



### **Company Description and Background**

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics, and consumer health products. Its oral, injectable, gene therapy, and respiratory delivery technologies address the full diversity of the pharmaceutical industry, including small molecules, protein and gene therapy biologics, and consumer health products. CTLT helps customers take products to market faster. They produce approximately 73 billion doses for nearly 7,000 customer products, or approximately 1 in every 20 doses of such products taken each year by patients and consumers around the world. CTLT is transforming its business mix to higher margin/growth Biologics.

The core technologies within its advanced delivery technologies platform include softgel capsules, Zydis orally dissolving tablets, blow-fill-seal unit-dose liquids, adeno-associated virus ("AAV") vectors, and a range of other oral, injectable and respiratory delivery technologies. The technologies and service offerings within its development solutions platform span the drug development process, ranging from OptiForm Solution Suite for enhancement of bioavailability and other characteristics of early-stage molecules, and Gene Product Expression ("GPEx") and SMARTag platforms for development of biologics and antibody-drug conjugates (ADCs), to formulation, analytical services, early-stage clinical development, and clinical trials supply, including its unique FastChain demand-led clinical supply solution.

Catalent is diversified by virtue of its geographic scope, large customer base, the extensive range of products, broad service offerings, and the ability to provide solutions at nearly every stage of a product's lifecycle. In fiscal 2019, CTLT produced nearly 7,000 distinct items across multiple categories; branded drugs (34%), generic prescription drugs (7%), protein and gene therapy biologics (32%), over-the-counter drugs (13%), and consumer health, veterinary products, medical devices, and diagnostics (14% combined). CTLT has executed ten acquisitions worth \$2.7B since 2013.

Its reportable segments are Softgel Technologies, Biologics/Specialty Drug Delivery, Oral Drug Delivery and Clinical Supply Services.

**Softgel** capsules are used in a broad range of customer products, including prescription drugs, over-the-counter medications, dietary supplements, unit-dose cosmetics, and animal health medicinal preparations. Representative customers of Softgel Technologies include Pfizer, Novartis, Bayer, GlaxoSmithKline, Teva, Johnson & Johnson, Procter & Gamble, and Allergan. Softgel Technologies segment represents 34%, 36%, and 40% of aggregate revenue before inter-segment eliminations for fiscal 2019, 2018, and 2017, respectively.

**Biologics and Specialty Drug Delivery** segment provides drug substance development and manufacturing, drug product clinical and commercial manufacturing, integrated clinical and commercial supply solutions for protein and gene therapy biologics and

Catalent (CTLT)

Healthcare

BioPharma Services - Drug Development & Delivery Technologies; CDMO

Key Markets: Biotech and Pharma

Thematic Tailwinds: Rising
Biotech R&D Spend; COVID-19
Vaccines; Gene Therapy;
Biologics

3 Year Average ROIC: 7.25%

EBITDA Margins 3 Year Average: 22.75%

Levered FCF Margin (3 Years): 5.5%

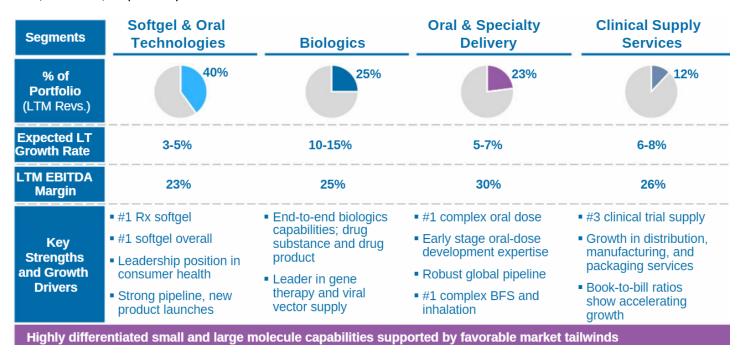
Debt/EBITDA (3 Year Average): 4.5X

R&D % of Sales: 0.2%

specialty small molecules administered via injection, inhalation, and ophthalmic routes, using both traditional and advanced delivery technologies. Representative customers of Biologics and Specialty Drug Delivery include Eli Lilly, Teva, Mylan, Roche, Novartis, Sarepta, and Genentech, along with multiple innovative small and mid-tier pharmaceutical and biologics customers. In 2019 Catalent acquired Paragon, which is focused on the development and manufacture of cutting-edge biopharmaceuticals, including viral vectors used in gene therapies. Biologics and Specialty Drug Delivery segment represents 29%, 24% and 17% of aggregate revenue before inter-segment eliminations for fiscal 2019, 2018, and 2017, respectively.

