FAIRMOUNT PARTNERS

Fairmount Partners
1001 West Conshohocken State Road
STE 1-660
West Conshohocken, PA 19428
Phone: 610.260.6200
Fax: 610.260.6285
www.FairmountPartners.com

Contents

Fairmount's Pharma Services Team

Neal McCarthy
Managing Director

Michael Martorelli
Director Emeritus

Roy Delizia
Director

Cecilia Gleason, Ph.D.
Senior Vice President

William Frame
Vice President

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Vice President

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Vice President

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Vice President

R.C. Wainwright
Vice President

Matt Wittig
Associate

Allison Doran
Analyst

Azfar Merchant
Analyst

Mihir Patel
Analyst

Pharmaceutical Outsourcing Monitor

Transitioning to a New Normal

March 11, 2021

The drug development industry has certainly been persistent in its work despite the continuing presence of the Covid-19 virus. We sense that the outsourcing firms we closely monitor have developed a grudging level of acceptance of this virus. They are also more confident than ever in the fundamental need for their activities and the soundness of their business prospects.

We begin this first *Monitor* of 2021 with some notes about the 2020 financial results of the outsourcing industry's main players.

We then address many business practices those firms have changed during the past year and others they have kept relatively consistent.

Michael A. Martorelli, CFA
Director Emeritus

Recent Observations & Trends

CRO Public Company Commentary

charles river

Charles River Laboratories: February 17

- Reported revenue in the Research Models and Services (RMS) segment increased 19.3% in the fourth quarter and 6.3% for the full year 2020. Organic revenues (excluding foreign exchange and acquisitions) increased 5.2% in the fourth quarter but declined 3.3% for the year, meeting management's previously stated expectations.
- The non-GAAP operating margin in RMS increased to 25.1% in the fourth quarter, reflecting strong operating leverage and operating efficiency initiatives taken earlier in the year. Due to the lost sales revenue in the first half of the year, that margin was 22.0% for the full year 2020 versus 26.2% in 2019.
- COVID had a much smaller impact on the Discovery and Safety Assessment (DSA) and Manufacturing Support (MS) segments. Full year revenues increased by 9.4% in the former and by 10.4% in the latter. The non-GAAP operating margin rose to 23.4% in DSA and to 37.4% in MS.
- Management believes CRL lost about $40 million in revenue from COVID in the RMS segment but gained about $60 million in the DSA segment. They believe the biggest problems of COVID are behind them.
- CRL is benefitting from its broad (and broadening) portfolio of early development services that are still in great demand by its academic and commercial customers.
- The pending acquisition of Cognate BioServices should add annualized revenue of about $140 million – of which $110 million will be in in 2021 if the acquisition is competed by the end of the first quarter. It should not have a meaningful impact on the operating margin in 2021 but should be accretive to EPS in 2022.
- For 2021, management expects organic revenue growth of about 10% and modest improvement on last year's 20.0% operating margin. They expect non-GAAP EPS to be about $9.00-$9.25, versus $8.13 in 2020.

Press Release Presentation Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

ERGOMED

Ergomed: January 26

- Management did not host a conference to discuss their January "Trading Update." But in comments in that press release and on a December conference call to discuss the acquisition of MedSource, they certainly affirmed the strong financial performance of the recent past.
- Revenue for the full year 2020 increased 26% to more than £86 million. CRO revenue was flat at £31 million. However, second half revenue in this segment rose 11%, following the COVID-related decline in the first half. Pharmacovigilance revenue increased more than 56% to £55 million; the organic growth rate in this segment was more than 30%.
- The final numbers to be released in late March should show EBITDA growing to £18+ million, ahead of the market's previous expectations.
- ERGO has continued to experience strong demand for its specialized services throughout the pandemic. The year-end order book was £190 million, 53% higher than at year-end 2019. It does include new orders for the acquired companies Ashfield PV and MedSource.
- Considering that backlog, analysts are anticipating revenue growth of about 35% in 2021 to about £120 million. They expect the EBITDA margin to approximate 18%.

Press Release   Presentation   Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

ICON

ICON plc: February 24

- The big news of the day, and perhaps the year, was ICLR's agreement to acquire PRA Health Sciences for $12 billion in cash and stock. PRAH shareholders will own approximately 34% of the combined company. After closing, the new ICON will be the second largest CRO, and one with a broad range of traditional services as well as digital and mobile platforms.
- Management opened their most recent conference call with positive comments on the potential for the ICON/PRAH combination. They anticipate revenue growth in the high single digits, adjusted EBITDA growth in the low double digits, and adjusted EPS growth in the mid-teens.
- ICLR then reported full-year 2020 results. Revenue was flat at $2.8 billion; operating income and EPS were slightly lower than in 2019 at $410 million and $6.53, respectively.
- The company posted net new business wins of $3.8 billion and increased its year-end backlog by more than 13%. Like many CROs, ICLR did not provide as many details as they had in previous calls about the about the impact of COVID on its business.
- Most of the questions on the call related to the acquisition. PRAH brings different technologies, a greater focus on Phase II-III work, a broad client base with only some overlap to ICLR, and good experience with decentralized trials.
- Both managements expect strong CRO industry growth, now that a larger percentage of people have become familiar with the clinical research process. Moreover, they noted that many emerging biotech companies that are deeply involved in rare disease research can really use the capabilities of a large CRO to bring their products along as fast and efficiently as possible. And they expect COVID work will continue to be important.
- For 2021, ICLR as a standalone company is guiding investors to expect revenue growth of 14-18% and EPS growth of 24-30%.

Press Release | Presentation | Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

IQVIA

IQVIA Holdings: February 10

- Full year 2020 revenue came in at $11.4 billion, beating management's previous guidance. The adjusted EPS was also better than expected at $6.42 per diluted share.
- The revenue increases in the fourth quarter of 2020 were very strong in IQV's two largest business segments (i.e., 14.5% in R&D Solutions and 17.4% in Technology and Analytics Solutions).
- The T&A segment posted a full year increase of 8.3%, reflecting its solid performance in the first half and the increase in RWE work in the second. Full year revenue was flat in the R&D segment, reflecting the decline in clinical trials activity in the first half.
- IQV has been gaining business from its new product/service offerings in both the T&A and R&D segments. The year-end backlog in the R&D segment was more than $22 billion, 18% higher than at year-end 2019.
- Management noted that IQV is continuing to benefit from its broad participation in COVID work. It is involved in post-approval RWE studies, diagnostic testing and monitoring of COVID patients, vaccine trials, and trials of novel therapeutic treatments.
- They believe 2021 revenue can increase by 14-17% in R&D and 9-12% in T&A. However due to continuing problems with physical access to physicians, they expect the much smaller Contract Sales and Medical Solutions segment (7% of total revenue) to report a decline of 2% on top of the 9% decline it reported in 2020.
- Most of the $22 billion R&D segment's backlog does not involve COVID work. After some slowdowns in mid-2020, the clinical pipelines in therapies for CNS and cardiovascular diseases, and diabetes are all growing in double digits.
- Unlike most of their peers, IQV's management had good line-of-sight on many 2021 financials back in October. On this fourth quarter conference call, they raised their initial guidance on revenue, adjusted EBITDA, and Adjusted Diluted EPS.
- The midpoints of the new guidance are $12.7 billion (revenue), $2.8 billion (adjusted EBITDA), and $7.92 (adjusted EPS). They compare to 2020 results of $11.4 billion in revenue, $2.4 billion in adjusted EBITDA, and $6.42 in adjusted diluted EPS.

