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# THE DRUG KINGPIN

# The Drug Kingpin

## Activists Help This Key Pharma Player Move Beyond COVID

Sandra Boyd knows almost too much about drugs.

The slender, bespectacled former research chemist has spent 14 years as a pharmaceuticals investigator for the U.S. Food and Drug Administration ("FDA"), which ensures the safety of consumer products like food, medicine, and cosmetics. She travels the world, inspecting huge factory warehouses where prescription drugs – a $527 billion business in the U.S. alone – are mixed, processed, and packaged.

Much can go wrong behind the scenes. Boyd knows just what to look for at pharmaceutical manufacturing facilities, because she's seen it all.

And when she sees something, she says something. That is – she whips out the dreaded Form 483, a detailed laundry list of health and safety violations that make drug-factory managers panic. If drugmakers don't fix the issues flagged on Form 483 – quickly – they'll be hit with an official FDA warning. If that doesn't bring about change, the FDA will close a facility. That's an extinction-level event.

August 1, 2022, started off as a normal workday for Boyd and three colleagues, as they pulled up for a routine inspection at a Bloomington, Indiana, plant operated by prescription-drug manufacturer Catalent.

The sprawling factory – with 16 football fields' worth of floor space – had recently undergone a $350 million upgrade, featuring state-of-the-art labs and bioreactors designed to process the COVID-19 vaccines produced by two of its biggest clients, Moderna and Johnson & Johnson.

But beyond the factory's swooping, futuristic entryway, Catalent hid a few very dirty secrets.

It started with mysterious black particles.

As Boyd reviewed regulatory paperwork at the Catalent facility, she noted that over the previous two years – since COVID vaccines, Catalent's mainstay, hit it big – the company's clients had been complaining. A lot.

*179 separate times, in fact.*

The companies reported seeing something that definitely doesn't belong in medicine: unidentified black bits in vials and syringes.

They described the substance in various ways: *foreign matter, particulate matter, black specks, black particles, foreign particle, or pieces of rubber.* Sometimes the companies sent samples of the material with their complaints.

But Catalent seemed to ignore all 179 letters. As Boyd learned, the company didn't analyze the particles or follow up with its concerned customers.

It turns out, Catalent had been shipping contaminated COVID vaccines, and it didn't seem to care.

But Boyd and her team did care. In the lab, they found defective vials, poor quality testing, and contaminated "sterile" areas.

An FDA inspection usually lasts two or three days. But Boyd and her colleagues ended up staying at Catalent for a month. At the end, they submitted an extensive Form 483, which read like a 19-page federal scolding that concluded:

> *"Your firm failed to establish laboratory controls that … assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity."*

And Boyd's damning conclusions were just the drizzle at the start of the deluge against Catalent. Over the next few months, FDA inspectors would uncover quality-control issues at three more Catalent facilities. Then in December 2022, short-seller Glasshouse highlighted increasingly serious inventory and cash-flow problems.

Catalent was in big trouble.

In this issue, we'll explore the story behind Catalent's COVID-era rise and fall… what happened… and why we believe a dramatic activist-led turnaround is in the cards…

**Activist Angle**

The stock we recommend in this issue is Catalent Inc. (NYSE: CTLT) – a servicing company that supports the efforts of many of the world's big pharma businesses. The company helps with everything from data analysis to facilitating clinical trials to manufacturing medicines.

Its services are in massive demand… and they will be for the foreseeable future. And soon, the company will be producing what could be the biggest-selling drugs of all time.

But the company has stumbled lately. And in a big way.

As we'll explain, this once-well-performing company made a bundle during the pandemic. It retooled its business and became a key producer of the COVID-19 vaccines. In fact, by the end of 2021, Catalent had produced more than 1 billion doses.

However, now that the pandemic is over, the cracks in its business are showing. The problems in its production processes spotted by the FDA team are a big deal. Fortunately, the company is working to solve its problems.

And a couple of smart activist investors have taken note – Corvex Management and Elliott Investment Management.

The activists are getting involved for three main reasons:

• A pressing need for a board shake-up...
• A big potential buyout deal...
• And a manufacturing contract for what could be the the best-selling drug of all time...

Let's get started...

