinical trials, our clinical development business might suffer.

The recruitment of principal investigators and patients for clinical trials is essential to our business. Principal investigators are typically located at hospitals, clinics or other sites and supervise the administration of the investigational drug to patients during the course of a clinical trial. Patients generally include people from the communities in which the clinical trials are conducted. Our clinical development business could be adversely affected if we are unable to attract suitable and willing principal investigators or recruit and enroll patients for clinical trials on a consistent basis. The expanding global nature of clinical trials increases the risk associated with attracting suitable principal investigators and patients, especially if these trials are conducted in regions where our resources or experience may be more limited. For example, if we are unable to engage principal investigators to conduct clinical trials as planned or enroll sufficient patients in clinical trials, we might need to expend additional funds to obtain access to more principal investigators and patients than planned or else be compelled to delay or modify the clinical trial plans, which may result in additional costs to us or cancellation of the trial by our customer. If realized, these risks may also inhibit our ability to attract new business, particularly in certain regions.

Many of the costs for our Phase I Services segment are fixed in nature, which could adversely affect our business, financial condition, results of operations and cash flows.

Since a large amount of the operating costs for our Phase I Services segment are relatively fixed while revenue is subject to fluctuation, moderate variations in the commencement, progress or completion of the Phase I studies in our Phase I Services segment may cause variations in our financial condition, results of operations and cash flows. Expenses must be recognized when incurred and the delay of a contract could adversely affect our service revenues and profitability. Net service revenue from our Phase I Services segment for the year ended December 31, 2015 represented less than 2% of our total net service revenue for that period.

If we lose the services of key personnel or are unable to recruit experienced personnel, our business, financial condition, results of operations, cash flows or reputation could be materially adversely affected.

Our success substantially depends on the collective performance, contributions and expertise of our senior management team and other key personnel including qualified management, professional, scientific and technical operating staff and business development personnel. There is significant competition for qualified personnel, particularly those with higher educational degrees, in the biopharmaceutical and related services industries. In addition, the close proximity of some of our facilities to offices of our major competitors could adversely impact our ability to successfully recruit and retain key personnel. The departure of any key executive, or our inability to continue to identify, attract and retain qualified personnel or replace any departed personnel in a timely fashion, might impact our ability to grow our business and compete effectively in our industry and might negatively affect our business, financial condition, results of operations, cash flows or reputation.

Exchange rate fluctuations may have a material adverse effect on our business, financial condition, results of operations or cash flows.

Approximately 25% of our fiscal year 2015 net service revenues were contracted in currencies other than U.S. dollars and 40% of our direct and operating costs are incurred in countries with functional currencies other than U.S. dollars. Our financial statements are reported in U.S. dollars and changes in foreign currency exchange rates could significantly affect our financial condition, results of operations and cash flows. Exchange rate fluctuations between local currencies and the U.S. dollar create risk in several ways, including:

Foreign Currency Risk from Differences in Customer Contract Currency and Operating Costs Currency. The majority of our global contracts are denominated in U.S. dollars or Euros while the currency used to fund our operating costs in foreign countries is denominated in various different currencies. Fluctuations in the exchange rates of the currencies we use to contract with our customers and the currencies in which we incur cost to complete those contracts can have a significant impact on our results of operations.

Foreign Currency Translation Risk. The revenue and expenses of our international operations are generally denominated in local currencies and translated into U.S. dollars for financial reporting purposes. Accordingly, exchange rate fluctuations will affect the translation of international results into U.S. dollars for purposes of reporting our consolidated results.

Foreign Currency Transaction Risk. We are subject to foreign currency transaction risk for fluctuations in exchange rates during the period of time between the consummation and cash settlement of a transaction. We earn revenue from our service contracts denominated in currencies other than U.S. dollars over a period of several months and, in many cases, over several years. Accordingly, exchange rate fluctuations during this period may affect our profitability with respect to such contracts.

We may limit these risks through exchange rate fluctuation provisions stated in our service contracts, or we may hedge our transaction risk with foreign currency exchange contracts or options. We have not, however, mitigated all of our foreign currency transaction risk, and we may experience fluctuations in financial results from our operations outside the United States and foreign currency transaction risk associated with our service contracts.

Unfavorable economic conditions could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Unfavorable economic conditions, including disruptions in the credit and capital markets, could have a negative effect on our business, financial condition, results of operations or cash flows. For example, our customers might not be able to raise money to conduct existing clinical trials, or to fund new drug development and related future clinical trials. In addition, economic or market disruptions could negatively impact our vendors, contractors, or principal investigators which might have a negative effect on our business.

Our effective income tax rate may fluctuate, which may adversely affect our results of operations.

Our effective income tax rate is influenced by our projected profitability in the various taxing jurisdictions in which we operate. Changes in the distribution of profits and losses among taxing jurisdictions may have a significant impact on our effective income tax rate, which in turn could have an adverse effect on our results of operations. Factors that may affect our effective income tax rate include, but are not limited to:

• the requirement to exclude from our quarterly worldwide effective income tax calculations the benefit for losses in jurisdictions where no income tax benefit can be recognized;

• actual and projected full year pre-tax income;

• the repatriation of foreign earnings to the United States;

• uncertain tax positions;

• changes in tax laws in various taxing jurisdictions;

• audits by taxing authorities;

the establishment of valuation allowances against deferred income tax assets if we determine that it is more likely than not that future income tax benefits will not be realized;

the release of a previously established valuation allowances against deferred income tax assets if we determine that it is more likely than not that future income tax benefits will be realized; and

changes in the relative mix and size of clinical studies in various tax jurisdictions.

These changes may cause fluctuations in our effective income tax rate that could adversely affect our results of operations and cause fluctuations in our earnings and earnings per share.

We may be limited in our ability to utilize, or may not be able to utilize, net operating loss ("NOL") carryforwards to reduce our future tax liability.

As of December 31, 2015, we had U.S. federal NOL carryforwards of approximately \$39.0 million and state NOL carryforwards of \$121.9 million, which are limited annually due to certain change in ownership provisions of Section 382 of the Internal Revenue Code of 1986, as amended ("IRC"). Based on our estimates, approximately \$5.1 million of our federal NOL carryforwards are subject to limitation under Section 382 of the Code and will expire unused. Our federal NOL carryforwards will begin to expire in 2018 and will completely expire in 2033. Our state NOL carryforwards may be used over various periods ranging from one to 20 years. See "Note 9 - Income Taxes" to our consolidated financial statements included in Part II, Item 8, in this Annual Report on Form 10-K for a further discussion of our tax loss carryovers and current limitations on our ability to utilize NOLs.

Future ownership changes within the meaning of IRC Section 382(g) may subject our tax loss carryforwards to annual limitations which would restrict our ability to use them to offset our taxable income in periods following the ownership changes. In general, the annual use limitation equals the aggregate value of our equity at the time of the ownership change multiplied by a specified tax-exempt interest rate.