Press Release Presentation Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

labcorp

Laboratory Corporation of America: February 11

- No outsourcing firm had a more distinct difference in financial performance between the first and second halves of 2020 than LH. Throughout the year, management cited ongoing uncertainties in the worlds of diagnostic testing and clinical research as the reason why they were withholding financial guidance for 2020, other than to suggest that the company would record increases in both revenue and earnings.
- Revenue in the Diagnostics segment declined 4% in the first half and increased 67% in the second. Full year 2020 results increased 32%. COVID testing was largely responsible for this strong second half performance. The segment accounted for 66% of total revenue, versus 61% in 2019.
- Revenue in the Drug Development segment declined 3% in the first half and increased 11% in the second. Increased business related to testing vaccines and therapeutics for COVID contributed to the increase. Covance increased total net orders by nearly $7.0 billion during the year and ended 2020 with a backlog that was $2.5 billion higher than at year-end 2019.
- Management issued unusually wide ranges of guidance for both revenue and adjusted EPS in 2020.
- Diagnostics Base Business revenue should increase by 11.0-13.5%. COVID testing work could decline by 35-50%, causing total segment revenue to range from down 7.5% to essentially flat.
- Drug Development Base Business revenue should increase by 9.5-12.0%. Reduced COVID work could bring the total segment revenue growth down to 8.0-10.5%.
- Adjusted EPS could range from -20.6% to -3.9%.

Press Release   Presentation   Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

MEDPACE

Medpace Holdings: February 16

- After a tough middle of 2020, business improved during the second half, allowing full year revenue ($926 million – up 7.5%) and GAAP net income per diluted share ($3.84 – up 43.8%) to beat management's expectations.
- Net new business awards increased by 19% in the second half, after declining by 5% in the first half. The year-end backlog of $1.5 billion was 20% higher than the year-end 2019 level.
- As one of the CROs most heavily involved in clinical research, MEDP is still suffering from some limitations on the direct access to sites. Management is making investments in areas such as wearables technologies, remote data access, and other hybrid trials to strengthen its position in those areas.
- A recent collaboration with Greenleaf Health will give MEDP more access to the regulatory affairs segment of the business.
- MEDP went into 2020 staffed for an anticipated increase of 20% in revenue. As the year unfolded, management was able to leverage its infrastructure and generate an increase of almost 3 percentage points in the EBITDA margin.
- Based on its backlog and the continuing growth of clinical trials, management is guiding investors to expect solid growth in 2021. However, given the lingering uncertainties related to COVID and the need to add staff as the year progresses, their guidance ranges are a bit broader than usual (i.e., revenue growth of 16-27%), EBITDA growth of 9-20%, and GAAP net income growth of 6-17%.

Press Release Presentation Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

PPD, Inc.: February 24

- In his opening comments on the fourth quarter conference call, the CEO, David Simmons, suggested that COVID-19 would become an "evergreen" component of PPD's infectious disease franchise. The company has about $5 million worth of COVID work in its backlog and is bidding on RFPs worth another $750 million. The CEO expects the volume of such potential RFPs to range from $1 billion to $2 billion during the next year.
- With business returning to almost normal in the last months of the year, management chose to not supply the extensive information about COVID work as they had done in previous quarters. They did note that site access is back up to about 60%. Like other CROs, however, PPD has used new techniques and technologies to continue conducting business even when physical site visits have been difficult. About 15% of its trials involved some direct to patient element.
- In other overall comments, management noted PPD's strong presence in the well-funded biotech industry and higher-than average employee retention rate as important competitive advantages throughout the pandemic.
- PPD's financial results in 2020 were strong, beating management's initial 2020 guidance. It recorded gains in revenue of $4.7 billion (16%), net authorizations of $4.6 billion (21%), backlog of $8.2 billion (16%), and adjusted EBITDA of $876 million (13%).
- Management issued guidance calling for further growth in 2021 in both revenue (10-13%) and adjusted EBITDA (11-14%).

Press Release | Presentation | Earnings Call

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

PRA Health Sciences

PRA Health Sciences: February 24

- Like many CROs, PRAH finished strong in the fourth quarter of 2020, beating management's guidance for revenue and income.
- Full year revenue grew almost 4% to $3.183 billion. Adjusted net income declined almost 10% to $308 million.
- PRAH reported strong new business wins in the second half of the year, bringing the full year total to $3.3 billion, compared to $3.0 billion in 2019.
- Backlog at year-end was $5.4 billion, up 15% over the year-end 2019 level.
- The company continued to experience a high rate of cancellations; they totaled $404 million for the year, versus $360 million in 2019.
- In light of the agreement to be acquired by ICON plc, management did not host a conference call to discuss 2020 results or give financial guidance for 2021.

Press Release

Recent Observations & Trends (cont.)

CRO Public Company Commentary (cont.)

Syneos Health: February 18

- In their opening remarks on the fourth quarter conference call, management updated some facts about the clinical research landscape. About 70% of sites permit physical visits. Another 25% are accessible only through remote monitoring. Only 5% remain inaccessible. New patient enrollment rates are close to 120% of their pre-COVID levels. New site activations are about 150% of pre-COVID levels.
- Full year 2020 adjusted revenue of $4.4 billion and adjusted diluted EPS of $3.41 were right in line with management's previous expectations.
- Full year revenue declines of 3.5% in the Clinical Solutions segment and 11.6% in the Commercial Solutions segment reflected the weak first half performance and some rebound in the second half. The fourth quarter was sequentially better than the third quarter in almost every business area.
- The year-end backlog of $10.2 billion in Clinical was almost 25% higher than at year-end 2019. The acquired companies Synteract and Illingworth Research contributed to that number. Both were acquired in December 2020, so they did not contribute materially to revenue or earnings.
- SYNH won 80 COVID projects in 2020; they represented about 7% of gross new business awards. Some vaccine projects will roll through backlog quickly while other therapeutic projects will take a few years to complete.
- The company did not experience any COVID related cancellations in Clinical. Some Commercial clients cancelled many non-COVID projects and limited physical visits to healthcare providers.
- Management issued 2021 guidance suggesting revenue growth of 16-21%, with only a small part related to the recent acquisitions. They expect an adjusted EBITDA margin about 30 basis points higher than 2020's level of 14.3%. They expect adjusted diluted EPS to range from $4.09 to $4.38, compared to the $3.41 number reported in 2020.

Press Release | Presentation | Earnings Call

Recent Observations & Trends (cont.)

Financial and Capital Markets
M&A Commentary

Later in this *Monitor*, we resume our practice of highlighting the valuation metrics characterizing the consolidating transactions various parties completed during the past year. After a sudden suspension of activity in the early spring, we witnessed a renewed surge of announcements in the fall. We counted more than 260 consolidating transactions across all segments of the outsourcing industry in 2020, a respectable total given the almost total shutdown of the M&A business in the spring and early summer.

When all the data for the year is recorded, industry observers are likely to characterize the period from mid-March to late August as the "quiet time" for M&A activity. But, the investment bankers who were involved in a transaction that was delayed or cancelled due to the Covid-19 outbreak would dispute that label. They found themselves trying to keep up with sales and earnings progress at their sell-side client companies while simultaneously maintaining the interest of potential buyers who were experiencing their own COVID-related business interruptions.

As has been the case in the past, strategic buyers accounted for about 80% of the acquisitions. Only a handful of large companies completed a transaction. The list of buyers included an unusually large number of small service providers that expanded their range of activities.

Large private equity firms were well-represented in the list of financial buyers. **Ampersand**, **Arsenal Capital**, **Clayton Dubilier**, **GHO Capital**, **Riverside Partners**, **Summit Partners**, and **Water Street Partners** each made more than one acquisition.

