INC Research Holdings, Inc. Form 10-K February 24, 2015	
UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549	
FORM 10-K (Mark One) ANNUAL REPORT PURSUANT TO SECTION 13 OR 1934 For the fiscal year ended December 31, 2014 or TRANSITION REPORT PURSUANT TO SECTION 13 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) 870	27-3403111 (I.R.S. Employer Identification No.) 27604-1547 (Zip Code) 6-9300
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: Not Indicate by check mark if the registrant is a well-known seaso Act. Yes " No $ý$ Indicate by check mark if the registrant is not required to file Exchange Act. Yes " No $ý$ Indicate by check mark whether the registrant (1) has filed all Securities Exchange Act of 1934 during the preceding 12 mor required to file such reports), and (2) has been subject to such Indicate by check mark whether the registrant has submitted e any, every Interactive Data File required to be submitted and	oned issuer, as defined in Rule 405 of the Securities reports pursuant to Section 13 or section 15(d) of the reports required to be filed by Section 13 or 15(d) of the nths (or for such shorter period that the registrant was filing requirements for the past 90 days. Yes ý No " electronically and posted on its corporate Web site, if

the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý 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.  $\oint$  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

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company" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer "

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

Accelerated filer "

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 ý

As of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's common stock and, therefore, the registrant cannot calculate the aggregate market value of its common stock held by non-affiliates as of such date. The aggregate market value of the registrant's common stock held by non-affiliates of the registrant on December 31, 2014 (based on the closing sale price of \$25.69 on that date), was approximately \$257,422,098. 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 16, 2015, there were approximately 61,253,673 shares of the registrant's common stock outstanding. Portions of the registrant's Proxy Statement for its 2015 Annual Meeting of Stockholders currently scheduled to be held on June 5, 2015, are incorporated by reference into Part III hereof.

INC RESEARCH HOLDINGS, INC. FORM 10-K For the Fiscal Year Ended December 31, 2014

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#### 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, or 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 central nervous system, or 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, or 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 5,600 employees in over 50 countries across six continents as of December 31, 2014. Our broad global reach has enabled us to provide clinical development services in over 100 countries. Our global footprint provides our customers with broad access to diverse markets and patient populations, local regulatory expertise and local market knowledge. We have developed our capabilities and infrastructure in parallel with our extensive, industry-leading relationships with principal investigators and clinical research sites, as demonstrated by our ranking as the "Top CRO" in the 2013 CenterWatch Global Investigative Site Relationship Survey, which was conducted by CenterWatch, a third-party leading publisher in the clinical trials industry. The survey covered responses from over 2,000 global sites across 36 specific relationship attributes about CROs that the sites surveyed have worked with in the past two years. We believe these attributes are critical for delivering high quality clinical trial results on time and on budget for our customers. We provide robust 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. Approximately 73% of our backlog as of December 31, 2014 was in CNS, oncology and other complex diseases, such as genetic disorders and infectious diseases.

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 II 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 three reportable segments: Clinical Development Services, Phase I Services and Global Consulting. 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 and study reports to assist customers with their drug development process. 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. Global Consulting provides consulting services regarding clinical trial regulatory affairs, regulatory consulting services, quality assurance audits and pharmacovigilance consulting, non-clinical consulting and medical writing consulting. For financial information about geographic areas of our revenue and long-lived assets, please see Note 14 "Operations by Geographic Location" in our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K. International operations expose us to risks that different from those applicable to operating in the Unites States, including foreign currency translation and transaction risks, risks of changes in tax laws and other risks described further in Item 1A "Risk Factors" of this Annual Report on Form 10-K.