Oral Drug Delivery segment provides various advanced formulation development and manufacturing technologies, and related integrated solutions including: clinical development and commercial manufacturing of a broad range of oral dose forms, including our proprietary fast-dissolve Zydis tablets and both conventional immediate and controlled-release tablets, capsules, and sachet products. Representative customers of Oral Drug Delivery include Pfizer, Johnson & Johnson, Bayer, Novartis, and Perrigo. Oral Drug Delivery segment represents 24%, 23%, and 27% of aggregate revenue before inter-segment eliminations for fiscal 2019, 2018, and 2017, respectively.

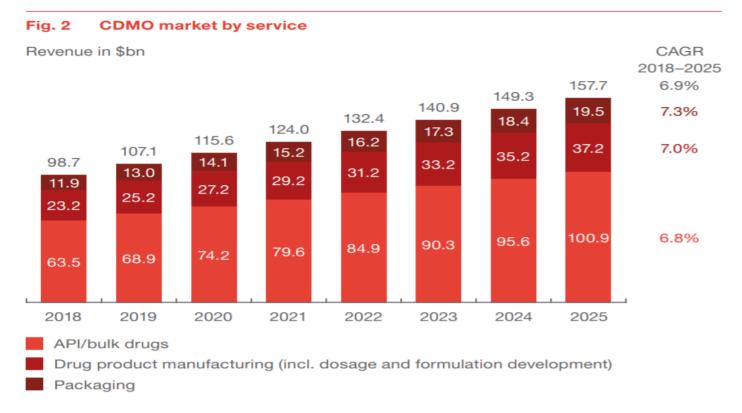
Clinical Supply Services segment provides manufacturing, packaging, storage, distribution, and inventory management for drugs and biologics in clinical trials. Representative customers of Clinical Supply Services include Merck KGaA, IQVIA, Eli Lilly, AbbVie, and Incyte Corporation. Clinical Supply Services segment represents 13%, 17%, and 16% of aggregate revenue before inter-segment eliminations for fiscal 2019, 2018, and 2017, respectively.



### **Industry Analysis and Market Opportunity**

CTLT operates in highly fragmented markets in both advanced delivery technologies and development solutions businesses. Within those markets, the five top players represent approximately 35% and 10% of the total market share, respectively, by revenue. The industry has high barriers to entry due to regulations, production know-how, service offering, scale, product availability, and established relationships. Grand View

Research estimates the CDMO market will growth to \$157.7B in 2025 from \$98.7B in 2018, a CAGR of 6.9% which is well above the pharmaceutical industry. The strong growth is a result of an increasing need for pharmaceuticals as well as a grater willingness to outsource by pharmaceutical companies.



Key industry trends include a robust R&D pipeline with oncology & rare disease leading growth, launches are more frequently being outsourced driven by small companies and orphan / fast-track products, and strong growth in Biologics for antibodies and gene therapy.

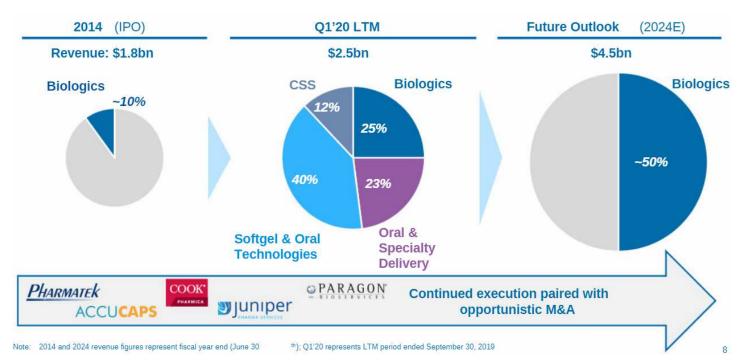


Fig. 4 Year	Acquisitions with disclosed deal values >\$100m between 2016–2019					
	Acquirer	Area of business (acquirer)	Acquirer location	Target	Target location	Deal value (\$m)
2017	Thermo Fisher Scientific	Life sciences	USA	Patheon	USA	7,200
2016	Lonza	CDMO	СН	Capsugel	USA	5,500
2019	Thermo Fisher Scientific	Life sciences	USA	Brammer Bio	USA	1,700
2017	Carlyle, GTCR	Private equity	USA	AMRI	USA	1,500
2019	Catalent	CDMO	USA	Paragon Bioservices	USA	1,200
2017	Fosun Pharma	Pharmaceuticals	CN	Gland Pharma	IN	1,090
2017	Catalent	CDMO	USA	Cook Pharmica	USA	950
2016	Mylan	Pharmaceuticals	USA	DPT Laboratories	USA	950

### **Customers and Costs**

In fiscal 2019, Catalent conducted business with 83 of the top 100 branded drug marketers, 21 of the top 25 generics marketers, 23 of the top 25 biologics marketers, and 21 of the top 25 consumer health marketers globally. Selected key customers include Pfizer, Johnson & Johnson, GlaxoSmithKline, Novartis, Roche, and Teva. In fiscal 2019, top 20 products represented approximately 20% of total revenue, with no single customer accounting for greater than 10% of revenue and with no individual product greater than 4%.