Our Comment: *Every time we address this topic, we present the same conclusion. Merely noting the number, size, or valuations of the M&A activity completed during any particular time period cannot convey the nature of the strong appetite for consolidating transactions across the various segments of the global pharmaceutical outsourcing industry. Indeed, recent evidence suggests that even in the era of Covid-19, there are large numbers of interested buyers in both the strategic and financial categories.*

Recent Observations & Trends (cont.)

Financial and Capital Markets
Particularly Interesting Transactions

Only a handful of industry leaders may have made large acquisitions in 2020. But, 2021 has certainly started off with a bang.

- **Charles River Laboratories** agreed to pay $875 million to acquire **Cognate BioServices, Inc.**, a cell and gene therapy contract manufacturing and development company.
- **ICON plc** agreed to acquire **PRA Health Sciences**. If that $12 billion deal closes in the third quarter as expected, it will create a CRO second in size only to IQVIA and represented in virtually every sector of the clinical research segment of outsourcing.

The last two months of 2020 saw several industry leaders announcing or completing a transaction.

- **Syneos Health** acquired **Illingworth Research Group**, a provider of clinical research home health services and completed the previously announced acquisition of **Synteract**, a late stage CRO focusing on the emerging biopharma customer base.
- **ERT** and **Bioclinica** agreed to merge. The combined company will be a leader in clinical end-point data solutions, imaging, cardiac safety, and wearables.
- **WCG** made its second acquisition of the year, buying **Trifecta Clinical**, a provider of technology-enabled clinical trial solutions.

In that same period, **Fairmount Partners** was pleased to provide the services that enabled two clients to find an attractive buyer.

- The non-clinical research and testing organization **Absorption Systems** agreed to be acquired by **Pharmaron**, a fully integrated contract research and manufacturing company based in Beijing, China.
- **Medsource**, a Texas-based specialty oncology and rare disease CRO, agreed to be acquired by **Ergomed**, a UK-based provider of clinical and pharmacovigilance services and specialist in orphan drug development.

We certainly do not intend to downplay the importance of dozens of acquisitions of an IRB, a contract manufacturing organization, a medical communications company, or many other types of businesses. However, in the midst of the COVID pandemic, and the integration of some unusual technologies into the armamentarium of many outsourcing firms, we think some recent transactions are particularly noteworthy.

Continued on next page

Recent Observations & Trends (cont.)

Financial and Capital Markets

Particularly Interesting Transactions (cont.)

- **Curi Bio** acquired **Dana Solutions**, a provider of artificial intelligence and machine learning to those developing in-vitro cell-based assays.
- **Elsevier** acquired **SciBite**, which provides artificial intelligence software to expedite life sciences research.
- **ERT** acquired **ADPM Wearable Technologies**, which provides wearables and digital biomarkers that can be integrated with ERT's current services.
- **Eversana** acquired **HVH Precision Analytics**, a provider of predictive analytics platforms.
- **PAREXEL** acquired **Model Answers**, a pharmacology modeling and analytics firm.
- **Simulations Plus** acquired **Lixoft**, which provides modeling and simulation software for model-based drug development.

In addition, three companies expanded their involvement in the Real-World Evidence (RWE) category that we have discussed many times.

- **Alira Health** acquired **Care Factory**.
- **Arsenal Capital** acquired **Cello Health.**
- **RTI International** acquired **Medical Data Analytics**.

Private equity firms were also active in making investments in firms providing advanced services of the type just noted.

- **Rallyday Partners** invested in **Genesis Research**, a provider of RWE services.
- **Water Street Healthcare Partners** and **JLL Partners** invested in **Thread Research**, a firm specializing in technology and services designed to enable decentralized research.

Our Comment: *Strategic investors and private equity investors alike both vote with their dollars. We think it's significant that a wide range of buyers have recently completed a transaction in an emerging area of technology or services.*

Recent Observations & Trends (cont.)

Business, Operations & Related
Clinical Research in a Post-COVID World

Here is just a sample of some headlines we've seen in various industry publications during the past few months.

COVID-Adapted Industry Moving Toward a More Flexible "New Normal"

Pandemic: A "Catalyst" For Trial Evolution

Pandemic Unleashes Momentous Changes in Clinical Research

Pandemic Prompts Trials to Reinvent Themselves…

Silver Linings of Post-Pandemic Trial Disruption

The COVID-19 Pandemic Has Pushed Several Focus Areas to the Forefront of the Industry

The stories under these headlines described the efforts of sponsors and/or their outsourcing partners to adjust to the realities of limited travel and limited face-to-face activities that have long been routine aspects of clinical research. They addressed the increasing use of technologies and practices that might have been used in a pilot program but are now used routinely if not universally.

More fundamentally, many observers have suggested the industry needs to spend more time and effort developing and executing range of emergency-response programs. Many have had to cope with sporadic disease outbreaks in a local community, natural disasters affecting a particular region, and temporary interruptions to the supply chain for clinical trial materials. However, various analyses have exposed many sponsors' inadequate preparations for long term interruptions related to unanticipated but not necessarily "un-anticipatable" events. One important recommendation involved better communications at the outset to not only the employees conducting any affected research project, but also to patients, collaborating organizations, regulatory agencies, vendors, suppliers, accreditation organizations, and the public.

Continued on next page

Recent Observations & Trends (cont.)

Business, Operations & Related

Clinical Research in a Post-COVID World (cont.)

Another variety of headlines have spotlighted troubles among the world's investigative sites.

…Pandemic Adjustments Have Led to Hike in Site Costs

Sites Overwhelmed by Cost and Trial Complexity…

Quality-Savvy Sites…Better Positioned for Post-Pandemic Risks…

Sites Plan to Continue Using Telemedicine Solutions…

Sponsors Place More Administrative Burden on Sites than Regulators…

Sites Walk a Fine Line of Responsibility Under the EU's GDPR

Many of those articles replayed some chronic complaints by the site community. In particular, they noted the unusual (and unnecessary?) degree of variability of sponsors' interpretations of the regulations. These views have made the sites comply with differing mandates, portals, and tools that seemed to accomplish similar objectives but that required differing processes to implement.

Sites using older technologies, and those with limited administrative staffs and/or internal budgets have been particularly hard hit by the pandemic. Many have been asked to adopt new technologies almost instantly. Training their personnel, many of whom have been reluctant to use such tools, has been problematic. Both large and small operators need to make their own decisions about expensive and unreimbursed personal protective equipment (PPE) and COVID-testing protocols for their employees. And most need to develop their own ways of dealing with problems of patient accessibility, which continue to vary across geographies.

The sites that have been the most successful in pivoting to electronic informed consent, remote monitoring, telemedicine, and quality and risk-based management systems seem poised to emerge from the disruption of the COVID pandemic in better shape than the average site. But those not as successful in adapting to many changes involving processes and/or tools might struggle to maintain their existence.

Continued on next page

Recent Observations & Trends (cont.)

Business, Operations & Related
Clinical Research in a Post-COVID World (cont.)

Yet another group of headlines has noted the challenges being faced by patients involved in clinical research.

Trials Industry to Focus on Patient-Centricity…

Researchers Urged to "Meet Patients Where They Are"…

Patient Willingness to Join Clinical Trials Drops Dramatically…

Misinformation, Mistrust Are to Blame for Lack of Diversity in COVID Trials

Recruiting Struggles Can Be Overcome…

Clinical Trials Have "Much Work to Do" in Boosting Diversity

The Industry-Wide Effort to Make Patent-Driven Supply Chains a Reality

"Patient-centricity" has been one of those buzzwords used by many parties involved clinical research for the past couple of years. And it appears that sponsors are indeed giving more consideration than in the past of the patient's perspectives on clinical research.

