OUTSOURCED PHARMACEUTICAL MANUFACTURING 2020

Current trends & future prospects

November 2019
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>3</td>
</tr>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Pharmaceutical sector overview</td>
<td>6</td>
</tr>
<tr>
<td>CDMO market overview</td>
<td>8</td>
</tr>
<tr>
<td>Key players &amp; market evolution</td>
<td>13</td>
</tr>
<tr>
<td>M&amp;A activity and industry developments</td>
<td>15</td>
</tr>
<tr>
<td>Concluding remarks</td>
<td>20</td>
</tr>
<tr>
<td>Glossary</td>
<td>21</td>
</tr>
<tr>
<td>Results Healthcare at a glance</td>
<td>22</td>
</tr>
</tbody>
</table>
I am pleased to introduce you to our 2020 review of the outsourced manufacturing sector, where we take a refreshed look at key trends in the industry, the state of the market today and outlook over the next few years. Since publishing our last review at the beginning of 2017, we have witnessed an exciting period of continued growth and evolution and this momentum is set to continue, as the trend towards further outsourcing of development and manufacturing services continues.

Despite concerns around the global political and economic landscape, the pharmaceutical sector appears in rude health, supported by clinical pipeline with a record number of new molecular entities in development. With cell and gene therapies finally making it to market over the past couple of years and providing real-life benefits to patients, the viral vector manufacturing market is expected to be the fastest growing segment of the CDMO industry. Consequently, the space is receiving considerable attention from industry players and two of the highest profile acquisitions of 2019 were of viral vector manufacturers.

On the corporate development side, we have witnessed an intense period of M&A activity. Both strategic buyers and private equity are highly active in the space and are competing fiercely for scale and differentiated assets with the highest value creation potential. This has driven private company valuations to all-time highs, making it a potentially exciting time for owners and investors considering a sale of their business.

At Results Healthcare we have been exceptionally busy, advising on a number of transactions in the CDMO sector. Most notable were the acquisition of Sterling Pharma by GHO (we advised GHO) and the sale of Sanofi’s UK CMO business to Recipharm (we advised Sanofi).

Looking towards the future, we believe that the fundamental drivers of the sector remain positive and deal activity and valuations are likely to continue at current levels, which will create substantial opportunities for M&A and other corporate development activities.

Warm regards,

Kevin Bottomley
Healthcare Partner

www.resultshealthcare.com
Introduction

Contract development and manufacturing organisations (CDMOs) provide highly valuable services to the pharmaceutical and biotech industry by offering additional development and manufacturing capacity, access to specialty capabilities and potential cost advantages over in-house manufacturing. The CDMO industry provides a broad set of services such as product development and characterisation, clinical and commercial manufacturing of API and drug products including final packaging, as well as a range of ancillary services such as clinical logistics and distribution, CMC (chemistry, manufacturing and controls) and regulatory support.

Over the past couple of decades, there has been a significant trend among pharma companies to increase the amount of discovery, development and manufacturing work that they outsource. It can be an effective way of reducing capital costs and gaining access to capacity and capabilities that are not available in-house.

However, the drive to outsource is not the same in all parts of the biopharma market. Small biotechs are often reliant on a CDMO to make their development products as they move through the pipeline. They rarely have the technical know-how and manufacturing capabilities to do this themselves, and the cost of building these is prohibitive both from a time and cash perspective, for a company with no revenue stream that is reliant on investment capital.

For a big pharma company, considerations are different, and will often depend on the type of product that is being made. Small molecule APIs are far more likely to be outsourced than biologics as, generally speaking, they are easier to manufacture, and tech transfer is more straightforward. There is, therefore, more trust that a CDMO will be capable of manufacturing it efficiently and in the required quality and timescale. Furthermore, pharma companies will also often dual source APIs for key products to ensure security of supply and may chose a CDMO as the second supply source. There is also enough capacity for standard small molecule manufacturing available in the market and from a price standpoint, contract manufacturers provide an attractive offering.

Biologics pose a different challenge to small molecules. Being much more technologically complex to make, there is a lot less price sensitivity. Although start-up biotechs are still outsourcing heavily, there is a tendency for big pharma to want to keep biologics API manufacturing in-house, not least because of the IP attached to cell strains and the manufacturing process. There are also significantly more concerns about quality and supply certainty for such complex, high-value APIs, where products can generate large profits.

Overall, we see a strong correlation between size of the company and likelihood to outsource. In 2017, manufacturing of only 20% of newly approved drugs was outsourced by big pharma. This increases to c. 80% of all manufacturing being contracted out by small biotech/pharma and all 15 newly approved drugs in 2017 owned by small companies were supplied by CDMOs. Consequently, small- and medium-sized companies (SMEs) generally form most customers for contract manufacturers, although they do not necessarily represent the majority share of revenue.

Big pharma in particular is now looking to consolidate their supplier base and form deeper ‘strategic partnership’ relationships with suppliers. Much of the driver here is to reduce complexity. There are examples of big pharma companies with as many as several hundred different CDMO suppliers, many added as a result of company and product M&A activity in the pharma sector which continues at a rate that makes supplier

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1. J. Miller, PharmSource, Contract Manufacturing Outlook, CPhI 2017
consolidation slow and complex. The logistical challenges are evident and reducing this number would represent a significant simplification of the supply chain.

This has led to several of the larger players in the market looking to extend their capabilities into a wider spectrum of the development pipeline, and M&A in the sector is buoyant. Companies such as Catalent, Lonza and Recipharm are pursuing a one-stop-shop model by offering services from early development right through to secondary manufacturing. This is being achieved partly via organic growth, but largely via acquisition. Market share is bought in to increase critical mass, and niche players purchased to expand capabilities into new areas.

Continued strong growth is anticipated in the CDMO market, mirroring growth in the underlying pharmaceutical market, as well as the increasing drive towards outsourcing, with the majority of pharma companies across all sizes expecting to increasingly use outsourced manufacturing services in the coming years. As a result, CDMOs are investing in capabilities and capacities ahead of time, in anticipation of future demands.

Another trend in the CDMO sector that we are increasingly seeing is blurring of the boundary between CROs and CDMOs. CROs are starting to realise that, having carried out a molecule's characterisation, it is a small leap into formulation development, and on to pre-clinical and early-phase clinical manufacturing. This is particularly the case in the biologics, cell and gene therapy sectors, where highly specialised development expertise is closely linked to manufacturing capabilities. SME customers are the key target demographic for such integrated services as there is an advantage of time and cost savings, arising from a significant reduction in tech transfer requirements.

Perhaps the biggest company to have gone in this direction is WuXi. Quotient is another example of a CDMO that combines formulation development and clinical development capabilities of small molecule APIs with phase I clinical support capabilities and CRO Eurofins acquired Amatsigoups in 2017 to gain manufacturing capabilities.