We have only a limited ability to protect our intellectual property rights, and these rights are important to our success. We develop, use and protect our proprietary methodologies, analytics, systems, technologies and other intellectual property. Existing laws of the various countries in which we provide services or solutions offer only limited protection of our intellectual property rights, and the protection in some countries may be very limited. We rely upon a combination of trade secrets, confidentiality policies, nondisclosure agreements, and other contractual arrangements, and copyright and trademark laws, to protect our intellectual property rights. These laws are subject to change at any time and certain agreements might not be fully enforceable, which could further restrict our ability to protect our innovations. Our intellectual property rights might not prevent competitors from independently developing services similar to or duplicative of ours or alleging infringement by us of their intellectual property rights in certain jurisdictions. The steps we take in this regard might not be adequate to prevent or deter infringement or misappropriation of our intellectual property or claims against us for alleged infringement or misappropriation by competitors, former employees or other third parties. Furthermore, we might not be able to detect unauthorized use of, or take appropriate and timely steps to enforce, our intellectual property rights. Enforcing our rights might also require considerable time, money and oversight, and we might not be successful in enforcing our rights.

If we are unable to successfully integrate potential future acquisitions, our business, financial condition, results of operations and cash flows could be materially adversely affected.

We have completed a number of acquisitions in the past and anticipate that a portion of our future growth may come from strategic tuck-in acquisitions. The success of any acquisition will depend upon, among other things, our ability to effectively integrate acquired personnel, operations, products and technologies into our business and to retain the key personnel and customers of our acquired businesses. In addition, we may be unable to identify suitable acquisition opportunities or obtain any necessary financing on commercially acceptable terms. We may also spend time and money investigating and negotiating with potential acquisition targets but not complete the transaction. Any acquisition could involve other risks, including, among others, the assumption of additional liabilities and expenses, difficulties and expenses in connection with integrating the acquired companies and achieving the expected benefits, issuances of potentially dilutive securities or interest-bearing debt, loss of key employees of the acquired companies, transaction expenses, diversion of

management's attention from other business concerns and, with respect to the acquisition of international companies, the inability to overcome differences in international business practices, language and customs. Our failure to successfully integrate potential future acquisitions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Potential future investments in our customers' businesses or drugs could have a negative impact on our financial results.

Although we historically have not engaged in business transactions with our customers other than to provide our services, we may in the future enter into arrangements with our customers or other drug companies in which we take on some of the risk of the potential success or failure of their businesses or drugs, including making strategic investments in our customers or other drug companies, providing financing to customers or other drug companies or acquiring an interest in the revenues from customers' drugs or in entities developing a limited number of drugs. Our financial results would be adversely affected if any such investments or the underlying drugs result in losses or do not achieve the level of success that we anticipate and/or our return or payment from any such drug investment or financing is less than our direct and indirect costs with respect to these arrangements.

Our relationships with existing or potential customers who are in competition with each other may adversely impact the degree to which other customers or potential customers use our services, which may adversely affect our business, financial condition, results of operations or cash flows.

The biopharmaceutical industry is highly competitive, with biopharmaceutical companies each seeking to persuade payers, providers and patients that their drug therapies are better and more cost-effective than competing therapies marketed or being developed by competing firms. In addition to the adverse competitive interests that biopharmaceutical companies have with each other, biopharmaceutical companies also have adverse interests with respect to drug selection and reimbursement with other participants in the healthcare industry, including payers and providers. Biopharmaceutical companies also compete to be first to market with new drug therapies. We regularly provide services to biopharmaceutical companies who compete with each other, and we sometimes provide services to such customers regarding competing drugs in development. Our existing or future relationships, particularly broader strategic provider relationships, with our biopharmaceutical customers may therefore deter other biopharmaceutical customers from using our services or may result in our customers seeking to place limits on our ability to serve other biopharmaceutical industry participants. In addition, our further expansion into the broader healthcare market may adversely impact our relationships with biopharmaceutical customers, and such customers may elect not to use our services, reduce the scope of services that we provide to them or seek to place restrictions on our ability to serve customers in the broader healthcare market with interests that are adverse to theirs. Any loss of customers or reductions in the level of revenues from a customer could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Our results of operations may be adversely affected if we fail to realize the full value of our goodwill and intangible assets.

As of December 31, 2015, we had goodwill and net intangible assets of \$705.3 million, which constituted approximately 58% of our total assets. We periodically (at least annually unless triggering events occur that cause an interim evaluation) evaluate goodwill and other acquired intangible assets for impairment. Any future determination requiring the write off of a portion of our goodwill or other acquired intangible assets could adversely affect our business, financial condition, and results of operations. If we are not able to realize the value of goodwill and indefinite-lived intangible assets, we may be required to incur material charges relating to the impairment of those assets. During the year ended December 31, 2014, we recorded an impairment of intangible assets of \$8.0 million and goodwill of \$9.2 million associated with our Global Consulting, a component of the Clinical Development segment, and Phase I Services reporting units. During the first quarter of 2015, we continued to observe deteriorating performance in our Phase I Services reporting unit, resulting in a triggering event requiring the evaluation of both long-lived assets and goodwill for potential impairment. As a result of this evaluation, for the year ended December 31, 2015, we recorded a total asset impairment charge of \$3.9 million, consisting of a long-lived assets impairment charge of \$1.0 million and a goodwill impairment charge of \$2.9 million. As of December 31, 2015, there were no

intangible assets associated with Phase I Services. Similar impairment charges in the future could materially and adversely affect our business, financial condition, results of operations and cash flows.

30

We face risks arising from the restructuring of our operations which could adversely affect our business, financial condition, results of operations, cash flows or reputation.

From time to time, we have adopted cost savings initiatives to improve our operating efficiency through various means such as reduction of overcapacity, primarily in our costs of services (billable) function, or other realignment of resources. For example, during 2015, we initiated restructuring activities to better align our resources worldwide, resulting in the reduction in workforce by approximately 70 employees, primarily in the United States and certain countries in Europe primarily within clinical operations, principally within the Clinical Development Services operations group and several corporate administrative functions. We completed these restructuring activities by the end of 2015. In the second quarter of 2014, we initiated restructuring activities related to the closure of our Glasgow facility and partial closure of our Cincinnati facility. The plan was substantially completed by December 31, 2014. Similarly, in March 2013, we adopted a plan to better align headcount and costs with current geographic sources and mix of revenue. The plan was completed by December 31, 2013 and involved the elimination of approximately 325 employee and contract positions. As a result of these restructuring activities, we incurred significant one-time costs, which consist primarily of severance, retention bonuses, professional fees, IT costs, facility closure costs, legal expenses and various other costs. During the years ended December 31, 2015, 2014 and 2013 we incurred total pre-tax charges of \$1.8 million, \$6.2 million and \$11.8 million, respectively, associated with our restructuring initiatives. Restructuring presents significant potential risks of events occurring that could adversely affect us, including a decrease in employee morale, a greater number of employment claims, the failure to achieve targeted cost savings and the failure to meet operational targets and customer requirements due to the loss of employees and any work stoppages that might occur, which, individually or in aggregate, could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation.

We operate in many different jurisdictions and we could be adversely affected by violations of the FCPA, UK Bribery Act of 2010 and/or similar worldwide anti-corruption laws.

The FCPA, UK Bribery Act of 2010 and similar worldwide anti-corruption laws prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. Our internal policies mandate compliance with these anti-corruption laws. We operate in many parts of the world that have experienced corruption to some degree and, in certain circumstances, anti-corruption laws have appeared to conflict with local customs and practices. Despite our training and compliance programs, we cannot assure that our internal control policies and procedures will protect us from acts in violation of anti-corruption laws committed by persons associated with us, and our continued expansion outside the United States, including in developing countries, could increase such risk in the future. Violations of the FCPA or other non-U.S. anti-corruption laws, or even allegations of such violations, could disrupt our business and result in a material adverse effect on our financial condition, results of operations, cash flows and reputation. For example, violations of anti-corruption laws can result in restatements of, or irregularities in, our financial statements as well as severe criminal or civil sanctions. In some cases, companies that violate the FCPA might be debarred by the U.S. government and/or lose their U.S. export privileges. In addition, U.S. or other governments might seek to hold us liable for successor liability FCPA violations or violations of other anti-corruption laws committed by companies that we acquire or in which we invest. Changes in anti-corruption laws or enforcement priorities could also result in increased compliance requirements and related costs which could adversely affect our business, financial condition, results of operations and cash flows.