At the Conference Forum's Patients as Partners virtual event in August, a representative from the FDA's Center for Drug Evaluation and Research (CDER) noted that about 80% of the research protocols being submitted to his agency include some amount of patient engagement. A colleague from the Center for Biologics Evaluation and Research (CBER) discussed her agency's expanding search for patient input, largely through "listening sessions" and meetings with patients and patient advocates. The agency has published several Guidance documents for sponsors seeking to identify characteristics most important to patients and suggestions for incorporating more patient experience data into their research efforts.

Yet, at that same virtual conference, Ken Getz from the Center for Information and Study on Clinical Research Participation (CISCRP) discussed the disturbing findings from his agency's ongoing study of patients' willingness to participate in clinical trials. Self-reported data from about 8,800 respondents in a July 2020 survey indicated that only 49% were willing to participate in such research; that "willingness" rate was 85% in the summer of 2019. Moreover, this year 36% of the respondents stated that they did not really understand clinical research; in the summer of 2019 only 10% of the respondents expressed that lack of knowledge.

Continued on next page

Recent Observations & Trends (cont.)

Business, Operations & Related
Clinical Research in a Post-COVID World (cont.)

Other conferences held in recent months featured speakers who were troubled by the general media's hyperventilation about some issues involving clinical trials on diagnostics or treatments for COVID-19. Many acknowledged sponsors' greater acceptance of hybrid studies, remote monitoring, and new tools for patient communications during the COVID pandemic. They also expressed the need for still more patient involvement in the earliest stages of protocol development, different types of clinical trial designs, continuous outreach to evaluate in-trial results, and better efforts to find patients (especially minorities) in settings other than their primary care physician's office.

Our Comment: *We don't know how many times we've written this cliche during the 18 years we've been publishing this Monitor. But it seems as relevant today as it's ever been.*

The more things change, the more they remain the same.

*The **process** of clinical research is constantly changing; new tools, enhanced online capabilities, and evolving practices of communication make the world existing during the writing of this sixty-fifth Monitor different from the one that existed when we published the first version of this report.*

*And yet, the **purpose** of clinical research always remains the same; the completion of rigorous clinical studies is critically important to the successful development of new drugs and medical devices.*

Recent Observations & Trends (cont.)

The Clinical Trials Transformation Initiative (CTTI): Strategic Vision for Clinical Trials in 2030

We're sure the reader is aware of the work of the Clinical Trials Transformation Initiative (CTTI). This public-private partnership was cofounded by Duke University and the Food and Drug Administration in 2007. Its mission is to develop and drive the adoption of practices that promise to increase the quality and efficiency of clinical trials. Representatives from its 80 member organizations across the clinical research enterprise conduct projects they hope will lead to evidence-based, actionable recommendations that can offer solutions to many clinical research challenges.

In April 2020, CTTI released its updated Vision for Clinical Trials; this version is focused on the world its members hope will exist in 2030. During the past few months, several conference speakers and/or magazine writers have described the major elements of this vision. Several phrases throughout the vision statement's five topics of discussion really illustrate CTTI's ambitious "state of the world" expectations for the future.

We offer the statement's website for those interested in more details than we present below about the hoped-for state of affairs in 2030. Link

Patient-Centricity

- "Patients and patient organizations are fully integrated in the design and governance of clinical trials…"
- "…individuals are involved in clinical trials without going to designated clinical sites to enroll or participate."
- "Enrolled clinical trial participants reflect the diversity of the population expected to use the medical product."

Integrating Clinical Research into the Healthcare Delivery System

- "Clinical trial data are collected via the electronic health record (EHR)…"
- "Healthcare systems and health plans are involved in planning studies and support the integration of trials into regular clinical practice…"

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Recent Observations & Trends (cont.)

The Clinical Trials Transformation Initiative (CTTI): Strategic Vision for Clinical Trials in 2030 (cont.)

Clinical Trials Are Designed with a Quality by Design (QbD) Approach

- "Clinical trials are fit for purpose – designed with study activities that are essential…"
- "Innovative trial designs…will continue to be developed and used…"

Clinical Trials Maximally Leverage Clinical and Nonclinical Data

- "Clinical trials are enhanced by the integration of new types of data…"
- "Data are accessible…to all researchers and sponsors."
- "Use of EHR data…is straightforward."

Clinical Trials Contribute Knowledge

- "New medical products are available to care providers and patients more quickly and efficiently than today."
- "Results of trials are broadly shared with participants and care providers…"
- "…more clinical trials…are done to answer the questions most important to patients."

Our Comment: *Over the years, we have spotlighted the work of many collaborations involving representatives of many participants in the clinical research enterprise. We have applauded the intent behind such efforts while wondering how widely these organizations' recommendations have been accepted. We suspect CTTI and others will find a more receptive audience for future recommendations, since we believe the post-pandemic clinical research ecosystem will be under more pressure than ever to deliver its results faster, with better quality, and at less expense.*

Recent Observations & Trends (cont.)

Pharma Outsourcing Landscape
The Clinical Development Industry's Workforce

During the past few months, several organizations have published some interesting commentaries on the nature of the clinical development industry's workforce of both today and tomorrow.

The Tufts Center for the Study of Drug Development (CSDD) wrote about the adequacy of the clinical development workforce in the age of digital transformation. Its June 2020 White Paper presented the findings of a December 2019 roundtable focusing on workforce development. Sixty participants from a range of organizations discussed the current state of that workforce as it enters an era characterized by more digital technologies such as machine learning and artificial intelligence. The report covered several major topics:

- New challenges in the digital era.
- Key trends shaping the future workforce.
- The need for new skills and competencies.
- The emergence of new roles and responsibilities.
- Evolving human resource needs.
- Developing new training strategies.
- Supporting digital transformation.

The written sections on each topic included several propositions and recommendations. The CSDD faculty hopes the report will stimulate many discussions around these issues and spur organizations to develop new strategies and responses.

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Recent Observations & Trends (cont.)

Pharma Outsourcing Landscape
The Clinical Development Industry's Workforce (cont.)

The Association for Clinical Research Professionals (ACRP) published an analysis conducted by TEConomy Partners on behalf of the ACRP that suggested the clinical research workforce may not be keeping pace with clinical trial demand. This statistical analysis included the geographic breakdown of the demand for clinical research professionals, the salary levels in the various positions of clinical research, and the evolving education and experience requirements in the industry. The report focused on several themes:

- There is strong demand for clinical research professionals, but the data indicates that workforce growth may not be keeping pace with growth in clinical trial demand.
- Clinical research jobs are nationally high-quality positions with entry-level opportunities to start careers in biomedical research.
- To attract and retain more people in clinical research careers, there is a need for industry-wide occupational definitions, standards, and certifications.
- Clinical research stakeholders need to define and align the competencies of the workforce and provide more equitable career paths as well as consistent salaries in order to sustain the workforce.

This October Special Report was only one of many reports, white papers, blog postings, guest columns, and virtual presentations made by ACRP leaders during the past nine months. Many repeated some familiar themes voiced by the organization over the past several years.

An executive from IQVIA discussed the need for the clinical development industry to bring on more tech-savvy employees, including a Chief Digital Officer (CDO). Udesh Dosanjh, practice leader of technology solutions, suggested in an interview with Outsourcing-Pharma that digital transformation involves not only systems and processes but also culture and people. Within every organization, some employees are more adept at handling the increased collection, analysis, and usage of digitized data; however, many others are not. He noted that most existing technology departments are concerned with hardware, software, and connectivity. They are not sufficiently focused on gathering information and making it available widely and rapidly. In the interview, he shared a checklist of qualifications and qualities he recommends for companies exploring the potential contributions of a CDO.