The one-stop-shop model is particularly attractive for SMEs with limited manufacturing capabilities and companies pursuing a virtual business model, as a single outsourcing partner will take care of much of their development and scale-up work, reduce pipeline risk and increase operating flexibility. However, this model may not work as effectively for a big pharma company, because of the way procurement operates in a large company with various budget holders and decision makers.

The pharmaceutical market continues to grow well, despite considerable political turmoil that is currently affecting the wider world economy. The Trump trade war against China and chaos of the Brexit process in the UK are both creating market uncertainty. However, the pharmaceutical industry tends to operate on longer timelines than the political cycles of four or five years, and the fundamentals of the business remain solid and confidence in future performance remains high.

The CDMO sector is currently outperforming global GDP growth by around three percentage points. We predict the total commercial and clinical CDMO market to grow by c. 6.8% CAGR until 2023, while global GDP is set to increase by c. 3.5% in the near term. This higher growth rate is a good indicator that the sector is in robust shape.
Pharmaceutical sector overview

- Global pharmaceutical sector will reach $1.52tr in annual sales in 2023, driven by fundamentals including global economic growth, a growing and ageing population and new product launches.
- Large molecule drugs (biologics, biosimilars and cell & gene therapies) are the fastest growing sectors, but small molecules will continue to have the largest market share in 2023.
- Oncology is the largest and fastest growing therapeutic area.

The total size of the pharmaceutical market is expected to reach c. $1,250bn in 2019 and grow at a CAGR of 4.9% to $1,516bn in 2023. This represents an absolute growth of $266bn from 2020 to 2023 and provides the basis for the ongoing expansion drive in the CDMO sector.

However, this overall growth figure masks diverging projections for different sectors of the pharma business. About 78% of the total pharmaceutical market in 2019 comprised small molecule drugs, split between prescription drugs marketed by its originator, generics and over-the-counter (OTC) products. In total, we estimate the small molecule segment of the market to increase by $133bn over the next four years.

Small molecules will remain the largest pharma market segment.

The largest of these sectors by value, clearly, is originator prescription drugs (drugs under patent and generics sold by the originator under the original brand name). With 2019 sales of $613bn, these high-margin products represent just under half of the overall pharma market. This may be the largest individual sector, but it is also the smallest growing in percentage terms with expected growth of c. $44bn to an overall total of $657bn in 2023, is a CAGR of only 2.0%.

Generics are growing three times as quickly; a CAGR of 6.0% will take the total market from $232bn in 2019 to $293bn in 2023. At 5.0% CAGR, an increase of $28bn is projected for OTCs, taking the sector from $132bn in 2019 to $160bn in 2023.

Much faster growth is expected to be experienced in the large molecules market, although volumes are significantly smaller. Absolute growth in the large molecules market, including both originator biologics, biosimilars and cell and gene therapies, is projected to be $133bn until 2023, in line with the absolute increase that is anticipated for the small molecule market. In 2023, we predict its market share to top 25%, up from the current 20% and only 17% in 2015.

The market size for originator biologics in 2019 is estimated to reach $262bn. With a CAGR of 9.1%, this is projected to rise to $371bn by 2023, representing an increase in market size of $109bn. This growth rate is dwarfed by that anticipated for biosimilars as market take-up escalates, particularly in the US (see our previous whitepaper Biosimilars – Prospects and challenges; resultshealthcare.com/insight/biosimilars-prospects-and-challenges/). From a low base of $7.8bn in 2019, a CAGR of 33.7% means the market should reach $25bn in 2023. This more than tripling in per annum sales provides a market increase of $17bn. However, despite this significant growth rate, the low base level means it will remain a small part of the pharmaceutical market, with just 1.6% of total sales in 2023.

IQVIA, 2018 and Beyond: Outlook and Turning Points
Whilst biosimilars has been the most eagerly followed new segment of the pharmaceutical market over the past 5 years, this honour now lies squarely with cell and gene therapies. We estimate the market to reach c. $2.6bn in 2019 and grow at a CAGR of over 40% to $10.3bn in 2023. Despite the significant growth curve, absolute market growth remains modest over the near term, as products continue to make their way through the early clinical development pipeline towards commercial launch and so cell and gene therapy products will still command less than 1% of the total pharmaceutical market by 2023. Nonetheless pharma is clearly viewing this space as a key future growth driver, as new technologies allow for ground-breaking scientific advances to treat currently incurable conditions. Unsurprisingly, this is an area of intense investment for pharma through in-house R&D spend, venture capital, M&A and introduction of captive production capacity – key technologies are stem cell therapies, chimeric antigen receptor (CAR) T-cell therapies and gene editing technologies.

The current size of the market is brought into context when considering that currently only nine cell and gene therapy products are approved by the FDA (excluding haematopoietic progenitor cell (HPC) transplants, a long-established treatment for blood cancers). Recent high-profile gene therapy launches have been Spark Therapeutic’s Luxturna for the treatment of retinal degeneration in 2017, the first gene therapy product approved in the US and AveXis’ (now Novartis) Zolgensma for the treatment of spinal muscular atrophy in paediatric patients with a price tag of over $2m. Key cell therapy products include Provenge (prostate cancer), Yescarta (B-cell lymphoma) and Kymriah (acute lymphoblastic Leukaemia), all of which are achieving annual sales of $250m or more.

The significant growth expectations for the market are supported by a strong clinical pipeline with over 1,000 clinical trials currently listed on clinicaltrials.gov across a broad range of therapeutic areas, with oncology commanding a c. 50% share. Given the current state of the development pipeline and level of R&D investment, the FDA is expecting to approve 10 to 20 new cell and gene therapies annually from 2025.

In terms of therapeutic areas, oncology is the standout market in sales terms, generating an eighth of all pharmaceutical market revenues in 2017. It is set to experience double-digit growth in percentage terms in the next five years and will expand its market share to account for more than a sixth of industry revenues by 2024. Cancer therapies are driving a large proportion of growth in the biologics market and also in the highly potent API (HPAPI) sub-sector.

Looking to the future, despite the hype around large molecules, small molecule drug approvals still outweigh biologics – in 2018, the FDA approved 42 new small molecule products, and just 17 biologics. The number of biologic approvals has, however, been increasing steadily over the past few years, which is reflected in the expected strong commercial market performance (see Table 1). Whilst the clinical pipeline is expected to grow across all molecule types, biologics are set to increase their share of the total clinical pipeline from currently c. 33% to over 50% in the next 5 years.