# CTLT's announced COVID-19 partnerships

- Johnson & Johnson (JNJ) as a drug product manufacturing partner for its COVID-19 vaccine candidate
- Arcturus Therapeutics (ARCT) as clinical and commercial drug substance manufacturing partner for its mRNA COVID-19 vaccine candidate (LUNAR-COVID)
- Humanigen (HGEN) as clinical supply services (CSS) partner for its COVID-19 monoclonal antibody (mAb) candidate
- 4. **Ennaid Therapeutics (private)** to develop a power-in-capsule formulation for its repurposed COVID-19 oral antiviral drug (ENU200)
- 5. Spicona (private) to develop a fermentation cell line for its COVID-19 vaccine
- AstraZeneca (AZN) as a drug product manufacturing partner for the University of Oxford's adenovirus vector COVID-19 vaccine candidate (AZD1222)
- ViralClear Pharmaceuticals (a subsidiary of BiSig Technologies (BSGM)) to develop and manufacture two oral dosage forms for ViralClear's Merimepodib antiviral agent as a potential treatment for COVID-19
- Moderna (MRNA) as a commercial fill/finish manufacturing partner for its COVID-19 vaccine candidate (mRNA-1273)

CTLT uses key materials such as gelatin, starch, and iota carrageenan for Softgel Technologies segment; packaging films for Clinical Supply Services segment; and glass vials and syringes for injectable fill-finish along with resin for the blow-fill-seal business in the Biologics and Specialty Drug Delivery segment. Past concerns of

contamination from Bovine Spongiform Encephalopathy ("BSE") have narrowed the number of possible sources of particular types of gelatin.

### **Competitors & Risk Factors**

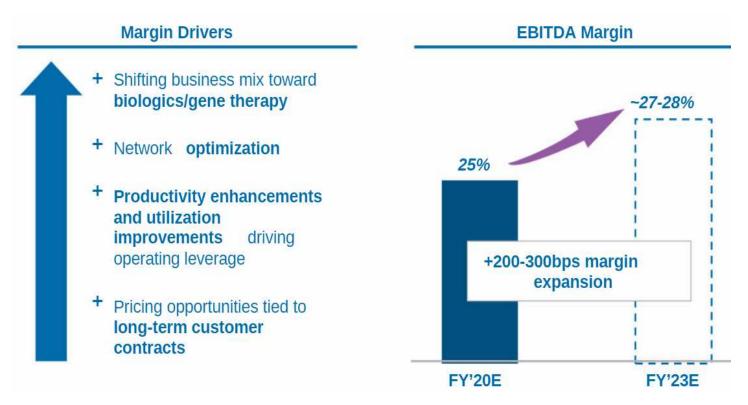
"While we do have competitors that compete with us in our individual offerings, and a few competitors that compete across many of our offerings, we do not believe we have competition from any directly comparable company." A few comps I would use are AptarGroup (ATR) Pharma business, Thermo Fisher(TMO), West Services (WST), IQVIA (IQV), and Charles River (CRL).

#### Risk Factors

The demand for offerings depends in part on customers' research and development and the clinical and market success of their products.