Our Comment: *We have long noted the unusual insularity of the drug development industry's recruitment of key personnel. These assessments seem to reinforce the notion we've expressed many times over the years that the industry would benefit by hiring more people with different combinations of training, experiences, talents, and capabilities than those schooled only in the medical field.*

Recent Observations & Trends (cont.)

Pharma Outsourcing Landscape
Capsule Comments

As usual, there have been many other news items and reports in the world of drug discovery and development that deserve at least a brief mention in this section of our *Monitor*.

The FDA published its Final Guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank:

- It's hard to believe, but it was back in 2007 that the Food and Drug Amendments Act (FDAAA) required "responsible parties" to submit clinical trial registration and results information for "applicable clinical trials" to the ClinicalTrials.gov data bank.
- In 2016, the Secretary of Health and Human Services issued the regulations detailing the requirements for submitting that data.
- In 2018, the FDA issued its Draft Guidance on complying with the rules to industry. That document identified monetary penalties and possible civil and/or criminal actions against those providing false or misleading information.
- Yet for the past few years, the users of data from ClinicalTrials.gov have repeatedly discovered the incomplete, untimely, and sometimes inaccurate nature of that source's data. It has included relevant data on about 70% (not 100%) of applicable clinical trials.
- In February 2020, a federal court reprimanded the National Institutes of Health (NIH) for not enforcing the long-mandated information requirements.
- And finally in August, the FDA's Final Guidance confirmed its earlier intention to assess monetary penalties for each violation, to consider civil and/or criminal actions, and to post on its website the identities of violators. It also outlined its procedures for determining the identity of an "applicable clinical trial."

Especially in the time of the COVID pandemic, TRANSPARENCY has become one of the most important and relevant watchwords in the modern world of medicine (not just clinical research). We look forward to the time (hopefully very soon) when ClinicalTrials.gov does indeed become the indispensable source of up-to-date registration and results information its proponents thought it would be some thirteen years ago.

Continued on next page

Recent Observations & Trends (cont.)

Pharma Outsourcing Landscape
Capsule Comments (cont.)

In September, former President Donald Trump, issued an Executive Order on Lowering Drug Prices. It stated that the Medicare program should not pay more for Part B or Part D drugs or biologicals than the most-favored nation price. With some adjustments for volume and differences in nations' gross domestic products, that price is the lowest a drug manufacturer charges in a member country of the Organization for Economic Co-operation and Development (OECD). The order charged the Secretary of Health and Human Services with developing and implementing rule-making plans to test payment models for Part B and Part D drugs. It is unclear when the Secretary will publish these plans. But, it seems likely that the Pharmaceutical Research and Manufacturers of America (PhRMA) will file suit to block their implementation.

In late October, Florida Governor Ron DeSantis announced the state had not received any bids on a $30 million contract to set up and to operate a drug importation program. In September, Secretary of Health and Human Services, Alex Azar, had approved the final rules under which states would be permitted to establish a program to import drugs from Canada. A 2003 law had allowed for the establishment of such a program pending the Secretary's assertion that it would be safe, cost-effective, and his/her publication of the rules.

Several other states are trying to design programs to help their citizens pay less for drugs by importing them from Canada. It is uncertain whether any will be able to implement a plan that is acceptable to Canadian authorities, private contractors, state legislatures, drug distributors, and consumers.

Our Comment: *These and other items of interest to those involved in drug development certainly seem to relate to the ancient Chinese blessing/curse that one should live in "interesting" times.*

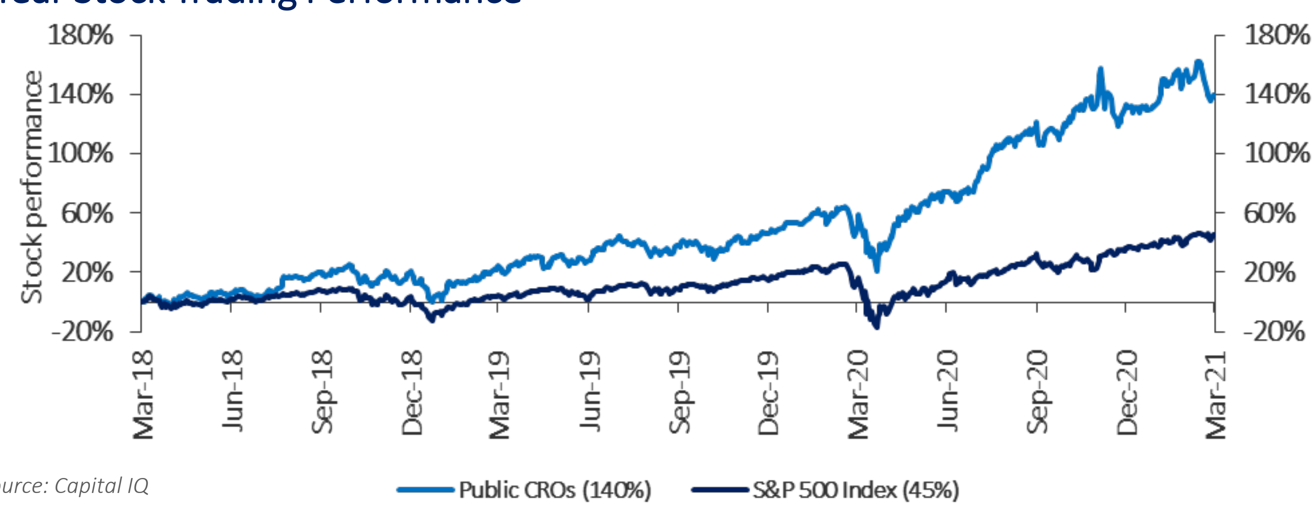
Public Company Performance: CRO

Company Trading Statistics *($ in millions)*

03/01/2020	Size & Profitability				Profit Margins		Trading Multiples	
Company	Enterprise Value	Market Cap	LTM Revenue	LTM EBITDA	GM%	EBITDA %	EV / Rev	EV / EBITDA
charles river	$16,375	$14,416	$2,924	$675	37%	23%	5.6 x	24.3 x
ERGOMED	$840	$850	$102	$17	55%	17%	8.2 x	49.0 x
ICON A Symbol of Excellence	$8,724	$9,132	$2,797	$476	29%	17%	3.1 x	18.3 x
IQVIA	$48,893	$37,278	$11,359	$1,830	34%	16%	4.3 x	26.7 x
labcorp	$29,027	$23,570	$13,979	$3,619	36%	26%	2.1 x	8.0 x
MEDPACE	$5,807	$5,954	$926	$187	62%	20%	6.3 x	31.1 x
PPD	$16,283	$12,443	$4,681	$788	64%	17%	3.5 x	20.7 x
PRAHEALTHSCIENCES	$10,283	$9,316	$3,183	$416	48%	13%	3.2 x	24.7 x
Syneos Health	$10,927	$7,962	$4,416	$575	23%	13%	2.5 x	19.0 x

Note: Gross margin figures subject to refinement based on individual company treatment of pass-through and reimbursed costs.
Note: PRA Health Sciences announced its acquisition by ICON on February 24, 2021.
Source: Capital IQ; data reported for latest twelve months (LTM).