## Catalent's COVID Rise and Fall

Catalent (NYSE: CTLT) is one of the largest companies providing services to big pharmaceutical, biotech, life-science, and other drug-development companies across the globe. It has an $8.5 billion market cap and is expected to deliver $4.4 billion in sales in 2024.


Catalent primarily supports the pharmaceutical industry in developing new drugs and then manufacturing them for patient use. This includes everything from Advil to vaccines to gene-therapy medicines, regardless of whether they come in pill, injectable, or inhaler forms. This is done at 50 facilities across four continents.

That said, the company has run into some recent challenges that we will detail in this report.

Over the past 10 years, Catalent has worked with over half of all drugs approved by the FDA. Annually, the company manufactures 80 billion doses of 8,000 products. This equates to one out of every 23 pills or needle jabs administered each year to global consumers.

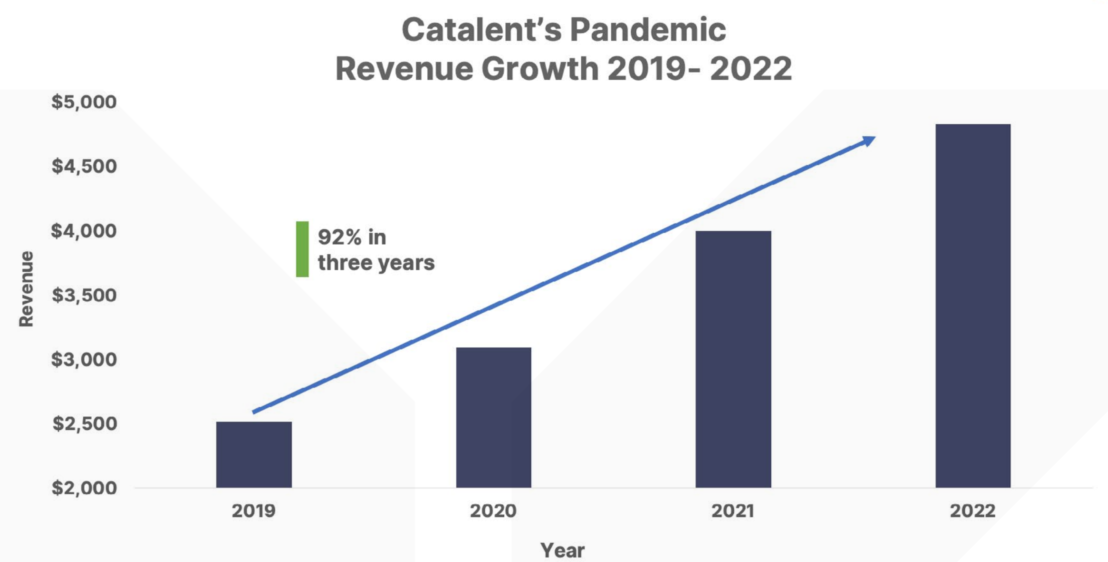
Given this broad footprint of facilities and expertise, the company can scale up and down for almost any customer… until the last couple of years.

Starting in 2021, Catalent helped get the COVID vaccine into hundreds of millions arms around the world. In 2020, the company quickly mobilized its facilities and was soon working with 60-plus pharmaceutical companies developing more than 100 versions of the prototype vaccine. These included Moderna and Pfizer, the two largest.

And the company's efforts were a success. By the end of that year, Catalent had produced more than 1 billion doses of various COVID-19 treatments. This Herculean effort was great for business.

From 2010 through 2020, revenue grew a steady 6.2% per year. Earnings before interest, taxes, depreciation, and amortization ("EBITDA") rose even more, at about 9% annually. Quarterly revenue averaged $683 million in 2019.

Revenues soared as the COVID-19 treatments took off. Quarterly sales rose 32% to $904 million between March 2020 and March 2021. On an annual basis, revenue jumped 92% in the three years from the beginning of the pandemic through 2022, when COVID-19-related revenues were $1.3 billion. That's a whopping 27% of total revenue for the year.




Fortunately for the health of mankind, but unfortunately for the health of Catalent's books, the pandemic was temporary. And as the COVID-19 vaccine requirements slowed, the company's management faced a new challenge: winding down its pandemic infrastructure. That process weighed heavily on the stock. Not only is the company losing a quarter of its revenue, but it has to find new business to replace it.