### Approvals of new biologic drugs are increasing

<table>
<thead>
<tr>
<th>Molecule</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
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<tbody>
<tr>
<td>Small molecule (NDA)</td>
<td>13</td>
<td>34</td>
<td>42</td>
</tr>
<tr>
<td>% of total approvals</td>
<td>59%</td>
<td>74%</td>
<td>71%</td>
</tr>
<tr>
<td>Biologic (BLA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of total approvals</td>
<td>32%</td>
<td>26%</td>
<td>29%</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>% of total approvals</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total NMEs approved</td>
<td>22</td>
<td>46</td>
<td>59</td>
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**Table 1** New chemical entity approvals by the FDA (2016-2018)

Although there is much talk about the prospects for both biologics, biosimilars and cell & gene therapy products and the large molecule market is growing more quickly across all areas, the small molecule market will continue to represent the largest share of the total market by quite some margin with c. 73% market share retained in 2023. However, both large and small molecules are expected to deliver the same share of absolute pharma market growth over the period.
CDMO market overview

- We estimate the total contract development and manufacturing market at $90.0bn in 2019, growing to $117.3bn in 2023 at a CAGR of 6.8%
- Clinical trial services, including clinical manufacturing only represent c. 12% of the total market, but are strategically key to locking in products early in their life cycle
- Small molecule manufacturing is c. 91% of the commercial contract manufacturing market and will provide the largest share of absolute growth to 2023

Our most recent market analysis performed for this report estimates that the CDMO market will reach a size of c. $90bn in 2019. We predict the overall sector to grow to $117.3bn in 2023 at a CAGR of 6.8%, outpacing growth in the underlying pharmaceutical market. Consequently, penetration of the CDMO market is set to increase modestly from 26% in 2019 to 28% in 2023. This evolution is driven by an increasing incidence of drug development and manufacturing outsourcing by pharma and biotech companies and ongoing divestment of non-core manufacturing facilities, which add both capacity and new outsourced products into the sector (see section M&A activity and industry developments for further information).

Overall manufacturing market penetration reached 26% in 2019 and will continue to increase over the forecast period

![Figure 2 Market penetration of the outsourced manufacturing sector](image)

In our analysis, we have segmented the market into clinical and commercial services. Our definition of the clinical market includes three distinct service areas: clinical trial manufacturing (CTM) of APIs and drug products and non-manufacturing services such as clinical trial logistics and distribution services and drug development and CMC (chemistry, manufacturing, controls) services, as these are commonly provided by CDMOs to clients during the clinical development stage. The commercial market is divided into generic small molecule, originator small molecule and biologics (including biosimilars and viral vectors) markets, which are then further sub-divided into their respective API and drug product manufacturing sub-sectors (Figure 3).

We estimate the total addressable market for CDMO services is about $341bn in 2019 (pure-play manufacturing component of $328bn). The potential for CDMO companies to expand their business is therefore significant, and current outsourcing levels leave substantial scope for CDMOs to increase market penetration.

In order to satisfy the increasing demand for outsourced manufacturing services, CDMOs continue to heavily invest capital in the expansion of capacity to drive growth, especially in areas of the market where there are capacity bottlenecks.

The global outsourced manufacturing market is forecast to reach $90bn in 2019

![Figure 3 Breakdown of the global outsourced manufacturing market by sub-sector](image)

12 Results Healthcare analysis of the CDMO sector
13 Excludes other non-manufacturing clinical services such as CMC and logistics and distribution
The likelihood of a project being outsourced very much depends on originator scale. In 2017, just 20% of newly approved drugs were outsourced by big pharma, whereas about 80% of manufacturing for small companies was outsourced, including all 15 newly approved products in 2017. Small- and medium-sized companies therefore often dominate the customer list for CDMOs.

Commercial vs clinical

The lion’s share of the total CDMO market – nearly 90% – comprises the commercial market. Pre-clinical and clinical manufacturing, plus associated development and logistics services, together clinical trial services (CTS), comprise the remaining c. 12% of the market. Clinical trial manufacturing (CTM) including clinical packaging and labelling is currently the largest sub-sector within clinical trial services at $60bn market size (split approximately into 2/3 API and 1/3 drug product). The clinical market is expected to grow at a CAGR of 6.9% to 2023, driven by a record number of molecules across all types in the pre-clinical and clinical development pipeline and increasing R&D spend.14

The CTS sector is already the most highly penetrated market by CDMOs (along with commercial small molecule API) at c. 35% and we expect this to increase to 40% in 2023, as the biopharma industry continues its shift towards greater outsourcing during the volatile and high-risk drug development phase. Given CROs have already achieved a market penetration in excess of 50%, there is clearly further scope for CDMOs to gain market share beyond the 5-year horizon.15 Although the total CTS market is relatively small, operating in this sector allows the ’lock-in’ of supply contracts at an early stage in the product life cycle, making it a progressively more important part of the commercial strategy of many CDMOs.

The commercial manufacturing market, which includes small molecule and biologics manufacturing, will reach $76.9bn market size in 2019 and continue to grow at a CAGR of 6.8% to 2023. Biologic and small molecule API production currently generates c. 63% of commercial CDMO revenues, which is not surprising when considering that APIs are a larger portion of drug cost-of-goods compared to the drug product manufacturing process. The API market is also more strongly penetrated by CDMOs than the drug product market, with almost 30% of all API production (largely driven by small molecule API) outsourced compared to only 22% of drug product manufacturing.

Biologics vs small molecules

Biologics API and drug product manufacturing currently represents just under 13% of the total commercial contract manufacturing sector. Although the sub-sector is growing strongly at c. 10% CAGR to 2023, biologics will remain a relatively minor part of the CDMO sector, with small molecule manufacturing delivering most of the absolute growth over the next 5 years (Figure 5).

Cost-of-goods for a biological API is far higher than it is for the drug product because of the technically challenging and capital-intensive nature of the API development and manufacturing process. About three-quarters of the revenue from biologics outsourcing comes from API production, and CDMOs are therefore investing heavily in this area to expand capacity.

An interesting observation within the biologics API manufacturing space is that, although the sector is growing strongly, we expect market penetration to decrease from currently c. 12% to closer to 11% by 2023 – the only CDMO sub-sector where this is the case. The reasons for this development become clear when looking at big pharma’s attitude towards biologics API manufacturing. Biologic drugs are high value, high margin products and so pharma companies are particularly focussed on security of supply. Retaining oversight over the most technically challenging part of the manufacturing process allows companies to ensure quality and regulatory compliance of supply, with cost being less of a concern than for lower margin small molecule products. IP protection of proprietary cell strains and manufacturing processes is also a consideration that is playing into a higher propensity to keep the API manufacturing process in-house. As a result of this strategy, the top-25 pharma companies have invested north of $100bn in captive manufacturing capacity over the past decade, mostly for biologics API production and far outstripping investment capabilities of CDMOs.