3-Year Stock Trading Performance



Source: Capital IQ

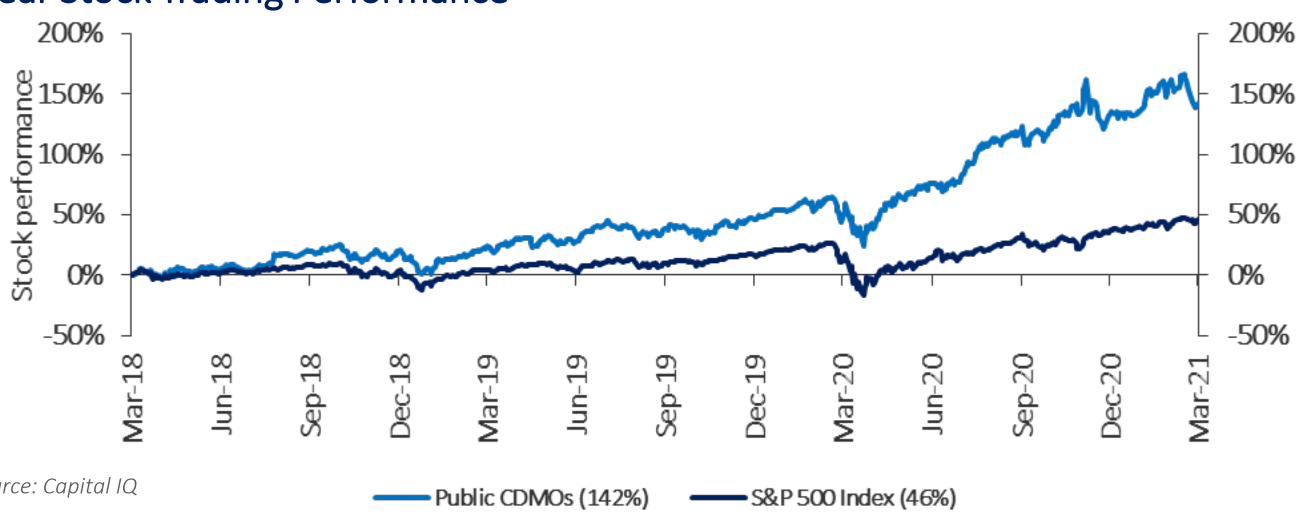
Public Company Performance: CDMO

Company Trading Statistics *($ in millions)*

03/01/2020	Size & Profitability				Profit Margins		Trading Multiples	
Company	Enterprise Value	Market Cap	LTM Revenue	LTM EBITDA	GM%	EBITDA%	EV/ Rev	EV/ EBITDA
AVID Bioservices	$1,305	$1,318	$73	$3	20%	4%	18.0 x	NM
Catalent	$22,041	$19,814	$3,465	$787	33%	23%	6.4 x	28.0 x
Johnson Matthey	$9,691	$8,499	$20,557	$789	6%	4%	0.5 x	12.3 x
Lonza	$50,379	$46,814	$4,935	$1,480	41%	30%	10.2 x	34.0 x
Recipharm	$3,876	$2,789	$1,311	$236	69%	18%	3.0 x	16.4 x
sartorius	$41,254	$40,594	$2,303	$696	52%	30%	17.9 x	59.3 x
Siegfried	$3,449	$3,352	$925	$147	21%	16%	3.7 x	23.4 x
ThermoFisher Scientific	$193,238	$180,972	$32,218	$10,227	50%	32%	6.0 x	18.9 x

Note: Gross margins for non-US based entities may not be comparable due to reporting limitations.
Source: Capital IQ; data reported for latest twelve months (LTM).

3-Year Stock Trading Performance



Source: Capital IQ

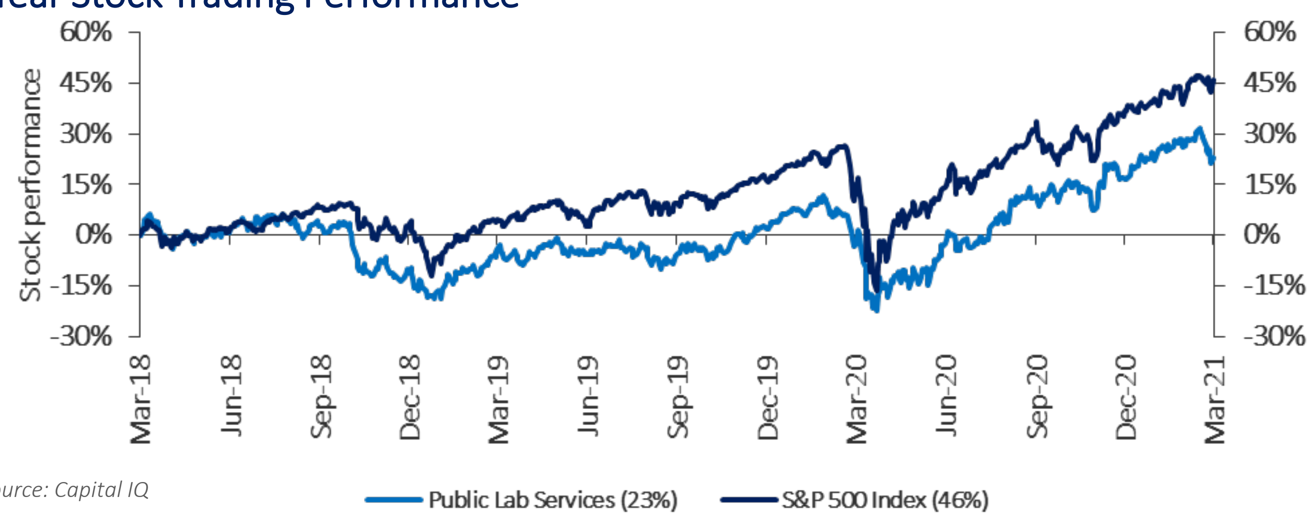
Public Company Performance: Laboratory Services

Company Trading Statistics *($ in millions)*

03/01/2020	Size & Profitability				Profit Margins		Trading Multiples	
Company	Enterprise Value	Market Cap	LTM Revenue	LTM EBITDA	GM%	EBITDA%	EV/ Rev	EV/ EBITDA
ALS	$4,292	$3,657	$1,362	$276	28%	20%	3.2 x	15.6 x
Bureau Veritas	$14,419	$12,238	$5,548	$872	20%	16%	2.6 x	16.5 x
eurofins	$20,230	$17,269	$5,690	$1,057	21%	19%	3.6 x	19.1 x
intertek	$13,220	$12,302	$4,010	$754	55%	19%	3.3 x	17.5 x
SGS	$24,301	$21,845	$6,135	$1,367	44%	22%	4.0 x	17.8 x

Note: Gross margins for non-US based entities may not be comparable due to reporting limitations.
Source: Capital IQ; data reported for latest twelve months (LTM).