For the year ended December 31, 2014, we had total net service revenue of \$809.7 million, net loss of \$23.5 million, Adjusted Net Income of \$44.6 million, and Adjusted EBITDA of \$145.3 million. For a reconciliation of Adjusted Net Income and Adjusted EBITDA, each of which are non-GAAP measures, to our net 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" 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. On November 7, 2014, we completed our initial public offering of stock, or IPO. In conjunction with the IPO, our Board of Directors approved a corporate reorganization by which our direct, wholly-owned subsidiary, INC Research Intermediate, LLC was merged with and into us. 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. Since January 2013, biotechnology companies in the United States have raised \$19.6 billion from the public equity markets, and we believe the growth in this sector will further enhance overall growth within the CRO industry. 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 2014 was approximately \$76.9 billion, of which the clinical development market, which is the market for drug development following pre-clinical research, was approximately \$67.0 billion. Of the \$67.0 billion, we estimate our total addressable market to be \$55.2 billion, after excluding \$11.8 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 2014, we estimate biopharmaceutical companies outsourced approximately \$23.0 billion of clinical development spend to CROs, representing a 9% increase in such spending compared to 2013 of approximately \$21.0 billion and a penetration rate of 42% of our total addressable market. We estimate that this penetration rate will increase to over 50% 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, or, 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 CNS, oncology and other complex diseases often require treatment-naïve patients, and sometimes have subjective endpoints, which can be difficult to measure. Accordingly, these 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. Over the past 20 years, 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 CNS, oncology and other complex diseases, which collectively constitute approximately 73% of our backlog as of December 31, 2014. Based on industry data, we estimate that CNS, oncology and other complex diseases together represent over 55% 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. Our total net service revenue grew by 24% in 2014 and our net service revenue for CNS, oncology and other complex diseases, collectively, grew by 26% in 2014. Our therapeutic expertise is managed by our senior leadership and delivered by our senior scientific and medical staff and our clinical research associates, or CRAs, within our various therapeutic areas. Industry analysts have reported that therapeutic expertise is the most influential factor for small to mid-cap and 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, primarily due 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. Ninety-two percent of our new business awards in 2014 were from repeat customers, 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 our ranking as the "Top CRO" in the 2013 CenterWatch Global Investigative Site Relationship Survey. In this survey, we ranked in the top three across all 36 attributes ranked and received an average of 80.4% of "excellent" or "good" ratings across all attributes compared to the median number of CROs ranking in the top three across eight attributes and receiving an average of 72.7% "excellent" or "good" ratings across all attributes. In addition, we ranked #1 in four of the five attributes that industry analysts considered the most influential factors in selecting a CRO and received some of our highest scores related to our professional staff and being well-organized and prepared in our studies. We also participate at the highest level of membership within the Society for Clinical Research Sites, or SCRS, as a Global Impact Partner, or 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 5,600 employees in over 50 countries as of December 31, 2014 and have conducted work in

over 100 countries. We have expanded our 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 66 compounds in 40 indications across 167 active projects and accounted for approximately 37% of our net service revenue in 2014. 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. For example, 31% of our 2014 net service revenue was associated with biopharmaceutical customers whose parent companies are headquartered in Japan. 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 92% of our new business awards in 2014 were from repeat customers and our top ten customers have worked with us for an average of 7.5 years, we were also awarded clinical trials from 58 new customers in 2014, 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 57% of our net service revenue in 2014 coming from large biopharmaceutical companies. In the last twelve months we have performed work for 19 of the top 20 companies in the large biopharmaceutical market. 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 2014, we increased our net service revenue, Adjusted EBITDA and Adjusted Net Income by 24%, 38%, and 174%, respectively, and decreased our net loss by 43%. 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, 2013 to December 31, 2014, our backlog increased by 7% and net new business awards grew by 17%. 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 Processs® 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. For example, a recent technology and process integration has contributed to a 25% reduction in time required for finalization of our clinical monitoring trip reports. If this integrated approach becomes the standard, and if personnel are able to be appropriately reassigned, this improvement in our productivity would equate to 55 full-time equivalents of additional capacity. 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. The acquisition of MEK Consulting is representative of our future acquisition

strategy. 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 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
•Patient recruitment and retention			
			•Specialized support for patient registries
•Project management		•Strategic development	C
•Clinical monitoring		services	•Safety surveillance studies, prospective observational
•Drug safety/ pharmacovigilance	•Clinical data management	•Regulatory consulting and submissions	studies
	•Electronic data capture		•Health outcome research
•Medical affairs	•Biostatistics	•Clinical operations optimization	•Patient-reported outcomes
•Quality assurance		•Pricing and reimbursement	•Phase IV effectiveness trials
•Regulatory and medical writing		planning	•Health economics studies and retrospective chart reviews

•Functional service

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, or GCP, International Conference on Harmonisation, or 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 regions of the globe. By maintaining a therapeutic focus, we attract CRAs who have a strong desire to dedicate themselves to working within CNS, oncology and other complex diseases, providing an environment where they can further develop their expertise in their chosen therapeutic 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 elinical 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, or 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, or 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, or 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 Phase Forward's

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, or 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, or 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 clinical research sites and up-to-date status reports of 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 elinical 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.