Market penetration for biologics drug product outsourcing is also low at less than 15%. However, fuelled by a CAGR of over 13% to 2023, we expect this to increase moderately over the next five years, as pharma companies are more comfortable with outsourcing the less technologically challenging and IP-dependent drug product part of the manufacturing process.

Biologics are also a major growth driver for the highly potent API (HPAPI) manufacturing market. HPAPIs are those molecules that have very high cytotoxic properties, such as monoclonal antibody-drug conjugates, and thus require special containment facilities in order to protect operators from exposure. Approximately 60% of all oncology drugs are classified as highly potent and so we estimate the HPAPI contract manufacturing

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14 Evaluate Pharma, 2018
15 Results Healthcare, CRO Sector M&A drivers and market trends, 2019
market to hold a c. 13% market share of the commercial API manufacturing market and expect strong growth at a CAGR of 8-9%. Capabilities to handle HPAPIs in dedicated suites are thus in strong demand (both for the API and drug product manufacturing stages) and the industry as a whole has been investing in containment capabilities to facilitate HPAPI production.

Although growing quickly, the biologics market lags behind small molecules in terms of absolute size and market penetration.

Small molecules are responsible for over 90% of the revenue of the total commercial manufacturing market in 2019. Although this segment is expected to grow more modestly than biologics, it will remain by far the largest market for the foreseeable future.

Inversely to the biologics market, outsourced small molecule API manufacturing has a considerably higher level of market penetration than the small molecule drug product space (34% vs. 22%). This is driven by stronger commercial pricing pressures on small molecule drugs compared to biologics which, combined with the lower technological manufacturing hurdles, leads pharma companies to select CDMO suppliers that provide cost advantages over in-house manufacturing more frequently. Both sub-sectors are however expected to grow at 6.5-7% CAGR to 2023 and increase market penetration by 2-3 percentage points over the period.

Despite the current focus on large molecule manufacturing, both from a capital investment and M&A strategy, small molecule API manufacturing represents over 50% of the commercial CDMO market (split approximately evenly between originator and generic molecules at $22bn market size each). Therefore, and despite slower growth than other sub-sectors, small molecule APIs will provide almost 50% of the absolute CDMO sector growth until 2023 (Figure 5).
Originator products vs generics

An important consideration to make when evaluating the size and growth of the CDMO market is the impact of manufacturing volumes rather than value and its dissociation from the end market commercial pharmaceutical sales. Whilst overall commercial sales of a product can be grown in part through price increases as well as increased market share, the CDMO sector is dependent on service derived sales from manufacturing volumes to drive its growth.

A good example of this phenomenon is the difference between the generic pharmaceutical and generic CDMO markets. In volume terms, generic products are estimated to represent nearly 90% of drugs dispensed but only generate less than 20% of pharmaceutical market sales. For the CDMO sector however, generics generate a similar level of commercial revenue to small molecule originator products ($36.4bn and $35.8bn respectively at similar market penetration), meaning generics contribute c. 46% of commercial CDMO sector revenue. This means that generics will provide 40% or $12bn of absolute market growth until 2023, driven by an expected loss of $71bn in originator drug sales to generics and biosimilars as products come off-patent. CDMO revenue from manufacturing is less dependent on the end market of the product, but volume demand for generics can be less stable, as product switching resulting from bundling and tender bids and price discounting can have a mid-term impact on volume demand.

Cell & gene therapy

The cell and gene therapy market, including the manufacture of viral vectors, remains a very small fraction of the overall market, with only a handful of products having been approved. However, this is an area of increasing focus for clinical and pre-clinical research and there is substantial ongoing investment in outsourcing capacity in anticipation of future demand, as well as in in-house capacity at pharma companies who are developing these complex advanced therapeutics.

The viral vector and DNA plasmid contract manufacturing space is estimated at c. $650m in 2019 and growing at c. 20% CAGR until 2023 to reach a market size of $1.36bn. Near-term growth will largely be driven by a growing clinical pipeline, rather than commercial projects and sector growth will be constrained by manufacturing capacity rather than demand, with some estimates putting the current capacity shortage at 5-times total demand, a situation that could worsen going forward.

Current manufacturing capacity is largely at phase II and III clinical scale, with both CDMOs and pharma slowly catching up with R&D to build commercial scale capacity. Manufacturing currently presents a significant hurdle to commercialisation of cell and gene therapy products, as the complexities of manufacturing processes make consistent production output at commercial scale highly challenging. Pharma companies have been investing hundreds of millions in new cell and gene therapy production facilities, such as Pfizer’s $500m investment into a new gene therapy facility in North Carolina and GSK’s $120m investment in a new advanced therapies site.

A good indicator of the high technological barriers to entry into the cell and gene therapy market and value of these rare skills, is the acquisition of CDMO CellforCure by Novartis in early 2019 in order to bring the manufacturing of Novartis’ approved CAR-T cell therapy product Kymriah in-house and strengthen its manufacturing capabilities in the space. Other notable investments in the sector have been the acquisition of Brammer Bio and Paragon Bioservices at record valuations in 2019 by leading CDMO players. The two acquired companies were two of the largest players in the viral vector manufacturing space with a combined revenue of c. $450m and a combined market share of c. two-thirds.

Market penetration is at around 65% – largely driven by small biopharma with assets in clinical development, which provides a good case study for the value of the CDMO sector to accelerating the development of new products, through faster speed to market, where smaller companies do not have or are not able to acquire the technical skills and capacity to perform complex manufacturing processes.

The size of the cell therapy contract manufacturing market is currently difficult to assess but we estimate it to be in the tens of millions with less than 50 companies currently possessing cell therapy contract manufacturing capabilities.

The global cell and gene therapy market is only in its infancy but is expected to more than triple by 2023 and continue to accelerate from there. The CDMO industry clearly sees huge future potential for this market and is starting to make this a focus of its investment and expansion strategy.

Drug product manufacturing

We estimate that the total drug product manufacturing sector (including clinical and commercial) at c. $32bn in 2019, a 35% share of the total CDMO market. Product types can be broken down into oral solid doses (OSD), sterile filled/injectable products, LOC products, including non-sterile liquids, ointments, creams and semisolids, and finally a small group of other more device-led products such as inhalers, implants and transdermal patches.

The OSD manufacturing sector continues to be the largest market at almost 50% market share. The sector is however quite mature and thus growing at a slower rate than other segments
and we expect market share to decrease to below 40% of the commercial drug product market by 2023. Driven by the growth in biologics, injectables manufacturing is the fastest growing drug product sector at 10.5% CAGR until 2023 and will also contribute the largest share of absolute growth to the market with $3.2bn. Breaking this segment down further, pre-filled syringes is the fastest growing sub-sector at c. 13% CAGR and leading to the generation of nearly 77% of sterile manufacturing revenue by 2023. The large share of sub-sector revenues is however not generated through increased manufacturing volumes over ampoule or vial manufacturing but rather the larger unit cost of pre-filled syringes. For LOC manufacturing, which contributes c. 19% of drug product sector revenue today, the growth shown in Figure 6 is mostly driven by OTC and generic products.