The failure of third parties to provide us critical support services could adversely affect our business, financial condition, results of operations, cash flows or reputation.

We depend on third parties for support services vital to our business. Such support services include, but are not limited to, laboratory services, third-party transportation and travel providers, freight forwarders and customs brokers, drug depots and distribution centers, suppliers or contract manufacturers of drugs for patients participating in clinical trials, and providers of licensing agreements, maintenance contracts or other services. In addition, we also rely on third-party CROs and other contract clinical personnel for clinical services either in regions where we have limited resources, or in cases where demand cannot be met by our internal staff. The failure of any of these third parties to adequately provide us critical support services could have a material adverse effect on our business, financial condition, results of

operations, cash flows or reputation.

31

The operation of our Phase I clinical facility and the services we provide there including direct interaction with clinical trial patients or volunteers could create potential liability that may adversely affect our business, financial condition, results of operations, cash flows and reputation.

We operate one facility where Phase I clinical trials are conducted. Phase I clinical trials ordinarily involve testing an investigational drug on a limited number of healthy individuals, typically 20 to 120 persons, to evaluate its safety, determine a safe dosage range and identify side effects. Some of these trials involve the administration of investigational drugs to known substance abusers. Failure to operate such a facility in accordance with applicable regulations could result in that facility being shut down, which could disrupt our operations and adversely affect our business, financial condition, results of operations, cash flows and reputation. Additionally, we face risks resulting from the administration of drugs to volunteers, including adverse events, and the professional malpractice of medical care providers. We also directly employ nurses and other trained employees who assist in implementing the testing involved in our clinical trials, such as drawing blood from healthy volunteers. Any professional malpractice or negligence by such principal investigators, nurses or other employees could potentially result in liability to us in the event of personal injury to or death of a volunteer in clinical trials. This liability, particularly if it were to exceed the limits of any indemnification agreements and insurance coverage we may have, may adversely affect our business and financial condition, results of operations, cash flows and reputation.

Risks Related to Our Industry

We face intense competition in many areas of our business and, if we do not compete effectively, our business may be harmed.

The CRO industry is highly competitive. We often compete for business with other CROs and internal development departments, some of which could be considered large CROs in their own right. We also compete with universities and teaching hospitals. Some of these competitors have greater financial resources and a wider range of service offerings over a greater geographic area than we do. If we do not compete successfully, our business will suffer. The industry is highly fragmented, with numerous smaller specialized companies and a handful of full-service companies with global capabilities similar to ours. Increased competition has led to price and other forms of competition, such as acceptance of less favorable contract terms, which could adversely affect our operating results. In recent years our industry has experienced consolidation. This trend is likely to produce more competition from the resulting larger companies, and ones without the cost pressures of being public, for both customers and acquisition candidates. In addition, there are few barriers to entry for smaller specialized companies considering entering the industry. Because of their size and focus, small CROs might compete effectively against larger companies such as us, especially in lower cost geographic areas, which could have a material adverse effect on our business.

Outsourcing trends in the biopharmaceutical industry and changes in aggregate spending and research and development budgets could adversely affect our operating results and growth rate.

Our revenues depend on the level of R&D expenditures, size of the drug-development pipelines and outsourcing trends of the biopharmaceutical industry, including the amount of such R&D spend that is outsourced and subject to competitive bidding among CROs. Accordingly, economic factors and industry trends that affect biopharmaceutical companies affect our business. Biopharmaceutical companies continue to seek long-term strategic collaborations with global CROs with favorable pricing terms. Competition for these collaborations is intense and we might not be selected, in which case a competitor may enter into the collaboration and our business with the customer, if any, may be limited. Our success depends in part on our ability to establish and maintain preferred provider relationships with large biopharmaceutical companies. Our failure to develop or maintain these preferred provider relationships could have a material adverse effect on our business and results of operations. Furthermore, in order to obtain preferred provider relationships, we may have to reduce the prices for our services, which could negatively impact our gross margin for these services.

In addition, if the biopharmaceutical industry reduces its outsourcing of clinical trials or such outsourcing fails to grow at projected rates, our business, financial condition, results of operations and cash flows could be materially and adversely affected. We may also be negatively impacted by consolidation and other factors in the biopharmaceutical industry, which may slow decision making by our customers, result in the delay or

cancellation of existing projects, cause reductions in overall R&D expenditures, or lead to increased pricing pressures. Further, in the event that one of our customers combines with a company that is using the services of one of our competitors, the combined company could decide to use the services of that competitor or another provider. All of these events could adversely affect our business, financial condition, cash flows or results of operations.

If we fail to comply with federal, state, and foreign healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, financial condition, results of operations, cash flows and prospects could be adversely affected.

Even though we do not and will not order healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws of both the federal government and the states in which we conduct our business. Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, imprisonment, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results.

We may be affected by healthcare reform and potential additional reforms which may adversely impact the biopharmaceutical industry and reduce the need for our services or negatively impact our profitability.

Numerous government bodies are considering or have adopted healthcare reforms and may undertake, or are in the process of undertaking, efforts to control healthcare costs through legislation, regulation and agreements with healthcare providers and biopharmaceutical companies, including many of our customers. By way of example, in March 2010, the Affordable Care Act was signed into law. Among other things, this law imposes cost-containment measures intended to reduce or constrain the growth of healthcare spending, enhances remedies against healthcare fraud and abuse, adds new requirements for biopharmaceutical companies to disclose payments to physicians, including principal investigators, imposes new taxes and fees on biopharmaceutical manufacturers and imposes additional health policy reforms. We are uncertain as to the full effect of these reforms on our business at this time and are unable to predict what legislative proposals, if any, will be adopted in the future. If regulatory cost-containment efforts limit the profitability of new drugs by, for example, continuing to place downward pressure on pharmaceutical pricing and/or increasing regulatory burdens and operating costs of the biopharmaceutical industry, our customers may reduce their R&D spending, which could reduce the business they outsource to us. In addition, if regulatory requirements are relaxed or simplified drug approval procedures are adopted, the demand for our services could decrease.

Government bodies have adopted and may continue to adopt new healthcare legislation or regulations that are more burdensome than existing regulations. For example, product safety concerns and recommendations by the Drug Safety Oversight Board could change the regulatory environment for drug products, and new or heightened regulatory requirements may increase our expenses or limit our ability to offer some of our services. We might have to incur additional costs to comply with these or other new regulations, and failure to comply could harm our financial condition, results or operations, cash flows, and reputation. Additionally, new or heightened regulatory requirements may have a negative impact on the ability of our customers to conduct industry-sponsored clinical trials, which could reduce the need for our post-approval development services.

Current and proposed laws and regulations regarding the protection of personal data could result in increased risks of liability or increased cost to us or could limit our service offerings.