3-Year Stock Trading Performance

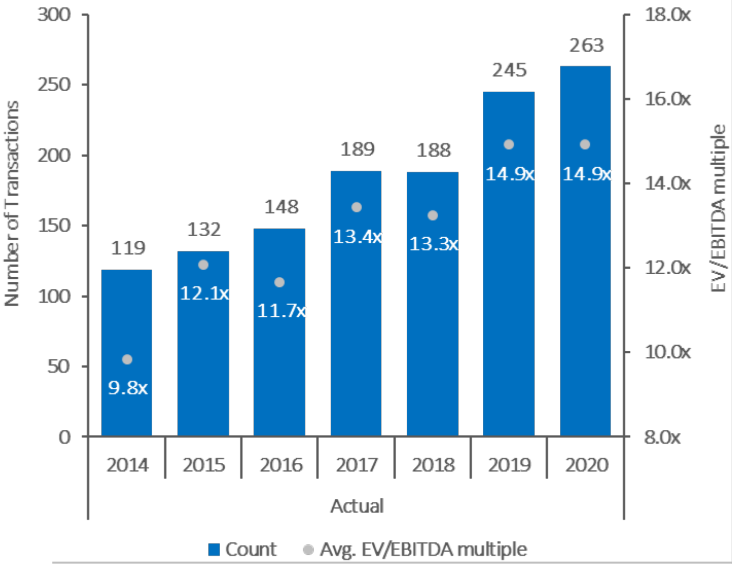


Source: Capital IQ

M&A Snapshot: Statistics

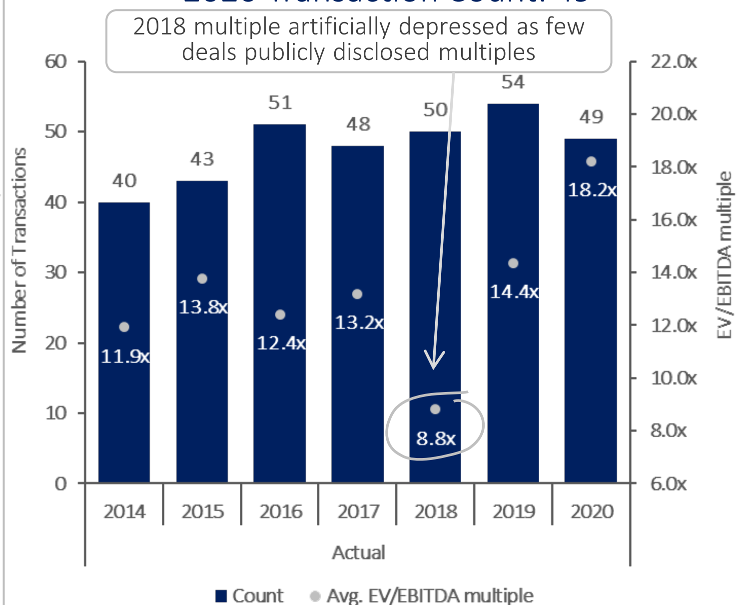
Outsourced Pharma Services Total

5Y Avg. Trading Multiple: 13.5 x
2020 Transaction Count: 263



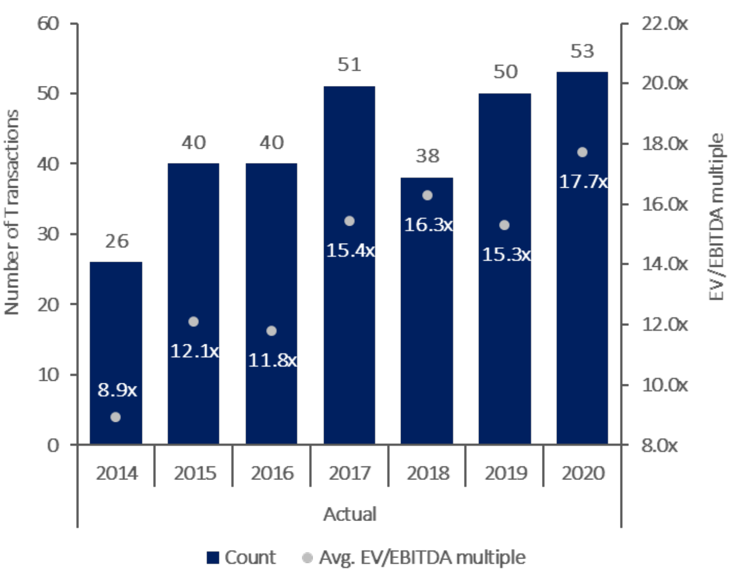
CROs & Related Services

5Y Avg. Trading Multiple: 13.1 x
2020 Transaction Count: 49



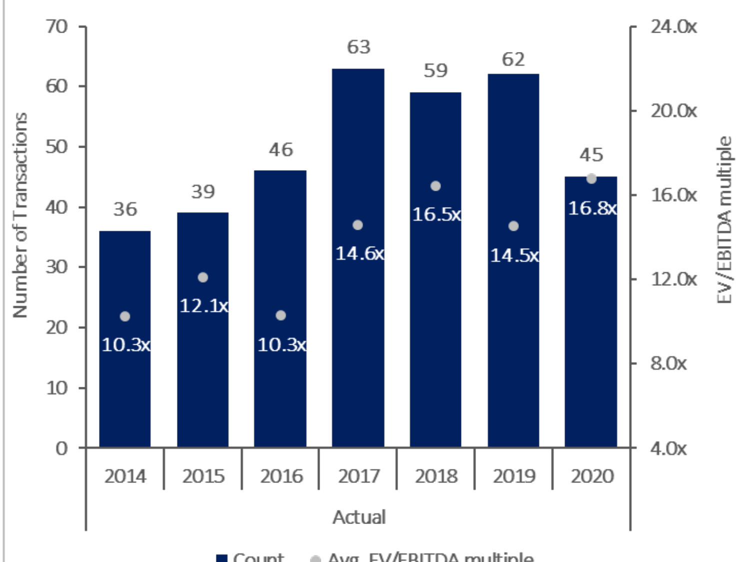
CDMOs

5Y Avg. Trading Multiple: 14.7 x
2020 Transaction Count: 53



Laboratory Services

5Y Avg. Trading Multiple: 13.7 x
2020 Transaction Count: 45



M&A Snapshot: 2020 Noteworthy Transactions

Date	Target	Acquirer	Commentary
CROs, Clinical Research Sites & Related Services			
Jan-20	Statistics Collaborative	WCG	▪ WCG acquires Statistics Collaborative, a biostatistics consultancy specializing in pharma and biologics clinical trials
Feb-20	MedPass International	ICON plc	▪ ICON plc (Nasdaq:ICLR) acquires MedPass International, a medical device CRO and regulatory and reimbursement consultancy; *Fairmount Partners advised ICON on the acquisition*
Jul-20	GlobalCare	Covance / LabCorp	▪ Covance acquires GlobalCare, a provider of patient-centric decentralized clinical trials support services, including mobile healthcare services and patient transport assistance
Sep-20	ProSciento	1315 Capital	▪ 1315 Capital closes a growth financing in ProSciento, a specialty CRO focused on non-alcoholic steatohepatitis (NASH), diabetes, obesity and related metabolic diseases
Dec-20	MedSource	Ergomed plc	▪ Ergomed plc (LSE:ERGO) acquires MedSource, a specialized CRO based in Houston, TX; *Fairmount Partners advised Ergomed on the acquisition*
CDMOs & Related Services			
Jan-20	Ardena	GHO Capital Partners	▪ GHO Capital Partners acquires Ardena, a specialist CDMO focused on early-stage drug development and manufacturing
Feb-20	MaSTherCell	Catalent	▪ Catalent Inc. (NYSE:CTLT) acquires MaSTherCell, a CDMO focused on cell and gene therapy
Aug-20	PCI Pharma Services	Kohlberg & Co., Mubadala Investment Co.	▪ Kohlberg & Company and Mubadala Investment Company acquire PCI Pharma Services, a provider of supply chain solutions from development through to commercial launch
Aug-20	Emerson Resources	Pace Analytical Services	▪ Pace Analytical Services, backed by Aurora Capital, acquires Emerson Resources, a CDMO specializing in dosage form development and clinical trial material manufacturing
Sep-20	Adare Pharma	Thomas H Lee / Frazier Healthcare	▪ Thomas H. Lee Partners and Frazier Healthcare Partners acquire Adare Pharmaceuticals, a specialty CDMO and provider of advanced pharmaceutical technologies