**Geographic distribution of the market**

Breaking down the CDMO market geographically by product demand (i.e. where customers are located and product is supplied to, rather than where product are manufactured), North America is the largest geography with c. 37% market share, followed by Europe at 25%. Notably, the EU5 countries account for c. 80% of demand within the European market. We expect both markets to grow at mid-single digit percentage points.

Japan is the least penetrated market amongst developed nations. Due to strict regulations in place until 2005, limiting the manufacturing tasks that could be outsourced, the majority of pharmaceutical manufacturing, packaging and market release is still performed in-house. Despite a relaxation of these regulations, a domestic CDMO market has been slow to emerge and most major pharma companies continue to be present in the market with an oversupply of capacity. Although the underlying pharmaceutical market in Japan is expected to remain relatively stagnant over the period to 2023, we can expect the CDMO market to maintain the growth we have observed since 2005, although at a slower rate than other developed nations.

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**Figure 6** Outsourced commercial drug product manufacturing sector by dosage form – bubble size indicates absolute growth from 2019 to 2023
The global CDMO market is highly fragmented with our estimates suggesting that over 1,000 companies are active in the sector as either pureplay CDMOs or companies with some CDMO services or capabilities. There are approximately 20 CDMO businesses generating in excess of $500m revenue and the top 10 players hold less than 20% total market share (Table 2). Ownership of leading companies is a mixture of public, private and private equity backed companies, with a clear bias towards European head quartered CDMOs amongst the largest players. Lonza remains the world’s largest CDMO at over twice the size of its closest competitor Catalent.

<table>
<thead>
<tr>
<th>Top 10 CDMOs by revenue (2018)</th>
<th>2018 revenue ($m)</th>
<th>HQ</th>
<th>Ownership</th>
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<tbody>
<tr>
<td>Lonza</td>
<td>5,901</td>
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<td>Public</td>
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<tr>
<td>Catalent</td>
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</tr>
<tr>
<td>Jubilant LS</td>
<td>1,217</td>
<td></td>
<td>Public</td>
</tr>
<tr>
<td>Aenova</td>
<td>960</td>
<td></td>
<td>Private (PE backed)</td>
</tr>
<tr>
<td>Siegfried</td>
<td>810</td>
<td></td>
<td>Public</td>
</tr>
<tr>
<td>AMRI</td>
<td>750</td>
<td></td>
<td>Private (PE backed)</td>
</tr>
<tr>
<td>Recipharm</td>
<td>709</td>
<td></td>
<td>Public</td>
</tr>
<tr>
<td>FIS</td>
<td>660</td>
<td></td>
<td>Private</td>
</tr>
</tbody>
</table>

A further indicator of the fragmentation of the sector is that companies generating less than $50m in annual revenue represent over two thirds of all CDMOs. This situation is driven by a number of factors:

- Barriers to entry into the market are relatively low for undifferentiated players
- Small, highly specialised CDMOs (e.g. in gene therapy or antibody-drug conjugate manufacturing) are established by experienced ex-pharma employees
- A large number of small, single facility CDMOs have been formed over the past 15 years, as pharma companies have divested manufacturing sites in spin-outs or MBOs, especially in Europe
- The sector includes companies that offer CDMO services as a secondary, non-core revenue stream (i.e. pharma companies selling spare manufacturing capacity)
- Many of the small- and mid-sized CDMOs are privately or family owned and so are content with steady revenue growth and have not participated in M&A

This contrasts starkly with the current state of the CRO market, where companies provide research services, including running clinical trials. There has been significant consolidation in recent...
years, as critical mass and geographic spread facilitates the running of multi-centre global clinical trials. Here, the total market of about $35bn (growing at 6–8% CAGR) is skewed far more heavily towards a few large players – the top 10 have a combined market share in excess of 70%.

Although M&A activity has been strong in the CDMO sector over the past 5 years with around 40 to 60 transactions per year, it still lags behind the CRO sector in terms of number of transactions and consolidation of market share. Consequently, we have not seen the top CDMOs meaningfully increase their market share compared to the last time we published our CDMO sector report in 2017, as consolidation activities have been off set by growth in the overall market, entry of new players and addition of new capacity. It is our expectation that M&A will continue to be strong, driven by market fundamentals and attention from investors, leading to ongoing market consolidation, albeit at a modest pace.

Consolidation in the sector to date has been driven by large public CDMOs that have access to the required capital for significant transactions. Recipharm (11 acquisitions), Catalent (8 acquisitions) and AMRI (7 acquisitions) have been most active.

Going forward we expect private equity backed companies to play an increasing role in sector consolidation. Private equity have been highly active in the sector over the past five years, acquiring some of the best-known large- and mid-sized CDMOs and are now pursuing a buy-and-build strategy (Figure 7).

In line with strong performance of the underlying CDMO market, ahead of the pharmaceutical sector and wider world economy, we have seen valuations of publicly listed CDMO increase substantially over the past 10 years to an all-time high today. Shares of public CDMOs have substantially outperformed the S&P 500 index and median EV/LTM EBITDA valuations have approximately doubled from 8.0x in 2019 to 16.0x today20. In addition to strong market dynamics, public market performance has been driven by improving margins as sector leaders move out of commoditised areas of the market into more specialised and value-add areas such as aseptic fill, strong revenue visibility compared to other markets and increasing confidence of investors as the outsourcing trend in the pharmaceutical sector continues.

20 Results Healthcare analysis
21 CapitalIQ, data correct as of 25 Oct 2019

### Drags and drivers of CDMO sector consolidation

**Drag**

- Expansion through pharma asset divestments, adding new manufacturing capacity rather than consolidation
- Private CDMOs pursuing organic growth strategies or lacking access to cash from capital markets or private equity
- Unwillingness of family/privately owned companies to be acquired
- Entry of new small players into the market
- Less pressure to reach critical mass than in other market—economics of scale not as pronounced as in CRO sector

**Drivers**

- Scale to increase financial stability – key consideration for pharma in selection suppliers
- Increasing presence of private equity in the sector pursuing a buy-and-build strategy
- Pursuit of an integrated or one-stop-shop model
- Drive of pharma to simplify their supply chain and work with fewer manufacturing partners
- Increasing appetite by small CDMOs to be acquired as technical and regulatory challenges increase
- Investor pressure on public CDMOs to maintain growth ahead of the underlying market