The confidentiality, collection, use and disclosure of personal data, including clinical trial patient-specific information, are subject to governmental regulation generally in the country in which the personal data was collected or used. For example, U.S. federal regulations under the Health Insurance Portability and Accountability Act of 1996, as amended, ("HIPAA") generally require individuals' written authorization, in addition to any required informed consent, before protected health information ("PHI") may be used for research and such regulations specify standards for de-identifications and for limited data sets. We may also be subject to applicable state privacy and security laws and

regulations in states in which we operate. We are

33

indirectly affected by the privacy provisions surrounding individual authorizations because many principal investigators with whom we are involved in clinical trials are directly subject to them as a HIPAA "covered entity." In addition, we obtain identifiable health information from third parties that are subject to such regulations. While we do not believe we are a "business associate" under HIPAA, regulatory agencies may disagree. Because of amendments to the HIPAA data security and privacy rules that were promulgated on January 25, 2013, some of which went into effect on March 26, 2013, there are some instances where HIPAA "business associates" of a "covered entity" may be directly liable for breaches of PHI and other HIPAA violations. These amendments may subject "business associates" to HIPAA's enforcement scheme, which, as amended, can yield up to \$1.5 million in annual civil penalties for each HIPAA violation.

In the EU personal data includes any information that relates to an identified or identifiable natural person with health information carrying additional obligations, including obtaining the explicit consent from the individual for collection, use or disclosure of the information. In addition, we are subject to EU rules with respect to cross-border transfers of such data out of the EU. The United States, the EU and its member states, and other countries where we have operations, such as Japan, South Korea, Malaysia, the Philippines, Russia and Singapore, continue to issue new privacy and data protection rules and regulations that relate to personal data and health information. Failure to comply with certain certification/registration and annual re-certification/registration provisions associated with these data protection and privacy regulations and rules in various jurisdictions, or to resolve any serious privacy or security complaints, could subject us to regulatory sanctions, delays in clinical trials, criminal prosecution or civil liability. Federal, state and foreign governments may propose or have adopted additional legislation governing the collection, possession, use or dissemination of personal data, such as personal health information, and personal financial data as well as security breach notification rules for loss or theft of such data. Additional legislation or regulation of this type might, among other things, require us to implement new security measures and processes or bring within the legislation or regulation de-identified health or other personal data, each of which may require substantial expenditures or limit our ability to offer some of our services. Additionally, if we violate applicable laws, regulations or duties relating to the use, privacy or security of personal data, we could be subject to civil liability or criminal prosecution, be forced to alter our business practices and suffer reputational harm. In the next few years, the European data protection framework may be revised as a generally applicable data regulation. The text has not yet been finalized, but it contains new provisions specifically directed at the processing of health information, sanctions of up to 2% of worldwide gross revenue and extra-territoriality measures intended to bring non-EU companies under the proposed regulation.

Actions by regulatory authorities or customers to limit the scope of or withdraw an approved drug from the market could result in a loss of revenue.

Government regulators have the authority, after approving a drug or device, to limit its indication for use by requiring additional labeled warnings or to withdraw the drug or device's approval for its approved indication based on safety concerns. Similarly, customers may act to voluntarily limit the availability of approved drugs or devices or withdraw them from the market after we begin our work. If we are providing services to customers for drugs or devices that are limited or withdrawn, we may be required to narrow the scope of or terminate our services with respect to such drugs or devices, which would prevent us from earning the full amount of service revenue anticipated under the related service contracts.

If we do not keep pace with rapid technological change, our services may become less competitive or obsolete. The biopharmaceutical industry generally, and drug development and clinical research more specifically, are subject to rapid technological change. Our current competitors or other businesses might develop technologies or services that are more effective or commercially attractive than, or render obsolete, our current or future technologies and services. If our competitors introduce superior technologies or services and if we cannot make enhancements to remain competitive, our competitive position would be harmed. If we are unable to compete successfully, we may lose customers or be unable to attract new customers, which could lead to a decrease in our revenue and have an adverse impact on our financial condition.

In addition, the operation of our business relies on IT infrastructure and systems delivered across multiple platforms. The failure of our systems to perform could severely disrupt our business and adversely affect our results of operations. Our systems are also vulnerable to demise from natural or man-made disasters, terrorist

34

attacks, computer viruses or hackers, power loss or other technology system failures. These events could adversely affect our business or results of operations.

The biopharmaceutical industry has a history of patent and other intellectual property litigation and we might be involved in costly intellectual property lawsuits.

The biopharmaceutical industry has a history of intellectual property litigation and these lawsuits will likely continue in the future. Accordingly, we may face patent infringement suits by companies that have patents for similar business processes 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, regardless of the outcome of the litigation. In the event an infringement lawsuit was brought against us and we did not prevail, we might have to pay substantial damages and we could be required to stop infringing activity or obtain a license to use technology on unfavorable terms.

Risks Related to Our Indebtedness

Our substantial debt could adversely affect our financial condition.

As of December 31, 2015, our total principal amount of indebtedness was \$505.0 million and we had up to \$119.2 million of additional borrowing capacity available under our revolving credit facility. Our substantial indebtedness could adversely affect our financial condition and thus make it more difficult for us to satisfy our obligations with respect to our senior secured facilities. If our cash flow is not sufficient to service our debt and adequately fund our business, we may be required to seek further additional financing or refinancing or dispose of assets. We might not be able to influence any of these alternatives on satisfactory terms or at all. Our substantial indebtedness could also:

- increase our vulnerability to adverse general economic, industry or competitive developments;
 - require us to dedicate a more substantial portion of our cash flows from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, investments, acquisitions, capital expenditures, and other general corporate purposes;
- limit our ability to make required payments under our existing contractual commitments, including our existing long-term indebtedness;
- limit our ability to fund a change of control offer;
- require us to sell certain assets;
- restricting us from making strategic investments, including acquisitions or causing us to make non-strategic divestitures;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a competitive disadvantage compared to our competitors that have less debt;
- cause us to incur substantial fees from time to time in connection with debt amendments or refinancings;
- increase our exposure to rising interest rates because a substantial portion of our borrowings is at variable interest rates; and
- limit our ability to borrow additional funds or to borrow on terms that are satisfactory to us.

Despite our level of indebtedness, we are able to incur more debt and undertake additional obligations. Incurring such debt or undertaking such additional obligations could further exacerbate the risks to our financial condition.

We may be able to incur substantial additional indebtedness in the future. Although covenants under our five-year \$675.0 million credit agreement ("2015 Credit Agreement") entered into on May 14, 2015, which is comprised of a \$525.0 million term loan A and a \$150.0 million revolving line of credit, limit our ability to incur certain additional indebtedness, these restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. To the extent we incur additional indebtedness, the risks associated with our leverage described above, including our possible inability to service our debt obligations, would increase.

Servicing our debt will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control.

Our ability to make payments on and refinance our debt, make strategic acquisitions and to fund capital expenditures depends on our ability to generate cash flow in the future. To some extent, our ability to generate future cash flow is subject to general economic, financial, competitive and other factors that are beyond our control. We cannot assure you that:

- our business will generate sufficient cash flow from operations;
- we will continue to realize the cost savings, revenue growth and operating improvements that resulted from the execution of our long-term strategic plan; or
- future sources of funding will be available to us in amounts sufficient to enable us to fund our liquidity needs.