During the Q4 2022 earnings conference call, the CFO put it this way:

> *"We have taken a two-thirds haircut to the volumes we saw in fiscal 2022 in our fiscal 2023 guidance. Given that decrease in volume and the absorption impact related to running at high levels of utilization on COVID dedicated lines, there will be a relative impact to our overall margin profile."*

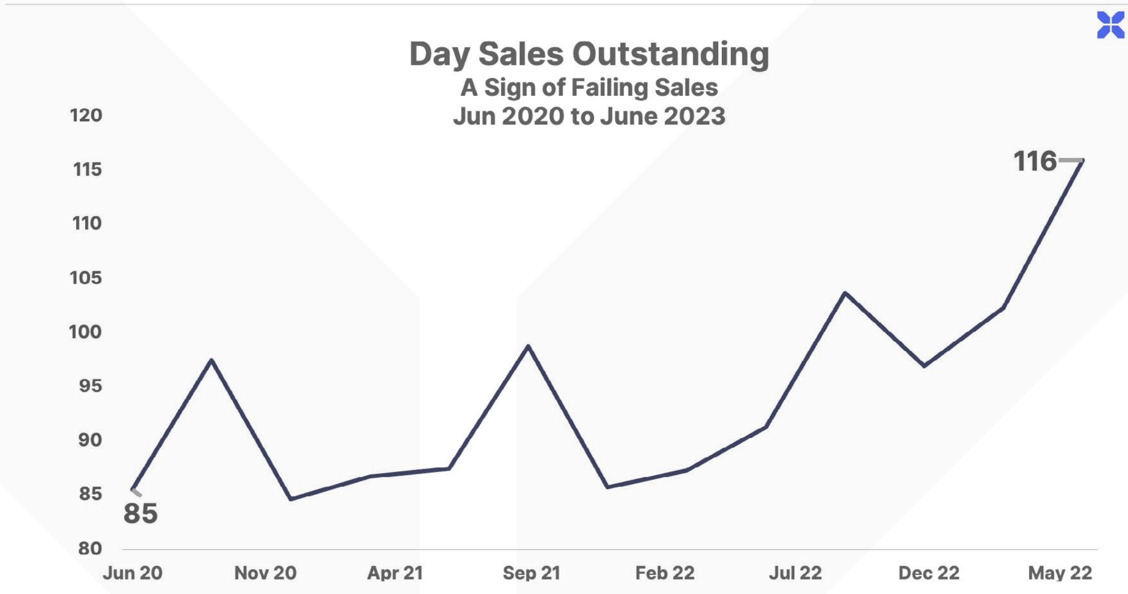
Translation: revenue and profits are coming down.

## The COVID Spike Subsides – And Catalent Stumbles

After Sandra Boyd's devastating August 2022 FDA report, a prominent short seller sounded the alarm on Catalent. But it had little to do with black particles appearing in drug samples.

Glasshouse Research, an independent source of equity research, published a report in December 2022 highlighting unusual accounting, executive turnover, low insider ownership, and increasing levels of inventory.

One especially big red flag that Glasshouse spotted was this uptick in inventory levels. This can be seen through a sharp jump in the company's days-of-sales-outstanding ("DSOs") – the number of days it takes for a company to collect payment.




When the pandemic ended, demand for vaccines began to decline. The first calendar quarter of 2022 proved to be the peak of pandemic-related activity. Revenue and earnings would soon trail the declining level of demand.

The company was continuing to produce vaccines but sales revenue owed was not being collected as quickly as before.

Accounts receivables per unit of sales was rising. Meaning, what pharma companies owed Catalent was rising relative to the orders that Catalent had fulfilled. Or it could mean an internal accounting oversight: perhaps the sales numbers were not as robust as the company thought.

Whatever the explanation, the company likely knew that vaccine sales were going to slow. But it hadn't communicated this to investors. To keep up with forecasts, it went on producing vaccines and maintaining sales projections similar to the prior period. This suggests the company might be recognizing revenue on its books sooner than it should. The result: future sales numbers might be lower than expected.

In November 2022, Catalent reported dismal earnings for fiscal 2023's first quarter (the three months ending September 2022). During this period, the company reported revenue and EBITDA below Wall Street expectations. Both measures also declined from the prior quarter.

Additionally, the company's free cash flow ("FCF") – the money left over after all the bills are paid – declined to negative *$241 million*. FCF is cash created by operating cash flow less capital expenditures ("CapEx"). This decline was directly related to CapEx the company had to make to meet pandemic needs. Then it had to invest more capital to make adjustments once pandemic manufacturing needs subsided.