M&A Snapshot: 2020 Noteworthy Transactions

Date	Target	Acquirer	Commentary
Laboratory & Related Services			
Jan-20	FairJourney Biologics SA	GHO Capital Partners	▪ GHO Capital Partners invests in FairJourney Biologics SA, a provider of outsourced antibody discovery, engineering, production and characterization services
Mar-20	Viroclinics Biosciences	Summit Partners	▪ Summit Partners announces a growth equity investment in Viroclinics Biosciences, a provider of non-clinical and clinical services to the global virology/vaccine development markets
Jun-20	Solvias AG	Water Street Healthcare Partners	▪ Water Street Healthcare Partners acquires Solvias AG, a provider of testing and development and manufacturing services for biopharma, including cell and gene therapies
Sep-20	GeneWerk	Ampersand Capital Partners	▪ Ampersand Capital Partners invests in GeneWerk, a cell and gene therapy testing company focused on preclinical and clinical trial patient sample analysis services
Nov-20	Absorption Systems	Pharmaron	▪ Pharmaron Beijing Co. acquires Absorption Systems, non-clinical CRO focused on research and testing for small and large molecules and cell and gene therapies; *Fairmount Partners advised Absorption Systems on the sale*
Consulting, Commercialization & Related Services			
Apr-20	Skysis	Fishawack Health	▪ Fishawack Health acquires Skysis, a provider of integrated market access and commercial strategy solutions; *Fairmount Partners advised Skysis on the sale*
May-20	Huntsworth plc (LSE:HNT)	Clayton, Dubilier & Rice	▪ Clayton, Dubilier & Rice acquires Huntsworth plc (LSE:HNT), a UK-based provider of healthcare communications services, for £575 million
Aug-20	Cello Health	Arsenal Capital Partners	▪ Arsenal Capital Partners acquires Cello Health, an advisory firm focused on scientific, commercial advisory and digital delivery capabilities, for a value of £182 million
Sep-20	TriNetX	The Carlyle Group	▪ The Carlyle Group makes a strategic growth investment in TriNetX, a global health research network providing real-world data for clinical and observational research
Sep-20	ProPharma Group	Odyssey Investment Partners	▪ Odyssey Investment Partners acquires ProPharma Group, a provider of regulatory and compliance consulting services to pharma, biotech and med device clients

About Fairmount Partners: Overview

Fairmount Partners: Spotlight Transaction

Fairmount Partners advised Absorption Systems on its recent sale to Pharmaron – a fully integrated contract research and manufacturing organization with signification operations in China, the US, and the UK – for up to $137.5M in cash. Absorption Systems is a leading scientific, non-clinical CRO that provides pharmaceutical, biotech, medical device companies, and regulatory agencies with research and testing for small and large molecules, cell and gene therapies, ocular and medical device products. Absorption Systems is based in the USA with facilities and laboratories in Philadelphia, San Diego, and Boston. This transaction will enhance Pharmaron's fully integrated, end-to-end drug R&D service offerings globally.

ABSORPTION SYSTEMS®

ACQUIRED BY

康龙化成 PHARMARON

Fairmount Partners: Spotlight Transaction

Fairmount Partners advised Ergomed plc (LSE: ERGO) on its acquisition of MS Clinical Services, LLC ("MedSource"), a specialized clinical research organization based in Houston, Texas, USA. The acquisition aligns with Ergomed's strategy to complement its specialist expertise in oncology and rare disease, expand its US presence, and significantly increase its order book, providing high forward visibility of contracted future revenue.

ERGOMED

ACQUISITION OF

MEDSOURCE

Fairmount Partners: Spotlight Transaction

Fairmount Partners advised IntelliSyn and its sister company, AviSyn, on their recent sale to X-Chem, a portfolio company of investment firm GHO Capital. IntelliSyn and AviSyn are drug discovery services companies specializing in medicinal chemistry, custom synthesis and process route development, and drug discovery support services. This acquisition enables X-Chem to provide a complete, seamless solution for screening, hit validation, and lead optimization in existing and new markets.

IntelliSyn

AVISYN

ACQUIRED BY

X-CHEM PHARMACEUTICALS

About Fairmount Partners: Overview (cont.)

Fairmount Partners: Spotlight Transaction

Fairmount Partners advised INVIVO Communications on its recent sale to Red Nucleus, a portfolio company of investment firm the Riverside Company. INVIVO Communications is a digital scientific communications agency that integrates deep therapeutic knowledge and insightful medical strategy with cutting-edge technology. The INVIVO deal positions Red Nucleus as a differentiated life science firm, grounded in commercial education, clinical operations, R&D process, and now scientific communications.

INVIVO®

ACQUIRED BY

red nucleus

A Portfolio Company Of

Riverside

Fairmount Partners is a leading M&A advisor to Pharma Services companies, offering unique and proprietary industry insights

150	41	20
Fairmount team has completed 150 Pharma Services M&A transactions	Fairmount has closed 41 Pharma Services M&A transactions in the past 4 years	Fairmount has closed M&A deals with buyers and sellers across 20 countries

Fairmount Partners is an independent investment bank focused on the needs of middle market and emerging growth companies. It provides a range of investment banking and capital advisory services, including merger and acquisition advisory, capital raising, fairness opinions, valuations and strategic advisory. The firm focuses its activities on targeted industries in which it has a record of experience and success. While headquartered in suburban Philadelphia, Fairmount works with companies across the globe.

About Fairmount Partners: Overview

- IntelliSyn / AVISYN — ACQUIRED BY — X-CHEM Pharmaceuticals
- ERGOMED — ACQUISITION OF — MEDSOURCE
- ABSORPTION SYSTEMS — ACQUIRED BY — PHARMARON
- INVIVO — ACQUIRED BY — rednucleus, A Portfolio Company Of Riverside
- Skysis — ACQUIRED BY — FISHAWACK HEALTH
- ICON — ACQUISITION OF — MEDPASS International
- Arbour Group, Portfolio Company Of KEYSTONE CAPITAL — ACQUIRED BY — PHARMALEX
- Cambridge BIOMEDICAL — ACQUIRED BY — BioAgilytix
- GSI Health — ACQUIRED BY — medecision
- novasyte health — ACQUIRED BY — IQVIA
- THREAD — ACQUIRED BY — WATER STREET And JLL Partners
- Quotient Sciences, Portfolio Company Of GHO CAPITAL — ACQUIRED BY — PERMIRA
- ICON — ACQUISITION OF — MEDINOVA Quality Research Sites
- GOODWIN BIOTECHNOLOGY — INVESTMENT FROM — SIGNET Healthcare Partners
- RCRI — ACQUIRED BY — COVANCE LabCorp
- ALTASCIENCES — ACQUISITION OF — Preclinical Testing Business Of SNBL USA
- ARGINTINT — ACQUIRED BY — PRECISION MEDICINE GROUP
- wellspring Manufacturing Solutions — ACQUIRED BY — ani Pharmaceuticals, Inc.
- ETHOS HEALTH COMMUNICATIONS — ACQUIRED BY — PRECISION MEDICINE GROUP
- REDBOCK — ACQUIRED BY — NES Global Talent
- GRAND RIVER ASEPTIC MANUFACTURING — GROWTH FINANCING AND RECAPITALIZATION BY — ACP ARLINGTON CAPITAL PARTNERS
- biobridges — ACQUIRED BY — Adecco
- neri New England Research Institutes — ACQUIRED BY — HealthCore
- ICON — ACQUISITION OF — Mapi Insight for solutions
- ALTASCIENCES — ACQUIRED BY — Management and Audax Group
- ThreeWire We deliver patients — ACQUIRED BY — wcg WIRB COPERNICUS GROUP
- QS PHARMA — ACQUIRED BY — QUOTIENT CLINICAL
- Agilux laboratories — ACQUIRED BY — charles river
- GLOBAL LANGUAGE solutions — ACQUIRED BY — welocalize doing things differently
- Xcelience — ACQUIRED BY — CAPSUGEL