We also may experience difficulties repatriating cash from foreign subsidiaries and accounts due to law, regulation or contracts which could further constrain our liquidity. If we cannot fund our liquidity needs, we will have to take actions such as reducing or delaying capital expenditures, marketing efforts, strategic acquisitions, investments and alliances, selling assets, restructuring or refinancing our debt or seeking additional equity capital. We cannot assure you that any of these remedies could, if necessary, be effected on commercially reasonable or favorable terms, or at all, or that they would permit us to meet our scheduled debt service obligations. Any inability to generate sufficient cash flow or refinance our debt on favorable terms could have a material adverse effect on our financial condition. In addition, if we incur additional debt, the risks associated with our substantial leverage, including the risk that we will be unable to service our debt or generate enough cash flow to fund our liquidity needs, could intensify.

Covenant restrictions under our 2015 Credit Agreement may limit our ability to operate our business.

Our 2015 Credit Agreement contains covenants that may restrict our ability to, among other things, borrow money, pay dividends, make capital expenditures, make strategic acquisitions and effect a consolidation, merger or disposal of all or substantially all of our assets. Although the covenants in our Credit Agreement are subject to various exceptions, we cannot assure you that these covenants will not adversely affect our ability to finance future operations or capital needs or to engage in other activities that may be in our best interest. In addition, in certain circumstances, our long-term debt requires us to maintain a specified financial ratio and satisfy certain financial condition tests, which may require that we take action to reduce our debt or to act in a manner contrary to our business objectives. A breach of any of these covenants could result in a default under our senior secured facilities. If an event of default under our 2015 Credit Agreement occurs, the lenders thereunder could elect to declare all amounts outstanding, together with accrued interest, to be immediately due and payable. In such case, we might not have sufficient funds to repay all the outstanding amounts. In addition, our 2015 Credit Agreement is secured by first priority security interests on substantially all of our real and personal property, including the capital stock of certain of our subsidiaries. If an event of default under our 2015 Credit Agreement occurs, the lenders thereunder could exercise their rights under the related security documents. Any acceleration of amounts due under our 2015 Credit Agreement or the substantial exercise by the lenders of their rights under the security documents would likely have a material adverse effect on us.

Interest rate fluctuations may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Because we have substantial variable rate debt, fluctuations in interest rates may affect our business, financial condition, results of operations and cash flows. We may attempt to minimize interest rate risk and lower our overall borrowing costs through the utilization of derivative financial instruments, primarily interest rate swaps. As of December 31, 2015 we had approximately \$505.0 million of total indebtedness with variable interest rates.

Risks Related to Ownership of Our Common Stock

Our stock price might fluctuate significantly, which could cause the value of your investment in our common stock to decline.

Since our initial public offering in November 2014 (the "IPO"), the price of our common stock, as reported by NASDAQ, has ranged from a low of \$19.61 on November 7, 2014 to a high of \$51.69 on August 3, 2015. In addition, securities markets worldwide have experienced, and are likely to continue to experience, significant price and volume fluctuations. This market volatility, as well as general economic, market or political conditions, could reduce the market price of our common stock regardless of our results of operations. The public market for our common stock continues to be relatively new, and its trading price is likely to be volatile and subject to significant price fluctuations in response to many factors, including:

- market conditions or trends in our industry, including with respect to the regulatory environment, or the economy as a whole;
- fluctuations in quarterly operating results, as well as differences between our actual financial and operating results and those expected by investors;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet those estimates or the failure of those analysts to initiate or maintain coverage of our common stock;
- changes in key personnel;
- entry into new markets;
- announcements by us or our competitors of new service offerings or significant acquisitions, divestitures, strategic partnerships, joint ventures or capital commitments;
- actions by competitors;
- changes in operating performance and stock market valuations of other companies;
- investors' perceptions of our prospects and the prospects of the industry;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC;
- announcements related to litigation;
- changes in the credit ratings of our debt;
- the development and sustainability of an active trading market for our common stock;
- investor perceptions of the investment opportunity associated with our common stock relative to other investment alternatives;
- future sales of our common stock by our officers, directors and significant shareholders;
- other events or factors, including those resulting from system failures and disruptions, cyber-attacks,

earthquakes, hurricanes, war, acts of terrorism, other natural disasters or responses to these events; and changes in accounting principles.

These and other factors may cause the market price and demand for shares of our common stock to fluctuate substantially, which may otherwise negatively affect the liquidity of our common stock. In that event, the price of our common stock would likely decrease. In the past, when the market price of a stock has been volatile, security holders have often instituted class action litigation against the company that issued the stock. If we become involved in this type of litigation, regardless of the outcome, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We do not expect to pay any cash dividends for the foreseeable future.

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. Our ability to pay dividends is restricted by the terms of our 2015 Credit Agreement and might be restricted by the terms of any indebtedness that we incur in the future. Consequently, you should not rely on dividends in order to receive a return on your investment. For additional information on our dividend policy, see Part II, Item 5 "Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities" in this Annual Report on Form 10-K. Future sales of our common stock in the public market could cause the market price of our common stock to decrease significantly.

Sales of substantial amounts of our common stock in the public market by our shareholders may cause the market price of our common stock to decrease significantly. The perception that such sales could occur could also depress the market price of our common stock. Any such sales could also create public perception of difficulties or problems with our business and might also make it more difficult for us to raise capital through the sale of equity securities in the future at a time and price that we deem appropriate.

As of December 31, 2015, we had 53,871,484 outstanding shares of Class A common stock, of which: 21,550,250 shares are "restricted securities," as defined under Rule 144 under the Securities Act, and are eligible for sale in the public market subject to the requirements of Rule 144; and 3,646,535 shares are shares of outstanding options and restricted stock units that, if exercised, will result in these additional shares becoming available for sale subject in some cases to Rule 144 and Rule 701 under the Securities Act.

Our Sponsors have significant influence over our company, and their interests may be different from or conflict with those of our other shareholders.

The Sponsors collectively beneficially own approximately 38% of our outstanding common stock. As a consequence, the Sponsors continue to be able to exert a significant degree of influence over our management and affairs and matters requiring shareholder approval, including the election of directors, a merger, consolidation or sale of all or substantially all of our assets, and any other significant transaction. Additionally, the Sponsors are parties to a stockholders agreement (the "Stockholders Agreement"). This Stockholders Agreement, among other things, requires such shareholders to vote in favor of certain nominees to our Board. The interests of the Sponsors might not always coincide with our interests or the interests of our other shareholders. For instance, this concentration of ownership and/or the restrictions imposed by the Stockholders Agreement may have the effect of delaying or preventing a change in control of us otherwise favored by our other shareholders and could depress our stock price.

The Sponsors each make investments in companies and may, from time to time, acquire and hold interests in businesses that compete directly or indirectly with us. Each of the Sponsors may also pursue, for its own account, acquisition opportunities that may be complementary to our business, and as a result, those acquisition opportunities might not be available to us. Our organizational documents contain provisions renouncing any interest or expectancy held by our directors affiliated with the Sponsors in certain corporate

opportunities. Accordingly, the interests of the Sponsors may supersede ours, causing the Sponsors or their affiliates to compete against us or to pursue opportunities instead of us, for which we have no recourse. Such actions on the part of the Sponsors and inaction on our part could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The Sponsors control four seats on our Board. Since the Sponsors could invest in entities that directly or indirectly compete with us, when conflicts arise between the interests of the Sponsors and the interests of our shareholders, these directors might not be disinterested.

Although we are no longer a "controlled company" within the meaning of the NASDAQ rules, we are relying on exemptions from certain corporate governance requirements during transition periods of up to one year.