From 2015-2019, CapEx averaged $160 million a year. During the pandemic period of 2021 to June 2023, this nearly quadrupled to $640 million – driving the negative FCF.

Outsized operational investments were clearly dragging the financials more than before the pandemic.

Catalent identified several reasons for this. At the time, inflation was high. It was hurting businesses everywhere. The dollar was strong, which created currency accounting problems for international companies like Catalent.

But in addition to elevated CapEx, COVID-19 sales were evaporating.

And the company knew it. Catalent lowered its already-reduced revenue and EBITDA expectations for 2023. Both measures were now forecast to be about 7% less than previously expected. CTLT shares fell 25% after the earnings announcement.

However, that was only the beginning of the story. Five months later, on April 14, 2023, the company provided an update.

It had uncovered "productivity issues" at three facilities, including two of its biggest manufacturing locations (Bloomington, Indiana, and Brussels, Belgium)… in short, these facilities were not operating as efficiently as they once had. For two years, these locations manufactured COVID-19 vaccines, and now they had to pivot away from the pandemic vaccine needs but did not have enough new products to fill the gap…

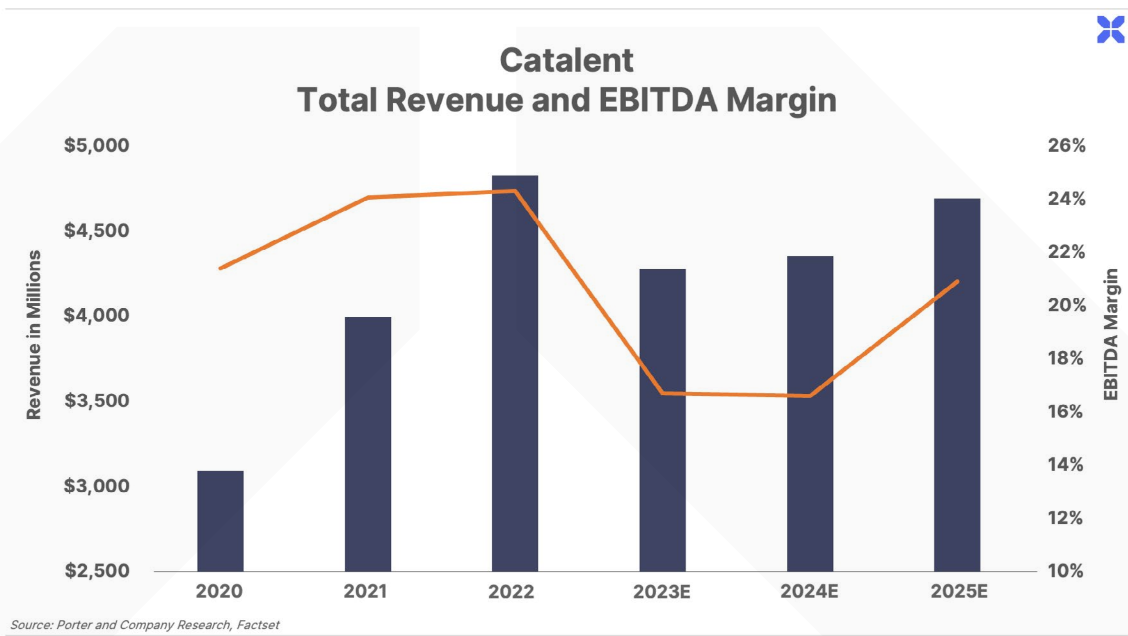
As a result, the company indicated that this new information "will materially and adversely impact the company's financial results for the third fiscal quarter and its outlook for the remainder of the 2023 fiscal year."

These "adverse impacts " included more downward revisions of financial forecasts, delayed earnings reports, and the resignation of CFO Thomas Castellano.

Ultimately, midpoint revenue guidance declined by $525 million and EBITDA by $535 million. From its original expectations for 2023, revenue was now lowered by 16% and EBITDA was down a staggering 46%.

In September 2021, the shares were trading around $140 per share. This new financial information sent the share price down to $32, where it bottomed out in mid-May 2023. It currently trades around $50 for a roughly 60% decline from its highs.


