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The pharma outsourcing market promises robust and attractive growth although with differences in growth rate and profitability by market segment. Are there differentiating strategies to capture the growth of the pharma contract manufacturing market? How can pharmaceutical companies take advantage of the on-going consolidation?

About growth and strategies in the CDMO business

"The whole is greater than the sum of its parts."

Aristotle's quote finds some resonance when it comes to assessing the global market for pharmaceutical outsourcing. Adding the sales estimates of the contract development manufacturing organizations (CDMOs) and contract research organizations (CROs) results in a market size greater than USD 120 billion, but it is likely far from reflecting its full potential. For 2017, the contract manufacturing alone is estimated at about USD 70-75 billion including clinical supplies, Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs). The share of the API contract manufacturing (merchant) market is roughly USD 50 billion which is still less than 40% of the global synthetic APIs market, comprising advanced intermediates and chemically synthesized APIs. Indeed, captive use, i.e. pharmaceutical companies' production for their own needs, still accounts for a larger proportion of total API supply. At a time when larger pharmaceutical companies are focusing on reducing their operational expenses and prioritizing capital investments on their most innovative products, this in-house capacity represents in itself a large reservoir adding to the growth potential of the CDMO industry.

Additional factors providing a solid foundation for growth include worldwide improvement in access to medicines, in particular for generic drugs. Innovative and targeted therapies constitute another growth driver and not only for larger molecules. For instance, the small molecules API market benefits from favorable dynamics fueled by strong drug approval rates by the FDA (46 novel drugs including 34 small molecules in 2017), an increasing number of

molecules in clinical phases and increasing outsourcing by the pharmaceutical companies.

These factors contribute to promising growth of 6% to 7% per year across all geographies resulting in outsourced manufacturing valued at above USD 100 billion by 2022.

Capturing the value in CDMO services

The main three segments in the CDMO value chain present different growth patterns; For companies such as Patheon, Lonza or AMRI, the revenue growth rates range:

- single digit for conventional FDFs (e.g. tablets), as opposed to
- between 10% and 20% for drug development services, or
- between 15% and 25% for more complex FDFs (e.g. injectables) and API production.

However, any assessment of the profitability requires a finer sub-segmentation.

For instance, the API market attractiveness is a result of the increasing global API demand and the limited number of CMOs with differentiated capabilities, capacity and scale. On the one hand, large volume businesses – typically commodity APIs mainly exported from Asia - return lower margins (3% to 4%). On the other hand, custom synthesis is a much more profitable business based on the exclusive know-how of the supplier, often integrated with contract research and drug discovery activity for innovative APIs. Many European API manufacturers enjoy 20% to 25% EBITDA margin. High-Potency APIs is another very valuable segment but also very demanding, process-wise, due to stringent containment requirements.

Similarly, in the FDF segment, the CDMOs which have followed a value-driven strategy (versus a volume approach) by adding services or investing in more complex technologies deliver higher returns (e.g. Catalent).

How can CDMOs achieve differentiation?

The last 12 months have seen a series of capital investment and acquisition announcements aiming at realizing differentiating strategies, such as gaining scale, establishing a specialist position or vertically integrating to offer a one-stop-shop.

Gaining scale

Successfully gaining scale requires outstanding execution. Lean initiatives throughout the organization are needed to achieve operational excellence, reduced complexity and competitive costs per unit. More conventional technologies may be adequate vehicles for growth as long as the entire organization shares this excellence mindset (e.g. commercial teams bring in relevant scalable volumes and manufacturing teams maximize capacity outputs with low waste levels). Another component of this strategy is geographic expansion, but under the condition of getting sufficient critical mass. We estimate the minimum revenue per FDF site should be at least USD 50 million in order to leverage economies of scale – and at USD 30 million for an API site. This seems to be the strategic path followed by Avara Pharmaceutical Services, a fairly recent entrant into the CDMO market which has built its network over the last three years by acquiring businesses from Big Pharma such as UCB, Astra Zeneca and Pfizer. Its latest acquisition is the largest sterile manufacturing facility for injectable medicines in Canada from SANDOZ as part of a continuing expansion of its global footprint.