We are no longer a "controlled company" within the meaning of the corporate governance standards contained in the NASDAQ listing standards. Consequently, as of December 7, 2015, the NASDAQ requires that we:

- appoint at least a majority of independent directors to our compensation and nominating and corporate governance committees within 90 days;

- appoint a majority of independent directors to our Board within one year; and

- appoint compensation and nominating and corporate governance committees composed entirely of independent directors within one year.

We intend to utilize the transition periods described above to achieve full compliance with these NASDAQ requirements. As a result, at this time we have a majority of independent directors, but our compensation and nominating and corporate governance committees do not consist entirely of independent directors. Accordingly, our shareholders do not, and during these transition periods will not, have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of the NASDAQ. In addition, if we are unable to comply with the heightened corporate governance requirements prior to the prescribed NASDAQ deadlines, we may incur penalties or our shares could be delisted.

Provisions of our corporate governance documents and Delaware law could make an acquisition of our company more difficult and may prevent attempts by our shareholders to replace or remove our current management, even if beneficial to our shareholders.

Provisions of our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that delay, defer or discourage transactions involving an actual or potential change in control of us or change in our management that shareholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace current members of our management team. Among others, these provisions include, (1) our ability to issue preferred stock without shareholder approval, (2) the requirement that our shareholders may not act without a meeting, (3) requirements for advance notification of shareholder nominations and proposals contained in our bylaws, (4) the absence of cumulative voting for our directors, (5) requirements for shareholder approval of certain business combinations and (6) the limitations on director nominations contained in our Stockholders Agreement.

Additionally, Section 203 of the Delaware General Corporation Law (the "DGCL") prohibits a publicly held Delaware corporation from engaging in a business combination with an interested shareholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested shareholder, unless the business combination is approved in a prescribed manner. The existence of the foregoing provision could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

If securities analysts or industry analysts downgrade our shares, publish negative research or reports, or do not publish reports about our business, our share price and trading volume could decline.

The trading market for our common stock is to some extent influenced by the research and reports that industry or securities analysts publish about us, our business and our industry. If one or more analysts adversely change their recommendation regarding our shares or our competitors' stock, our share price might decline. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we might lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

We are incurring increased costs and obligations as a result of being a public company.

As a relatively new public company, we are required to comply with certain additional corporate governance and financial reporting practices and policies required of a publicly traded company. As a result, we have and will continue to incur significant legal, accounting and other expenses that we were not required to incur as a privately held company, due to compliance requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley"), the Dodd-Frank Act, the listing requirements of the NASDAQ, and other applicable securities rules and regulations. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results with the SEC. We are also required to ensure that we have the ability to prepare financial statements that are fully compliant with all SEC reporting requirements on a timely basis. Compliance with these rules and regulations will increase our legal and financial compliance costs, and might make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. We might not be successful in complying with these obligations and the significant commitment of resources required for complying with them could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our internal control over financial reporting is required to meet all the standards of Section 404 of Sarbanes-Oxley, and failure to achieve and maintain effective internal control over financial reporting could have a material adverse effect on our stock price, reputation, business, financial condition, results of operations and cash flows.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of internal control over financial reporting, starting with this annual report. Management and our independent registered public accounting firm are required to attest to the effectiveness of our internal control over financial reporting on an annual basis beginning with this annual report. The rules governing the standards that must be met to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation of our existing controls and could result in incurring significant additional expenditures. We had to design, implement and test our internal control over financial reporting in order to comply with this obligation. The process necessary to meet these requirements was time consuming, costly, and complicated, and we will need to evaluate and refine the process on an ongoing basis. We might encounter problems or delays in completing the implementation of any required improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Further, material weaknesses or significant deficiencies in our internal control over financial reporting may exist or otherwise be discovered in the future. If we are not able to meet the compliance requirements of the applicable provisions of Section 404, we will be unable to issue securities in the public markets through the use of a shelf registration statement. In addition, failure to achieve and maintain an effective internal control environment could limit our ability to report our financial results accurately and timely, result in misstatements and restatements of our consolidated financial statements, cause investors to lose confidence and have a material adverse effect on our stock price, reputation, business, financial condition, results of operations and cash flows.

We are a holding company and rely on dividends and other payments, advances and transfers of funds from our subsidiaries to meet our obligations and pay any dividends.

We have no direct operations and no significant assets other than ownership of 100% of the capital stock of our subsidiaries. Because we conduct our operations through our subsidiaries, we depend on those entities for dividends and other payments to generate the funds necessary to meet our financial obligations, and to pay any dividends with respect to our common stock. Legal and contractual restrictions in our 2015 Credit Agreement and other agreements which may govern future indebtedness of our subsidiaries, as well as the financial condition and operating requirements of our subsidiaries, may limit our ability to obtain cash from our subsidiaries. The earnings from, or other available assets of, our subsidiaries might not be sufficient to pay dividends or make distributions or loans to enable us to pay any dividends on our common stock or other obligations. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and cash flows.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of December 31, 2015, we had 70 facilities located in 44 countries. During the year ended December 31, 2015, we utilized approximately 82% of our available facility space. Most of our facilities consist solely of office space. We lease all of our facilities, with the exception of office space owned in Madrid, Spain. Our headquarters and principal executive offices are located in Raleigh, North Carolina, where we lease space in two locations totaling approximately 187,700 square feet. The leases for both of our Raleigh locations expire in February 2019.

In addition, we lease substantial facilities in Austin, Texas; Beijing, China; Camberley, United Kingdom; Cincinnati, Ohio; Gurgaon, India; Mexico City, Mexico; Munich, Germany; Paris, France; Toronto, Canada and Wilmington, North Carolina, with leases expiring between 2016 and 2019. We also maintain offices in various other Asian-Pacific, European, Latin American and North American locations, including Australia, the Middle East and Africa. None of our leases is individually material to our business model and all either have options to renew or are located in major markets where we believe there are adequate opportunities to continue business operations at terms satisfactory to us.

Item 3. Legal Proceedings.

We are party to legal proceedings incidental to our business. While our management currently believes the ultimate outcome of these proceedings, individually and in the aggregate, will not have a material adverse effect on our consolidated financial statements, litigation is subject to inherent uncertainties. Were an unfavorable ruling to occur, there exists the possibility of a material adverse impact on our financial condition and results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

On November 7, 2014, our common stock began trading on the NASDAQ under the symbol "INCR". Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported by the NASDAQ for the period indicated.

| | High | Low |
|--|---------|---------|
| Fiscal Year 2015: | | |
| Fourth Quarter | \$50.40 | \$37.51 |
| Third Quarter | \$51.69 | \$37.53 |
| Second Quarter | \$42.45 | \$29.03 |
| First Quarter | \$34.54 | \$22.17 |
| | High | Low |
| Fiscal Year 2014: | | |
| Fourth Quarter (from November 7, 2014) | \$26.85 | \$19.61 |

Holders of Record

On February 18, 2016, there were approximately 34 shareholders of record of our common stock. This number does not include shareholders for whom shares are held in "nominee" or "street" name.

Dividend Policy

Since becoming a public company, we have not declared or paid cash dividends on our common stock, nor do we intend to pay cash dividends on our common stock in the foreseeable future. However, in the future, subject to the factors described below and our future liquidity and capitalization, we may change this policy and choose to pay dividends.