The following chart illustrates both total revenue and EBITDA for 2020-2025E. The massive increase in pandemic-related revenues is clearly seen. However, as vaccine sales waned, the decline in revenue and profitability is evident as well.




Though this chart paints a grim picture, we believe profitability is at a low point and will rise over the next two years. The operational problems have been identified and the company has taken action.

We believe the company has effectively identified its issues and what needs to be fixed. At least 17 Wall Street analysts cover this stock so there are many eyes on what has been happening lately. They have started to raise profitability forecasts.

Importantly, two prominent activist investors are now involved.

## Why Activists Are Betting Big on Catalent

Activist investors Corvex Management and Elliott Investment Management have recently turned their focus on Catalent.

Among the biggest activists on Wall Street, Elliott has pushed for change in companies such as Salesforce, Twitter, and Pinterest.

Most recently, Elliott instigated improvements at Constellation Brands (maker of Corona beer). Elliott secured two new independent board seats and created an open dialogue about how the company is operating. This sent Constellation shares higher. In return, Elliott agreed to limit its public activism of the company through 2024.

Now it has moved on to Catalent. In July 2023, the *Wall Street Journal* reported that Elliott had taken a sizable stock position in the pharma manufacturer.

Soon after, Corvex Management joined Elliott's lead. Corvex founder Keith Meister had long been known as Carl Icahn's right-hand man – learning from the legendary activist before going out on his own. Corvex often partners with Elliott. In 2017, the duo invested in Energon, an underperforming energy company. They bought in at $57 a share, got their hands dirty, and it paid off. A year later Energon was sold for $85 a share.

While it's not clear how much Elliott invested, SEC filings showed that Corvex bought $245 million of Catalent stock. That is a very big bet – representing 12% of the total money it can invest.

Both groups proposed new board members and rallied other large shareholders to support this effort.

On August 29, 2023, their work paid off. Catalent and its activists reached an agreement, which calls for four new independent board members. Two of these would sit on a new strategic review committee focused on improving operations. The new members and the strategic committee will represent Elliott and Corvex's interests going forward.

The wheels are now in motion to propel Catalent forward, out of its post-pandemic stagnation.

Why would Elliott and Corvex get involved now? From our research, we believe there are three primary reasons:

1. Catalent has been stumbling, as detailed above. While revenues have remained stable, profitability has fallen. We believe Elliott and Corvex are looking to shake-up the board with these newly added members and potentially refresh management.
2. Earlier in the year, there were unconfirmed reports that Danaher – a global conglomerate – was interested in acquiring Catalent. The stock surged almost 30% on this news. But nothing has happened. These activist investors may be looking to get that potential deal back on track.
3. They see huge value in a potentially new revenue stream. Catalent is one of the primary manufacturers of the new Glucagon-like peptide (GLP-1) diabetes drugs that create safe and sustained weight loss. Demand for these drugs will be contained only by how much can be produced. (More on this shortly.)

Let's dive in deeper...

## Could Elliott Be Brokering a Deal?

In February 2023, there were unconfirmed reports that Danaher (NYSE:DHR) was interested in buying Catalent.

Danaher is a $31 billion global conglomerate with products in life sciences, technology, and several other sectors. Catalent would be a good fit within Danaher.

In fact, Danaher strengthened its life science presence recently. In June 2021, it acquired privately held Aldevron for $9.6 billion. Aldevron makes products that support genetic research in making drugs. A pharma-servicing company like Catalent that manufactures drugs after development would dovetail nicely for Danaher. Then, in August 2023, Danaher announced the $5.7 billion acquisition of Abcam – which provides biological supplies to drug developers.

Early coverage of Danaher's potential acquisition of Catalent suggested Danaher valued the company at a "significant premium" to where it was trading – at about $56 when the news came out. It quickly moved above $70 a share.

However, as Danaher discovered Catalent's operational challenges, it pulled back on its plans. This sent shares back down.

If the activists can drive operational improvements and get Danaher's interest back, where might these shares trade?

Let's look at a simple enterprise-value(EV)-to-EBITDA multiples analysis. EV is how the market prices a company, excluding cash and debt. This is an alternative measure of profitability that removes financing, taxes, and non-cash expenses.