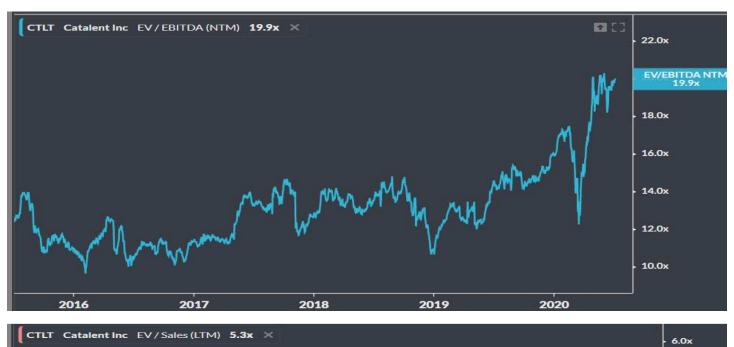
## **Key Metrics and Seasonality**

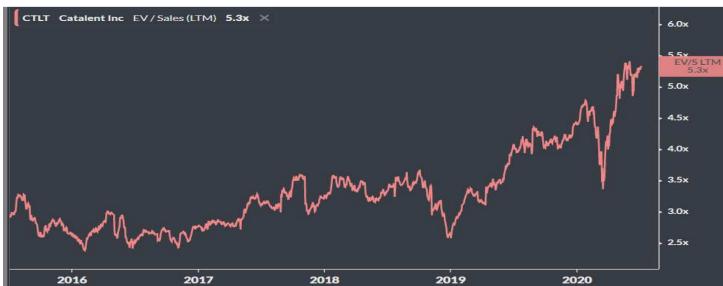
CTLT focuses on organic and acquisition revenue growth, EBITDA margins, and FCF. Day Sales Outstanding is a metric that Analysts have focused on in calls.



CTLT revenue and net earnings are generally higher in the third and fourth quarters of each fiscal year, with the first fiscal quarter typically generating the lowest revenue of any quarter, and the last fiscal quarter typically generating the highest revenue. These fluctuations are primarily the result of the timing of annual operational maintenance periods at locations in continental Europe and the U.K., the seasonality associated with pharmaceutical and biotechnology budgetary spending decisions, clinical trial and research and development schedules, the timing of new product launches and length of time needed to obtain full market penetration, and, to a lesser extent, the time of the year some of customers' products are in higher demand.

## Ratios and Valuation (Current vs. Historical)







## **Management Commentary**

On Gene/Cell Therapy Outsourcing:

"If you look at our gene therapy, in particular, and cell therapy, for that matter, it lends itself to outsourcing. We see about -- long term, about 65% of cell therapy activities will be outsourced in the long term. Now you will have companies that either have a strategy to do so in-house exclusively or have a hybrid approach to have a portion done in-house and a portion done externally. We see that across the gamut, and we're factoring all of those. We see about 65% outsourcing in this arena. The gene therapies are largely curative in nature. They run through a faster development process. And so if you're waiting until you have proof of concept, for example, in gene therapy, that you know that it works, before making a commitment to deploy capital, it's essentially too late. Because by the time you do that, you're going to see an acceleration through the rest of development to launch, and that doesn't provide enough time to launch and deploy capital to put your own capacity in and, more importantly, get the capability to be able to do so from an execution standpoint. And so for those reasons, we continue to see -- and because they're curative in nature, they'll go through addressing the current, I would say, population with the prevalence of the particular disease state, and then you're down to just the new occurrences. And for those reasons, it lends itself to more -- far more outsourcing. And again, some companies that have an in-house/insource, I would say, strategy, some of them have a hybrid where they're doing both."

## On Growing the Biologics Business:

"We continue to grow our Biologics business and really integrating the premier set of assets that we have acquired and deploy capital to further build our capacity and capability across the network. We acquired Anagni just on January 1, which really expands our European capabilities in Biologics for drug products, but also has solid oral dose manufacturing packaging. We acquired MaSTherCell on February 10, which establishes Catalent as now a leader in both cell and gene therapy. And our build-out for gene therapy is progressing and growth -- strong growth is expected in that business for us as well. We expect revenue and adjusted EBITDA growth from our Biologics offering over time to continue to target that Biologics segment that make up approximately 50% of our revenues in fiscal 2024 versus approximately 1/3 of our revenues today. And if you look at the gene therapy space, it's about a \$40 billion overall space. And we've already seen that these gene therapies, they literally are -- were manufacturing miracles, where you're curing people. And payers are being creative and finding a way because of the curative nature of these diseases to actually find a way to fund and pay for them. So from an overall standpoint, we're still very bullish on the gene therapy space. We have aggressive investment plans there. We had built out -- they had 2 suites when we had acquired them. They completed out up to the 4 suites through the end of last calendar year. By the end of this calendar year, we'll have 10 suites. And I would just say that we've got a tremendous amount of that capacity already allocated. And we'll probably be looking to do additional organic investments in that space. And then the other thing is I would say that with regards to MaSTherCell, I would say we caught it probably 2 to 3 years earlier in its life cycle than we caught Paragon. Certainly, we paid a significant premium at \$1.2 billion for Paragon. And with MaSTherCell, I would say, we caught it 2 to 3 years earlier. So we really don't see significant financial results contributing to the company for about 2 to 3 years out. Again, we talked about that during the time of the acquisition. But the halo effect of having now a gene and cell therapy combined with being associated with -or being part of Catalent that is known for doing things at scale, investing organically, having operational and quality excellence actually has already made a difference in the customers that we have in MaSTherCell and customers that we've signed up since we've closed the overall deal."