We are a holding company that does not conduct any business operations of our own. As a result, our ability to pay cash dividends on our common stock is dependent upon cash dividends and distributions and other transfers from our subsidiaries. The ability of our subsidiaries to pay dividends is currently restricted by the terms of our Credit Agreement, and may be further restricted by any future indebtedness we or they incur. In addition, under Delaware law, our Board of Directors may declare dividends only to the extent of our surplus (which is defined as total assets at fair market value minus total liabilities, minus statutory capital) or, if there is no surplus, out of our net profits for the then current and/or immediately preceding fiscal year.

Any future determination to pay dividends will be at the discretion of our Board of Directors and will take into account restrictions in our debt instruments, including our 2015 Credit Agreement, general economic business conditions, our financial condition, results of operations and cash flows, our capital requirements, our business prospects, the ability of our operating subsidiaries to pay dividends and make distributions to us, legal restrictions, and such other factors as our Board of Directors may deem relevant. For additional information on these restrictive covenants, see Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" and "Note 4 - Debt and Leases" to our audited consolidated financial statements included in Part II, Item 8, in this Annual Report on Form 10-K.

In the years ended December 31, 2014 and 2013, we paid special dividends of \$0.4 million and \$0.5 million, respectively, to holders of our former Class C common stock. The Company redeemed the outstanding share of Class C common stock and eliminated the Class C common stock from its authorized capital stock in connection with the IPO in November 2014. Additionally, we utilized proceeds from our IPO of \$3.4 million to terminate the advisory services agreement and \$3.4 million to redeem Class C common stock.

Recent Sales of Unregistered Securities

We did not have any sales of unregistered securities during 2015.

Purchases of Equity Securities by the Issuer

In May 2015, we repurchased 5,053,482 shares of our Class A common stock pursuant to an agreement with investment funds affiliated with our Sponsors, Avista Capital Partners, L.P. ("Avista") and Ontario Teachers' Pension Plan Board ("OTPP"), in a private transaction at a price of approximately \$29.68 per share, resulting in a total purchase price of approximately \$150.0 million. In conjunction with this transaction, our Sponsors and certain other shareholders sold in a registered secondary offering at the same price 8,050,000 shares of our common stock, including 1,050,000 shares that were offered and sold pursuant to the underwriters' exercise in full of its option to purchase additional shares.

In December 2015, we repurchased 3,000,000 shares of our Class A common stock pursuant to an agreement with investment funds affiliated with our Sponsors, Avista and OTPP, in a private transaction at a price of \$45.00 per share, resulting in a total purchase price of approximately \$135.0 million. In conjunction with this transaction, our Sponsors sold in a registered secondary offering at the same price 6,000,000 shares of our common stock.

Stock Performance Graph

The information included under the heading “Stock Performance Graph” is “furnished” and not “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed to be “soliciting material” subject to Regulation 14A or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended.

Our common stock is listed for trading on the NASDAQ under the symbol “INCR.” The Stock Price Performance Graph set forth below compares the cumulative total shareholder return on our common stock for the period from November 7, 2014 through December 31, 2015, with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Health Care Index over the same period. The comparison assumes \$100 was invested on November 7, 2014 in the common stock of INC Research Holdings, Inc., in the Nasdaq Composite Index, and in the Nasdaq Health Care Index and assumes reinvestment of dividends, if any.

The stock price performance shown on the graph above is not necessarily indicative of future price performance. Information used in the graph was obtained from the Nasdaq Stock Market, a source believed to be reliable, but we are not responsible for any errors or omissions in such information.

Equity Compensation Plans

The information required by Part II, Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to “Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.”

Item 6. Selected Financial Data.

The following tables set forth our selected consolidated financial data for the periods ending on and as of the dates indicated. We derived the consolidated statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015 and 2014 from our audited consolidated financial statements included in Part II, Item 8, in this Annual Report on Form 10-K. We derived the consolidated statements of operations data for the year ended December 31, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013, 2012 and 2011 from our audited consolidated financial statements not included in this Annual Report on Form 10-K. You should read the consolidated financial data set forth below together with our consolidated financial statements and the related notes thereto included in Part II, Item 8, and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of future results of operations.

| | Year Ended December 31, | | | | |
|---|--|------------|------------|------------|------------|
| | 2015 | 2014 | 2013 | 2012 | 2011(1) |
| | (in thousands, except per share amounts) | | | | |
| Statement of Operations Data: | | | | | |
| Net service revenue(2) | \$914,740 | \$809,728 | \$652,418 | \$579,145 | \$437,005 |
| Reimbursable out-of-pocket expenses | 484,499 | 369,071 | 342,672 | 289,455 | 218,981 |
| Total revenue | 1,399,239 | 1,178,799 | 995,090 | 868,600 | 655,986 |
| Costs and operating expenses: | | | | | |
| Direct costs | 542,404 | 515,059 | 432,261 | 389,056 | 279,840 |
| Reimbursable out-of-pocket expenses | 484,499 | 369,071 | 342,672 | 289,455 | 218,981 |
| Selling, general, and administrative | 156,609 | 145,143 | 117,890 | 109,428 | 95,063 |
| Restructuring and other costs (3) | 1,785 | 6,192 | 11,828 | 35,380 | 27,839 |
| Transaction expenses (4) | 1,637 | 7,902 | 508 | — | 10,322 |
| Asset impairment charges (5) | 3,931 | 17,245 | — | 4,000 | — |
| Depreciation | 18,140 | 21,619 | 19,175 | 19,915 | 15,700 |
| Amortization | 37,874 | 32,924 | 39,298 | 58,896 | 48,436 |
| Income (loss) from operations | 152,360 | 63,644 | 31,458 | (37,530) | (40,195) |
| Other income (expense), net: | | | | | |
| Interest expense, net | (15,448) | (52,787) | (60,489) | (62,007) | (65,482) |
| Loss on extinguishment of debt | (9,795) | (46,750) | — | — | — |
| Other income (expense), net | 3,857 | 7,689 | (1,649) | 4,679 | 11,519 |
| Income (loss) before provision for income taxes | 130,974 | (28,204) | (30,680) | (94,858) | (94,158) |
| Income tax (expense) benefit | (13,927) | 4,734 | (10,849) | 35,744 | 34,611 |
| Net income (loss) | 117,047 | (23,470) | (41,529) | (59,114) | (59,547) |
| Class C common stock dividends | — | (375) | (500) | (500) | (4,500) |
| Redemption of New Class C common stock | — | (3,375) | — | — | — |
| Net income (loss) attributable to common shareholders | \$117,047 | \$(27,220) | \$(42,029) | \$(59,614) | \$(64,047) |
| Earnings per share attributable to common shareholders: | | | | | |
| Basic | \$2.02 | \$(0.51) | \$(0.81) | \$(1.14) | \$(1.46) |
| Diluted | \$1.95 | \$(0.51) | \$(0.81) | \$(1.14) | \$(1.46) |
| Weighted average common shares outstanding: | | | | | |
| Basic | 57,888 | 53,301 | 52,009 | 52,203 | 43,875 |
| Diluted | 60,146 | 53,301 | 52,009 | 52,203 | 43,875 |