### Public CDMOs have significantly outperformed the wider market and are at an all-time high21

#### Evolution of share price performance

![Chart showing the share price performance of CDMOs and S&P 500](image)

#### Current EV/2019 EBITDA valuations

<table>
<thead>
<tr>
<th>CDMO</th>
<th>EV / 2019 EBITDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermo Fisher</td>
<td>20.8x</td>
</tr>
<tr>
<td>Lonza</td>
<td>18.3x</td>
</tr>
<tr>
<td>Catalent</td>
<td>16.8x</td>
</tr>
<tr>
<td>Cambrex</td>
<td>16.0x</td>
</tr>
<tr>
<td>Sefried</td>
<td>12.3x</td>
</tr>
<tr>
<td>Recipharm</td>
<td>10.8x</td>
</tr>
<tr>
<td>Consort Medical</td>
<td>9.1x</td>
</tr>
<tr>
<td>Median</td>
<td>16.0x</td>
</tr>
</tbody>
</table>

![Chart showing the EV/2019 EBITDA valuations of CDMOs](image)
M&A activity and industry developments

- M&A valuations have increased considerably since 2012 and are at record levels today, as competition for desirable assets has increased from strategic and private equity acquirers
- Scale and full-service capabilities carry valuation premiums
- Leading CDMOs continue to pursue the one-stop-shop model and seek to fill capability gaps through acquisitions
- Big pharma continue to divest manufacturing assets in an effort to reduce their manufacturing footprint

Deal activity in 2019 has already been strong and will surpass the deal volume seen in 2018. More notable – and striking – than the evolution of deal volumes over the past few years, however, has been the rise of valuations in the CDMO space (Figure 9). Our analysis shows that whilst median deal valuation between 2012 and 2015 was c. 10x EBITDA, this has increased to nearly 15x between 2016 and today (Figure 10), with transactions regularly and significantly exceeding this number. This sharp rise of valuations has been driven by a number of factors:

1. Increasing competition from private equity firms, as financial investors have realised the value creation potential of the CDMO sector
2. Highly active large (publicly listed) CDMOs that have looked to acquire market share and expand capabilities through M&A. Access to cash remains plentiful and cost of debt continues to be very low. This combined, with generally strong share price evolution has allowed public CDMOs to pursue more aggressive inorganic expansion strategies
3. A shortage of scale, high quality assets, leading to highly competitive processes when companies come to market.

We continue to see strong appetite and increasing valuations in the CDMO sector, driven both by strategic and private equity buyers

Figure 9 M&A activity in the CDMO sector over time – bubble size indicates Enterprise Value of target company
In line with increasing valuations we are also seeing an increase in larger transactions. Since the end of 2016 there have been seven transactions with enterprise values in excess of $1bn, including the two largest sector transactions to date, the acquisition of Patheon by Thermo Fisher for $7.2bn at 20.5x EBITDA and acquisition of Capsugel by Lonza for $5.5bn at 16x EBITDA.

As larger players expand their capacity and capabilities through M&A, some interesting patterns are emerging that allow us to sort strategic rationales behind acquisition decisions into a few categories:

1. Diversification of revenue and service offering to increase the addressable market size, gain access to a larger share of client spend and provide a one-stop-shop service

2. Continued drive to increase margins and exploit niches of higher profitability through the addition of high value, specialist or differentiated capabilities, such as HPAPI handling, aseptic fill/finish and viral vector manufacturing

3. Development capabilities in order to capture or ‘lock-in’ products at an early stage of the life cycle

4. Expansion of geographic reach to access new customers.

Additionally, scale is, as it has been in the past, a driver of valuation. Due to the considerable fragmentation of the sector, transactions over $200m are rare and gaining significant market share through a single transaction is more attractive to acquirers than having to do the same through several smaller transactions and needing to deal with the risk of integrating several companies. Unsurprisingly, we are seeing a premium of c. 3x EBITDA paid for larger (>200m EV) companies compared to their smaller counterparts and for CDMOs with integrated drug product and API services compared to pure-play competitors (Figure 10).

Valuations in the CDMO sector are impacted by a number of factors such as scale and capabilities

Valuation by buyer type

- Strategics: 11.5x EBITDA
- Private Equity: 12.3x EBITDA

Impact of scale on valuation

- EV<200m: 10.5x EBITDA
- EV>200m: 12.3x EBITDA

Impact of capabilities on valuation

- DP: 10.5x EBITDA
- API: 11.5x EBITDA
- Full service: 14.0x EBITDA

Valuation evolution over time

- 2012–2015: 10.0x EBITDA
- 2016–2019 YTD: 14.8x EBITDA

*Figure 10 Valuations in the CDMO sector based on a multiple of enterprise value / historic EBITDA*
We have summarised the key acquisition drivers for some of the most notable recent transactions by strategic buyers in Table 3. All of the targets listed here fulfil the majority of valuation drivers. This strong strategic fit, in addition to likely highly competitive sales processes, explains the premium prices paid in each case, for a median valuation in excess of 17x EBITDA.

The two most high-profile transactions of 2019 to date have been the acquisition of Brammer Bio by Thermo Fisher and Paragon Bioservices by Catalent. Both companies were valued in excess of $1bn and well over 20x EBITDA, representing record-setting multiples. Both acquisitions are a good indicator of the current enthusiasm for the potential of the cell and gene therapy market. Although the segment is expected to be the fastest growing CDMO sub-sector, outsourced viral vector manufacturing will only reach a market size of c. $1.4bn in 2023, which is in contrast to the enterprise values in excess of a billion dollars achieved today. One factor for such premium valuations are the strong margins achieved by viral vector manufacturers, but Catalent and Thermo Fisher are clearly also recognising the future market opportunity beyond a five-year horizon and are investing in the sector today to establish a leading market position ahead of the curve.

Another sub-sector that has received a lot of attention from acquirers and seen high multiples (see acquisition of Cook Pharmica by Catalent for 17.3x EBITDA), is the sterile and aseptic drug product sector. Sterile manufacturing is expected to be the second fastest growing sub-sector behind viral vector manufacturing and will provide the largest share of absolute growth within the drug product market until 2023, in particular driven by pre-filled syringe manufacturing. Accordingly, and supported by a strong clinical pipeline, CDMOs are investing today to add capacity and capabilities in anticipation of future demand and in order to be best positioned to win new business coming down the pipeline.

While pharma companies are increasingly more comfortable and willing to outsource the secondary manufacturing and packaging stages of their biologics (and other specialty) products, there continues to be a greater tendency to keep biologic API manufacturing in-house (see CDMO market overview section). This trend is also reflected in the M&A market, where less transactions with biologic API CDMOs are taking place due to a lack of available assets compared to other sub-sectors.

