Consolidation in Outsourced Pharmaceutical Services

Contract Research Organizations (CROs) and Contract Development & Manufacturing Organizations (CDMOs) are utilizing strategic mergers, acquisitions, and private equity partnerships to capitalize on tailwinds in the outsourced pharmaceutical services sector.



Executive Summary

Provident's Perspective

The outsourced pharmaceutical services industry has benefited from recent trends in the pharmaceutical landscape, as traditional drug manufacturers have divested their clinical research, development, and manufacturing assets to focus on core competencies and brand Pharmaceutical companies equity. are increasingly utilizing contract research organizations (CROs) and contract development and manufacturing organizations (CDMOs) to manage their drug development processes, from early-stage pre-clinical research and discovery, through large-scale commercialization. In order to obtain and service these highly lucrative sponsorships, middle-market, closely held CROs and CDMOs are turning to both the capital and M&A markets to drive scale and integration within their areas of expertise.



The Provident Healthcare Partners investment banking team partners with healthcare organizations to provide advisory services related to mergers and acquisitions, equity and debt capital raises, private placements, and financial restructuring. The team has a vast network of high-level, senior industry contacts, a thorough knowledge of market sectors and specialties, and unsurpassed experience and insight into the transaction process. Our specialized and industry focused approach uncovers value and opportunities that others often overlook to create transaction premiums for clients.

We have successfully closed transactions with clients operating in North America and Asia, while providing financial advisory services to healthcare leaders in the following sectors:

- Contract Development & Manufacturing
- Contract Research
- Clinical Trial Services
- Healthcare Consulting
- Healthcare IT
- Healthcare Distribution
- Emergency Medical Services
- Home Health
- Infusion Services

- Pharmacy Services
- Life Science Services
- Health Plans
- Post-Acute Care
- Behavioral Health
- Veterinary Medicine
- Multi-Site Physician Providers
- Outsourced Hospital Services
- Medical Supplies & Equipment

20+	Years of Healthcare Investment Banking
130+	Healthcare Deals Closed
65+	Healthcare Services Deals Closed since 2014
12-15	Landmark Deals Per Year
24	Banking Professionals



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Introduction

The outsourced pharmaceutical services sector has experienced continued consolidation activity as both macro and microeconomic trends have altered the pharmaceutical and broader healthcare landscapes. While the healthcare industry continues to outpace U.S. GDP with 3-4% annual growth, the pharmaceutical industry has captured 20% of total spend, with annual growth rates measured around 6%. Recent and future growth expectations have placed the pharmaceutical industry in the forefront of attention of healthcare investors and stakeholders.

Within the outsourced services sector, contract research organizations (CROs) and contract manufacturing and development organizations (CDMOs) underwent aggressive expansion in the early stages of the most recent credit cycle, dating back to 2010. Historically, pharmaceutical drug manufacturers held robust, vertically integrated assets in the clinical stage drug development process, with the goal of maximizing return on R&D and commercialization investments.

To cope with pressures from the Great Recession and downturn of "blockbuster drug" era R&D

large pharmaceutical players began returns, divesting many of these non-core clinical stage discovery, research, development, and manufacturing assets in pursuit of shareholder value in the late 2000's. As a result, the outsourced pharmaceutical services sector has outpaced the greater pharma industry growth trajectory in the latter stage of this economic cycle. As the pharmaceutical industry continues to rely more heavily on outsourced services, stakeholders have utilized strategic mergers, acquisitions, and private equity investment to pursue aggressive growth strategies in the fragmented CRO and CDMO industries (See Appendix 1).

Changes in the drug commercialization process, technological advancements, and economies of scale have created multiple growth considerations shareholders for and management teams. Additionally, non-traditional strategics and investors see the CRO and CDMO spaces as an opportunity to capitalize on the growing healthcare industry, while minimizing the reimbursement risk that other healthcare subsectors are typically exposed to.



The Pharmaceutical CRO & CDMO Value Continuum

Trends in Outsourced Pharmaceutical Services

Emergence of Biologics

While traditional small-molecule and generic drugs still account for ~60% of U.S. drug spend, the growth of biologics and their biosimilars has been a key driver for mergers and acquisitions for CDMOs and CROs. With biologic and biosimilar drug development being significantly more time and capital intensive than small molecule and generic development, smaller pharma clients have mainly utilized outsourced partners. Statistically, commercial biopharma smaller companies currently outsource 73% of API production, compared to large drug sponsors who only outsource ~40% of their API production. To capitalize on this opportunity, middle-market independent CROs and CDMOs are aligning themselves with capital and strategic partners to make necessary investments in equipment and talent to serve the growing needs from smaller

pharma sponsors.