Establishing a "specialist" position

Developing expertise in selected advanced technologies usually leads to higher profitability as illustrated by specialized API CMOs (e.g. steroids or hormones) which exhibit higher EBITDA margin, typically in the 20% to 25% range.

On the FDF CMO side, Recipharm's Solids and Others segment delivers 15.2% EBITDA margin when, in comparison, its Sterile Liquids segment including vials and ampoules, lyophilizates and blow-fill-seal products delivers close to 20%. Its Sterile Liquid segment is built on technology-driven acquisitions such as Nitin Lifesciences, Corvette Pharmaceuticals, Mitim or Alcon's Kaysersberg plant.

Is there a sweet spot? A significant proportion

of new drugs in development are targeting more specialized medicines, with immuno-oncology being an area of intense activity. Hence, combining development capabilities, High Potency API production and sterile liquid formulation dosages is certainly an attractive playground.

Offering a one-stop-shop

This model requires vertical integration and is limited to the major players and consolidators:

The acquisition of Capsugel was a major milestone in LONZA Pharma&Biotech's strategic plan to become a provider of one-stop-shop services and solutions for its customers. The takeover of Micro-Macinazione is complementing its micronization capabilities to meet the growing demand for improved bioavailability and efficacy of drug products.

Similarly, Catalent's USD 133 million deal for Juniper Pharmaceutical further supports its strategic goal to be the most comprehensive partner for pharmaceutical innovators adding high-end, fee-for-service development and clinical trials manufacturing to its offering.

The one-stop-shop model seems clearly beneficial to smaller biotechs and virtual pharma companies with biologics needs. Big pharmaceutical companies, in which development and procurement teams usually follow different reporting lines, remain to be convinced.

Pharma companies may take advantage of the players' M&A appetite

The last five years have seen the emergence of larger players through consolidation or acquisition of pharma sites: Aenova or Catalent have favored targeting CDMOs as illustrated by Catalent's acquisition of Cook Pharmica. Delpharm, Famar, Corden, Patheon or more recently Avara have been identified as the usual suspects when it comes to bidding for Pharma divestments. The M&A activity remains intense for FDFs capabilities as illustrated by Recipharm's recent acquisition of Sanofi's inhalation business. There have been fewer divestments in the API area, but a consolidation is also taking place in that segment driven by European-based companies backed by private equity groups: Spanish Suanfarma, Italian P&R Holding (including Olon and Fidia with sales above EUR 750 m) or French Novacap (reaching sales of USD 1 billion since the acquisition of PCAS and PCI Synthesis).

In addition, we observe an increasing interest for both facilities and products of credible Korean, Chinese and Indian CMOs or generic companies as well as other associations of western financial investors supported by operating vehicles, all pursuing a strategy to become integrated generic companies.

As the larger pharma companies reshuffle their product portfolio to focus on selected therapeutic areas, they also prioritize in-house investments on their most innovative products, e.g. Novartis with its investment into a cell- and gene-therapy manufacturing unit at their site in Stein, Switzerland.

The pharma companies can benefit by divesting manufacturing operations together with products before their patent expiry. This requires internal competencies to better manage product lifecycle, anticipate capacity planning and to engage early enough in a transaction process. Many larger pharma companies clearly state that acting as a CMO does not fit with their strategy and recognize the divestment decision is still a tough one. The valuation expectations need to account for many variables: the commercial long-term landscape, future CAPEX constraints, operational efficiency in comparison to best-in class and true market value of the assets. It also requires M&A advisory that not only masters the transaction process from carving-out to closing but as importantly understands the full span of the value chain and achievable synergies.

Kurmann Partners will be attending the CPhI in Madrid from October 9th to 11th, 2018 and we will be pleased to exchange views on the market.

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