M&A activity has been broadly similar in the North American and European markets over the past 5 years, with a notably lower deal flow from the Asian markets. We are, however, witnessing increased activity from cash-rich Asian buyers, looking to acquire assets in Western markets and expand their geographic reach closer to key clients. Examples of this activity include SK Biotek’s acquisition of AMPAC in the USA and BMS’ small molecule API facility in Ireland (Results Healthcare acted for SK Biotek) and the acquisition of Apceth Biopharma in Germany by Hitachi Chemical.

<table>
<thead>
<tr>
<th>Date</th>
<th>Target</th>
<th>Buyer</th>
<th>EV/EBITDA</th>
<th>Scale (&gt;US $100m revenue)</th>
<th>Diversifies service offering</th>
<th>Differentiated / specialist capabilities</th>
<th>Significant development capabilities</th>
<th>Geographic expansion</th>
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<tr>
<td>Apr-2019</td>
<td>Paragon Biosciences</td>
<td>Catalent</td>
<td>21.4x</td>
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<tr>
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<td>Thermo Fisher</td>
<td>20-25x²</td>
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<td>Avista Pharma</td>
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<td>✓</td>
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<tr>
<td>Jul-2018</td>
<td>Halo Pharma</td>
<td>Cambrex</td>
<td>15.7x</td>
<td>✓</td>
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<td>Jul-2018</td>
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<td>SK Biotek</td>
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<tr>
<td>Sep-2017</td>
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<td>Thermo Fisher</td>
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<td>Dec-2016</td>
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<td>Median</td>
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<td>17.3x</td>
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</table>

Table 3 Valuation drivers in recent strategic CDMO acquisitions

² Results Healthcare estimate
The one-stop-shop

When evaluating the M&A strategy of leading CDMOs, expansion of capabilities either in development services or commercial manufacturing technologies, is a key rationale for acquisitions. This drive to broaden the service offering is consistent with the one-stop-shop model and leading CDMOs continue to pursue the strategy of becoming a fully integrated player that can offer its clients services across the entire drug life-cycle, drug supply chain from API to packaging and across all key geographies. It is this approach of offering a broad set of services that is driving large CDMOs to pay strategic premiums for assets that fill capability gaps, with a particular focus and premium placed on specialist and high value capabilities that drive margins, such as sterile and aseptic fill.

In theory, providing a one-stop-shop offering has benefits both for the customer and the supplier. The notion is to offer a multitude of services to a customer, who should benefit from the convenience, time savings and cost efficiency of dealing with a single provider. This can be particularly valuable during the drug development stage, where speed to market can be improved by removing the need to tech transfer between suppliers. Furthermore, for technically difficult to manufacture products such as biologics, where tech transfer can be a lengthy and expensive process, a single supplier relationship has the potential to reduce the risk of supply issues. The relationship should in-turn create opportunities for the CDMO to sell more services to the same customer, as well as locking in products at an earlier stage in their life cycle.

In reality, we are seeing the model work differently for different customer groups. The one-stop-shop is likely most beneficial for SMEs that do not have the capacity to manage multiple supplier relationships across legal agreements, compliance and performance monitoring and material transfers. Geographic reach is also a key consideration when working with SMEs. Most small biopharma are inexperienced in working with outsourcing providers and so prefer to work with suppliers that have close physical proximity, in order to stay ‘close’ to the development and production of their key product(s). Big pharma, on the other hand, continue to work with large numbers of suppliers driven by procurement departments that may make independent decisions about outsourcing providers at different points of the supply chain.

Leading CDMOs however are clearly committed to the model as it increases the addressable market size and provides opportunities to gain a larger share of client spend. As some big pharma have stated a desire to work with fewer suppliers and switch to a strategic partner model, this strategy is making increasingly more sense from a commercial rather than just a marketing standpoint.

Adoption of the model is however going to be a gradual process, as existing supply arrangements and tech transfer costs, make it in most cases unattractive for commercial products to switch manufacturer for the sake of consolidating the supplier base. Rather, we can expect the entire or large parts of the development and supply chain of new products to be contracted to single CDMOs as they progress through the clinical pipeline towards commercial launch.

Pharma asset divestments

Big pharma asset divestments continue to be an active part of many CDMO’s M&A strategy. Pharma companies continually assess, reorganise and rationalise their manufacturing networks. In the recent past this has meant increased investment in new capabilities for biologics and gene and cell therapy manufacturing at the expense of non-core activities which are shut down or divested. Pharma asset divestments are seen as an attractive acquisition opportunity by many CDMOs, as assets are generally of high quality with a well experienced workforce. Additionally, assets can often be acquired at a lower cost than the capital required to build a new facility, with the benefit of including ongoing activities and cashflows from supply agreements for products that continue to be manufactured at the site for the previous owner.

A number of large CDMOs have successfully utilised a string of pharma asset divestments to grow their business and expand their manufacturing capabilities, including Delpharm, Fareva, Corden Pharma and Recipharm. We have seen around 10-15 asset divestments by big pharma annually over the past five years and we expect activity to remain strong going forward, as pharma companies continue to reduce in-house manufacturing footprint and increase the use of outsourced manufacturing services. Notable recent asset divestments include the sale of Sanofi’s UK inhaler fill facility (including CMO business) to Recipharm (Results Healthcare advised Sanofi), the acquisition of GS’ small API facility in Ireland by Thermo Fisher, the divestment of Biogen’s biologics facility in Denmark to Fujifilm Diosynth, Lonza’s acquisition of a Novartis sterile fill facility in Switzerland and Catalent’s acquisition of a site from BMS in Italy, focussed on specific product launch capabilities.

Pharma companies more commonly divest manufacturing assets in European countries, where strict labour laws make the closure of facilities lengthy, complex and expensive, meaning divestment is often the economically more beneficial option. In the USA on the other hand, where labour laws provide less protection to employees, this is less commonly the case.
Private equity activity in the CDMO market

In addition to ongoing M&A interest from strategic buyers, strengthening valuations in the sector have in part been driven by rising activity of private equity firms, that see the wider pharmaceutical outsourcing market as an increasingly attractive place to deploy their considerable capital reserves. Investors are drawn to the sector by strong underlying market conditions, favourable margins, growth potential, revenue visibility through long-term supply contracts (up to 5 years is not uncommon), as well as perceived relatively good protection in the event of a market down-turn or recession. Although there is little difference between valuations paid by private equity and strategic buyers over the past 5 years (Figure 10), most recently we have seen private equity pay market leading prices for high quality companies. Furthermore, private equity firms continue to have large amounts of cash and need to deploy capital, leading to substantial pressure to complete transactions. This may drive firms in some circumstances to pay higher valuations than they would ordinarily do, in order to ensure a successful outcome in competitive auction processes. Key recent transactions by private equity include the acquisition of Quotient Sciences by Permira, acquisition of Sterling Pharma Solutions by GHO Capital (Results Healthcare advised GHO) and acquisition of Alcami by Madison Dearborn Partners.