Traditional large-scale CDMOs and CROs such as Lonza, Boehringer-Ingleheim, and Cook Pharmica have historically controlled outsourced biologics commercialization, leveraging their breadth of services and vertical integration to service drug sponsors from early Phase One trials to commercial manufacturing. Given the increase in small-scale biopharmaceutical drug sponsors who value the simplicity of managing one CRO or CDMO partnership, this key differentiator has allowed those with scale to capture significant market share. However, smaller, nimble players are using private equity partnerships to compete in niche service areas, like sterile liquid dosage and domestically concentrated geographies like North America.



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Trends in Outsourced Pharmaceutical Services (continued)

North America a Focal Point for Cross-Border Investment

CROs and CDMOs have benefitted from global integration, with the goal of targeting new drug sponsors, patient populations, and disease states. In the early stage commercial manufacturing realm, CDMOs with global footprints have differentiated themselves through flexibility, communication and regulatory efficiency, as well as broader access to human capital. That being said, North America has been the most active region for CRO and CDMO acquisition activity, as both the level of fragmentation amongst service providers and the presence of many large pharmaceutical drug sponsors attracts investment. This heightened level of investment interest, coupled with sustained access to low-interest debt in North America is contributing to high valuations from both strategic and private equity acquirers.



Emergence of "Virtual" Pharmaceutical Clients

Virtual, or asset-light pharmaceutical companies have become increasingly prevalent in the FDA drug pipeline. These drug sponsor models utilize lean management teams, typically in partnership with venture and traditional pharma capital, with the goal of getting one or a small portfolio of drugs to market as quickly as possible. In exchange, these asset-light pharmaceutical sponsors must rely heavily on outsourced consultants, CROs, and CDMOs to carry most of the drug development workload. Past Big Pharma divestitures and downsizing initiatives have led to a surplus of experienced executives with the relationships to execute clinical development under the pressure of a high burn-rates and tight investment windows. These virtual pharmaceutical clients most often turn to vertically integrated or one-stop-shops for their CRO and CDMO contracting, with the goal of securing one or a few partner(s) from pre-clinical stages through commercialization.

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CDMO Consolidation Trends

Specialty & Niche Focused CDMOs

Contract development and manufacturing organizations have historically used acquisitions to double down on their core competencies. Strategic players typically often have utilized asset purchases from big pharma divestment, broken up by siloed segments like formulation development, API production, and early stage commercial manufacturing. best-in-class Many of these organizations benefitted from horizontally integrating segments like oral solid dosage, sterile and non-sterile liquid dosage, and infusibles. As the space has become increasingly commoditized due to technologic, competitive, and global pressures, CDMOs are leveraging capital partners to invest in technological efficiencies and expand C-suite capacity. Through these initiatives, middle-market CDMOs can differentiate themselves in the pursuit of valuable drug sponsor partnerships.

One-Stop-Shop Models

Large strategic consolidators are leveraging acquisitions to build vertically integrated,

marketable one-stop shop models, with the goal of locking in drug partnerships at the early stage clinical level. In 2017, Thermo Fisher Scientific completed its acquisition of U.S.-based Patheon, one of the largest global CDMOs, for \$7.2 Billion. While Thermo Fisher has historically focused on clinical trials and production services, the acquisition of Patheon has created the most complete end-to-end pharmaceutical services organization in the industry.

Closely-held, middle-market organizations have leveraged private equity capital to acquire complementary service providers and utilize operating expertise to create cohesive, targeted one-stop-shop models. Many of these private equity platforms are tailoring their expertise towards specific disease states, geographies, and service lines. Due to the stickiness of their contracts, middle-market CDMO's are uniquely positioned to capture small and mid-size pharmaceutical clients with a capital partner, and service these contracts for greater economic benefit.

Specialty CDMO Partnership Case Study	• As founder-owned, PCI Synthesis had established itself as the largest small-molecule CDMO in New England			
PCI 2018 NOVACAP HQ: Massachusetts HQ: France	 By partnering with European-based Novacap, PCI is positioned as the lead North American offering of a global strategic, with the ability to win and service more sophisticated contracts Post-deal, the PCI management team will continue operating in their roles, while PCI maintains autonomy as an independent subsidiary 			
Vertically-Integrated CDMO Partnership Case Study 2015 2018 Cambrex HQ: New Jersey SK CAPITAL HQ: New Jersey	 Halo Pharma had established itself as a technology- enabled CDMO, specializing in solid, semi-solid, and liquid dosage forms prior to partnering with SK Capital Due to SK Capital's past success in the space with six prior pharmaceutical CDMO portfolio investments, the management team of Halo maintained a minority position in the company Within 3 years, SK Capital sold Halo to Cambrex, with the goal of integrating Cambrex's API production with Halo's FDF capabilities 			

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CRO Consolidation Trends

Strategic consolidators have solidified significant market share in the CRO space, particularly in the latter half of this current credit cycle. Despite this, the diverse needs of drug companies as well as a plethora of new technologies impacting clinical and non-clinical development are motivators for CRO shareholders and the investor community to consider partnerships.