| | Year Ended December 31, | | | | |
|---|-------------------------|-------------|-------------|-------------|-------------|
| | 2015 | 2014 | 2013 | 2012 | 2011(1) |
| | (in thousands) | | | | |
| Statement of Cash Flow Data: | | | | | |
| Net cash provided by (used in): | | | | | |
| Operating activities | \$204,740 | \$131,447 | \$37,270 | \$42,999 | \$(18,533) |
| Investing activities | (21,111) | (27,853) | (17,714) | (12,974) | (369,670) |
| Financing activities | (211,399) | (67,698) | (6,841) | (18,932) | 422,053 |
| Other Financial Data: | | | | | |
| EBITDA(10) | \$202,436 | \$79,126 | \$88,282 | \$45,960 | \$35,460 |
| Adjusted EBITDA(10) | 221,360 | 145,276 | 105,521 | 84,366 | 65,450 |
| Adjusted Net Income (Loss)(10) | 120,174 | 44,647 | 16,290 | 1,539 | (9,950) |
| Adjusted Diluted Earnings per share(10) | \$2.00 | \$0.83 | \$0.31 | \$0.03 | \$(0.23) |
| Capital expenditures | (21,111) | (25,551) | (17,714) | (9,591) | (4,763) |
| Dividends paid | — | (375) | (500) | (500) | (4,500) |
| Redemption of New Class C common stock | — | (3,375) | — | — | — |
| Net new business awards(9) | 1,176,533 | 949,790 | 814,177 | 676,250 | 449,254 |
| | As of December 31, | | | | |
| | 2015 | 2014 | 2013 | 2012 | 2011(1) |
| | (in thousands) | | | | |
| Balance Sheet Data: | | | | | |
| Cash and cash equivalents | \$85,011 | \$126,453 | \$96,972 | \$81,363 | \$70,960 |
| Total assets(7) | 1,211,219 | 1,241,365 | 1,227,455 | 1,250,985 | 1,366,033 |
| Total debt and capital leases(7)(8) | 501,839 | 416,257 | 588,823 | 587,517 | 597,721 |
| Total shareholders' equity | 217,434 | 392,209 | 276,207 | 316,830 | 379,490 |
| Other Financial Data: | | | | | |
| Backlog(6) | \$1,813,178 | \$1,589,386 | \$1,490,787 | \$1,320,548 | \$1,221,641 |
| Net Book-to-Bill ratio(9) | 1.3x | 1.2x | 1.2x | 1.2x | 1.0x |

(1) We acquired Trident Clinical Research Pty Ltd., or Trident, on June 1, 2011 and Kendle on July 12, 2011. The financial results of these entities have been included as of and since the dates of these acquisitions.

(2) During the second and third quarters of 2014, we experienced higher-than-normal change order activity estimated to be between \$6 million and \$12 million. Net service revenue for 2014 after adjusting for the estimated impact of \$9.0 million in higher-than-normal change order activity was \$800.7 million.

(3) Restructuring and other costs consist of: (i) severance costs associated with the reduction of our workforce in line with our future business operations and duplicative staff; and (ii) lease obligation and termination costs in connection with the abandonment and closure of redundant facilities as a result of our restructuring initiatives.

Other costs consist primarily of information technology and other consulting and legal fees attributable to our integration of Kendle.

(4) Transaction expenses for the year ended December 31, 2015 were \$1.6 million and primarily consisted of fees associated with the Company's May, August, and December 2015 secondary common stock offerings, debt placement and refinancing and other corporate transactions. Transaction expenses for the year ended December 31, 2014 were \$7.9 million and primarily consisted of \$4.2 million in debt issuance costs and third party fees associated with the debt refinancing in February and November 2014, \$3.4 million of fees associated with the termination of the Avista Capital Partners, L.P. consulting agreement, and \$0.3 million of legal fees associated with the MEK Consulting acquisition. Transaction expenses of \$0.5 million for the year ended December 31, 2013 related to third-party fees associated with debt refinancing and the legal fees associated with our acquisition of

MEK Consulting which was completed in March 2014. Transaction expenses of \$10.3 million for the year ended December 31, 2011 related to legal fees, accounting fees and the noncapitalizable portion of bank fees related to our acquisitions of Kendle and Trident.

During the year ended December 31, 2015, we recorded a \$3.9 million impairment charge related to goodwill and long-lived assets associated with our Phase I Services reporting unit. During the year ended December 31, 2014, we recorded a \$17.2 million impairment charge related to intangible assets and goodwill associated with our (5) Global Consulting, a component of the Clinical Development segment, and Phase I Services reporting units. During the year ended December 31, 2012, we recorded a \$4.0 million impairment charge related to the goodwill associated with our Phase I Services reporting unit.

Backlog consists of anticipated future net service revenue from contract and pre-contract commitments that are supported by written communications. The dollar amount of our backlog consists of anticipated future net service revenue from business awards that either have not started but are anticipated to begin in the next 12 months, or are in process and have not been completed. The majority of our contracts can be terminated by our customers with 30 days' notice. Backlog has been adjusted to reflect any cancellations or adjustments to the related contracts and (6) changes in the foreign currency exchange rates of awards not denominated in U.S. dollars. Included within backlog at December 31, 2015 is approximately \$0.84 billion that we expect to generate revenue in 2016, with the remainder expected to translate into revenue beyond 2016. Backlog is not necessarily indicative of future financial performance because it will likely be impacted by a number of factors, including the size and duration of projects, which can be performed over several years, project change orders resulting in increases or decreases in project scope, and cancellations.

During 2015, we adopted ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the (7) Presentation of Debt Issuance Costs. As a result, total assets, total debt and capital leases have been reduced by \$3.2 million, \$3.7 million, \$5.7 million, \$6.7 million and \$7.9 million of debt issuance costs associated with the our Term Loans and 2015 Revolver as of December 31, 2015, 2014, 2013, 2012 and 2011, respectively.

(8) Total debt and capital leases includes \$5.5 million, \$4.6 million, \$6.7 million and \$8.0 million of unamortized discounts as of December 31, 2014, 2013, 2012 and 2011, respectively.

Net new business awards represent the value of future net service revenue awarded during the period supported by contracts or written pre-contract communications from our customers for projects that have received appropriate internal funding approval, are not contingent upon completion of another trial or event, and are expected to commence within the next 12 months, minus the value of cancellations in the same period. Net book-to-bill ratio represents "net new business awards" divided by net service revenue. We believe net book-to-bill ratio is (9) commonly used in our industry and represents a useful indicator of our potential future revenue growth rate in that it measures the rate at which we are generating net new business awards compared to our current revenues. Net book-to-bill is better viewed on a trailing twelve month basis due to the variability within any particular quarter that can be caused by a very large award or cancellation. However, we cannot assure you that the net book-to-bill rate is predictive of future financial performance because it will likely be impacted by a number of factors, including the size and duration of projects, which can be performed over several years, project change orders resulting in increases or decreases in project scope, and cancellations.

We report our financial results in accordance with GAAP. To supplement this information, we also use the following non-GAAP financial measures in this report: EBITDA, Adjusted EBITDA, and Adjusted Net Income (10) (Loss) and Diluted Adjusted Earnings per share. For a discussion of the non-GAAP financial measures in this Annual Report on Form 10-K, see "Non-GAAP Financial Measures" below. Investors are encouraged to review the following reconciliations of these non-GAAP measures to our closest reported GAAP measures.

Reconciliation of GAAP Measures to Non-GAAP Measures

| | Year Ended December 31, | | | | |
|-----------------------------|--|-----------|-------------|------|------|
| | 2015 | 2014 | 2013 | 2012 | 2011 |
| | (in thousands, except per share amounts) | | | | |
| EBITDA and Adjusted EBITDA: | | | | | |
| Net income (loss) | \$ 117,047 | \$(23,470 |) \$(41,529 |) \$ | |