In addition to acquisitions of private companies, private equity are also active in the public markets. Most notable here are the ongoing take-private of Cambrex by Permira and take-private of AMRI by Carlyle Group and GTCR in 2017. Both transactions were performed at significant (30%+) premiums to the pre-transaction announcement share price.

With many of their assets, private equity owners are looking to pursue a buy-and-build strategy to supplement organic growth with acquisitions in order to create additional value for investors, such as the rapid expansion of LSNE following investment by Permira. We can thus expect private equity and private equity backed CDMOs to remain very active in the M&A space and be a major driver of deal activity over the near and medium term.

Outlook of the M&A market

Given that highly favourable conditions in the underlying CDMO market are likely to persist in the medium term and access to capital will continue to be plentiful and cheap, we expect the M&A market to remain buoyant. Competition to acquire high quality, scale assets is certain to remain fierce from strategic buyers as well as private equity, due to the rarity factor (especially in the US) and potential to create value through combination of complementary service offerings. Consequently, we are likely to see valuation multiples maintained at current high levels for targets with a strong mix of capabilities and scale.
Concluding remarks

CDMOs have become a vital part of the drug development and manufacturing process with the majority of SMEs and an increasing number of big pharma relying on outsourced services. CDMOs have the ability to be both technology leaders, providing access to manufacturing capabilities and technologies that may not be available in-house, and low-cost outsourcing providers, allowing customers to reduce supply chain costs and reliance on fixed cost bases in the face of increasing pricing pressures across the market.

Our analysis suggests that the CDMO sector is continuing to perform strongly, with growth ahead of the underlying market, this is leading to increasing market penetration, albeit from a still relatively modest position today. Whilst we expect the overall CDMO market to grow at a CAGR of 6.8% to 2023, certain sub-sectors of the market, such as sterile injectables, pre-filled syringes, biologics APIs and viral vectors will expand significantly more quickly, driven by an accelerating shift in the pharmaceutical market toward innovative biologic and cell and gene therapy products. Nonetheless, small molecules will continue to represent the majority of prescribed drugs for the foreseeable future and so are the major growth driver for the CDMO market in absolute terms.

In order to respond to the evolving market and capitalise on the substantial current growth opportunities, CDMOs are investing in significant capital projects to drive organic growth as well as M&A to accelerate expansion. The strategic direction of many leading CDMOs is to acquire differentiated capabilities in an attempt to generate additional value, including the one-stop-shop model, which appears to start bearing fruit, as big pharma are looking to consolidate their supplier base and move from outsourcing provider to strategic partner relationships. M&A valuations have been driven to all-time highs, as strategic buyers are having to compete for rare, scale assets against financial investors that have discovered the CDMO sector as an attractive space with strong underlying fundamentals and exceptional value creation potential.

With a positive M&A environment, substantial ongoing investments and attractive forecast growth, our outlook for the sector to 2023 remains very positive. CDMOs are continually adapting to stay ahead of market developments and so we can expect to witness exciting advancements in the sector over the coming years.
## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
</tr>
<tr>
<td>C(D)MO</td>
<td>Contract (Development) Manufacturing Organisation</td>
</tr>
<tr>
<td>CAGR</td>
<td>Compound Annual Growth Rate</td>
</tr>
<tr>
<td>CAR-T</td>
<td>Chimeric Antigen Receptor T-cell</td>
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<tr>
<td>CMC</td>
<td>Chemistry, Manufacturing, Controls</td>
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<td>CRO</td>
<td>Contract Research Organisation</td>
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<td>CTM</td>
<td>Clinical Trial Manufacturing</td>
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<td>CTS</td>
<td>Clinical Trial Services</td>
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<tr>
<td>DP</td>
<td>Drug Product</td>
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<tr>
<td>EBITDA</td>
<td>Earnings before Interest, Tax, Depreciation &amp; Amortisation</td>
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<td>EV</td>
<td>Enterprise Value</td>
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<tr>
<td>FDA</td>
<td>Food &amp; Drug Administration</td>
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<tr>
<td>GDP</td>
<td>Global Domestic Product</td>
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<td>HPAPI</td>
<td>Highly Potent API</td>
</tr>
<tr>
<td>HPC</td>
<td>Haematopoietic Progenitor Cell</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>LOC</td>
<td>Liquids, Ointments &amp; Creams</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>Mergers &amp; Acquisitions</td>
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<tr>
<td>OSD</td>
<td>Oral Solid Dose</td>
</tr>
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<td>OTC</td>
<td>Over-the-Counter</td>
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<td>R&amp;D</td>
<td>Research &amp; Development</td>
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<tr>
<td>SM</td>
<td>Small Molecule</td>
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<tr>
<td>SME</td>
<td>Small &amp; Medium-sized Enterprise</td>
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</table>
Results Healthcare at a glance

- Based in London and New York, Results Healthcare has an experienced and entrepreneurial team, which has completed over 75 healthcare transactions to date.
- Part of the globally renowned advisory firm, Results International, Results Healthcare was established in 2012, in recognition of client need for a specialist team with dedicated skills in the healthcare, pharmaceutical and biotech sectors.
- Results Healthcare offers strategic advice, fundraising, licensing, divestment and M&A support for both sellers and buyers worldwide.
- The company has a dedicated team centred in London and New York, providing international coverage through Results’ network in Atlanta, Mumbai, Singapore and Tokyo.

Our recent deals:

- **GH Capital** has acquired **Sterling International Solutions Ltd**.
- **Novartis** has divested its sterile fill and finish facility to **Lonza**.
- **DUKE STREET** has acquired **Kent Pharmaceuticals**.
- **Prescribing Support Services** has been acquired by **MCKESSON**.
- **CreativCeutical** has been acquired by **Huntsworth**.
- **Linguamatics** has been acquired by a Tier-1 CRO.
- **Pfizer** has divested its global rights to LEUKINE® and associated manufacturing assets to **Baxter***.
- **SANOFI** has divested its Holmes Chapel manufacturing site to **Recipharm**.
- **SANOFI** has divested the global rights to LEUKINE® and associated manufacturing assets to **PTX Therapeutics**.
- **Biotek** has acquired the Swords, Dublin manufacturing site from **Bristol-Myers Squibb**.
- **INC Research** has signed a definitive merger agreement, valuing inVentiv at $4.6bn with a joint enterprise value of $7.4bn.
- **SANOFI** has divested its Tucson research facility and operations to **ICagen**.
- **SANOFI** has divested nitrate product rights in selected markets to **RMS Labs**.
- **SANOFI** has entered a major multi-component strategic alliance with **Evotec**.

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