In the contract research space, Provident Healthcare Partners successfully represented Blue Sky Biotech in their private equity partnership with Boston-based Ampersand Ventures. Posttransaction, the General Partner for Ampersand Ventures joined Blue Sky as Chairman of the Board, allowing the management team to leverage his prior experience merging Primedica with Charles River Labs.

Within five years of the initial majority recapitalization, Ampersand Ventures sold Blue Sky to LakePharma, establishing the largest biologics-

focused CRO in the United States. The transaction allowed the existing management team, who had maintained significant equity in Blue Sky, to share in the equity appreciation the organization had accrued through the partnership with Ampersand.

CROs have established themselves as essential in the pharmaceutical continuum through operational efficiencies and regulatory expertise, which continues to attract investment. Mergers and acquisitions are a key lever in any CRO growth strategy, as no CRO has grown to \$100m in revenue organically in the past. Moving forward, Provident expects integration between CROs, traditional CDMO players, and other commercialization services to spur the next wave of consolidation. Given their early-stage focus and the previously mentioned stickiness of these partnerships, CROs are attractive acquisition targets for downstream service providers that are searching for competitive advantages in an increasingly commoditized space.



Despite the three largest contract research organizations controlling ~50% of global revenues, the CRO sector received unprecedented private equity investment and strategic interest as recently as 2016 and 2017, as formerly closely-held founder-owned businesses are utilizing growth capital to finance investment in emerging technologies, hire key management and staff, and compete for new drug sponsor partnerships.

Private equity and strategic interest in the space is expected to continue, credited to the record fundraising that early stage biotech and pharmaceutical start-ups have raised in the venture and angel capital markets in the latter stage of this current credit cycle (peaking in 2017). These highburn pharmaceutical start-ups rely on their CRO partners to minimize the time-to-market, while seamlessly transitioning drug development from early pre-clinical research and discovery to large scale production and commercialization.

Concluding Thoughts

Due to the continued growth of outsourced pharmaceutical services, an evolving early-stage drug landscape, and a history of successful partnerships, the CDMO and CRO industries will continue to be attractive opportunities for investment from both private equity and strategic consolidators. As global players leverage M&A to vertically integrate their offerings, private equity partners are actively seeking to invest in differentiated middle-market service providers, with the goal of expanding into new geographies and disease states.

To the extent that it is of interest, members of the Provident team would be happy to elaborate on any of these trends & provide specific insights on healthcare niches, specialties, and industry verticals. Please contact us at (617) 742-9800 for additional information.

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Appendix 1: Recent U.S. Based CRO & CDMO Transactions

Year	Acquirer	Target	٦	arget
fedi	Acquirer	Target	Sub-Sector	Enterprise Value
2019	Ampersand Capital Partners	Vibalogics	CDMO	N/A
2019	Evotec	Biotherapeutics	CDMO	\$90M
2019	Navitas Life Sciences	KAI Research	CRO	\$27M
2019	WuXi Clinical	Pharmapace	CRO	N/A
2019	Bioanalytical Systems	Smithers Avanza Services (CRO Division)	CDMO	\$1.5M
2019	Advent International	BioDuro	CRO	N/A
2018	Cambrex Corporation	Halo Pharma	CDMO	\$425M
2018	Madison Dearborn Partners	Alcami Corporation	CDMO	N/A
2018	SK Group	AMPAC Fine Chemicals	CDMO	N/A
2018	Tropichem Research Labs	TetraGenx	CDMO	N/A
2018	Cambrex Corporation	Avista	CDMO	\$250M
2018	Novacap	PCI Synthesis	CDMO	N/A
2018	The Carlyle Group	Ambio	CDMO	N/A
2018	Nautic Partners	Mikart	CDMO	N/A
2018	Catalent	Juniper Pharmaceuticals	CDMO	\$130M
2018	LSNE	PSC Biotech	CDMO	N/A
2017	The Carlyle Group, HarbourVest Partners, GTCR	Albany Molecular Research	CRO	\$925M
2017	Catalent	Cook Pharmica	CRO	\$950M
2017	Pamplona Capital Management	Parexel International	CRO	\$5B
2017	LabCorp	Chiltern	CRO	\$1.2B
2017	Inc. Research	InVentiv Health	CRO	\$4.6B
2017	PRA Health Sciences	Symphony Health Solutions	CRO	\$530M



Provident is the leading investment banking firm specializing in merger and acquisition advisory, strategic planning, and capital formation for middle-market and emerging growth healthcare companies.

The firm has a vast network of senior industry relationships, a thorough knowledge of market sectors and specialties, and unsurpassed experience and insight into the investment banking process.

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