**Catalent**
**Enterprise Value to EBITDA, 2019-2023**

| Year | EV | EBITDA | EV/EBITDA |
|---|---|---|---|
| 2019 | $11,133 | $541 | 20.6 |
| 2020 | $13,939 | $662 | 21.1 |
| 2021 | $21,102 | $962 | 21.9 |
| 2022 | $22,861 | $1,174 | 19.5 |
| 2023 | $12,417 | $714 | 17.4 |
| Average | | | 20.1 |

*Source: Porter&Co., FactSet. In millions.*

Over the past five years, the EV-EBITDA multiple has averaged 20.1x. This includes the influence of more normalized operations in 2019, the realization of pandemic revenues, the Danaher acquisition news, and the recent operational challenges.

In 2025, EBITDA estimates are $980 million. These estimates have stabilized recently given the company's fiscal third quarter earnings report. Management provided a full update of operational challenges and firmed up financial expectations for the remainder of 2023.

This communication to shareholders cleared up some uncertainty about all the things that pushed the stock lower in the last year.

But what the estimates don't seem to account for are big new opportunities such as manufacturing revenues from cutting-edge weight-loss drugs, alluded to above and which we will get to shortly.

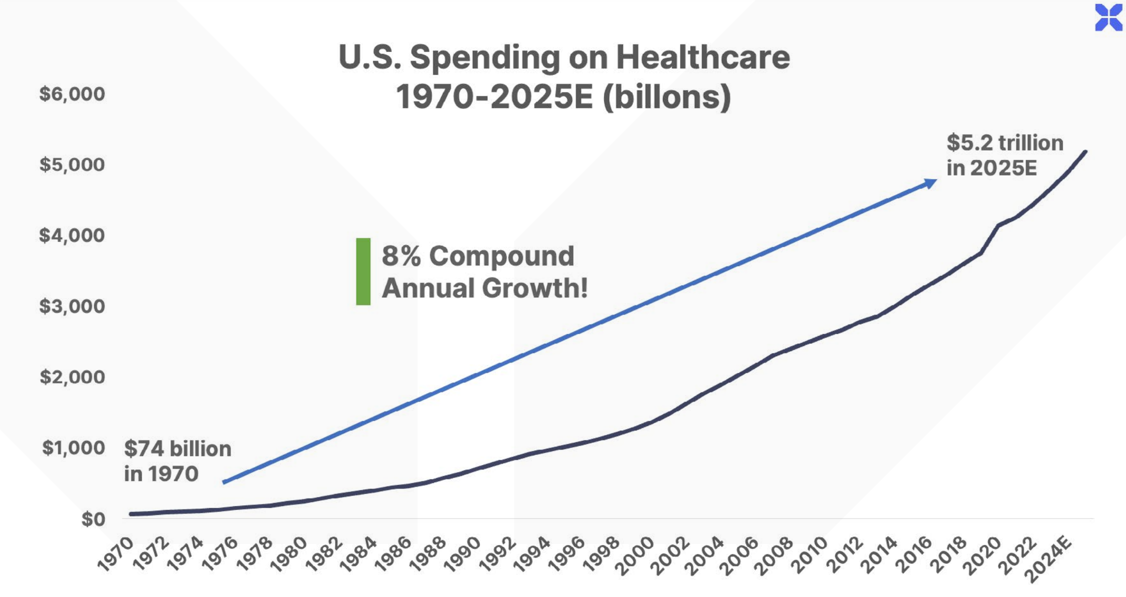
With the additional revenue generated by these new drugs, we believe EBITDA will increase 46% by 2025. Catalent's recent financial update and favorable growth trends support a profitable growth profile. As such, using an average EV-EBITDA multiple in establishing a future target price seems quite reasonable.

At the average five-year multiple of 20.1x, this suggests a two-year target price of $117 using 181 million shares outstanding. This is well above the current market price of $50.

This will be driven by Catalent's manufacturing what could be the largest selling drug of all time.

## Biologics Are Now CTLT's Bread and Butter

Healthcare is a great sector to invest in. We are customers from birth to death. The industry is complex, emotional, frustrating, and... lucrative. In 1970, the U.S. spent $74 billion on healthcare. In 2025, that is projected to be $5.2 trillion.




There are myriad reasons for this meteoric rise in spending – medical and surgical advances, an aging population, third-party payments, and lawyers adding litigation costs. However, drug discoveries are a big part of it. An increasing number of amazing drugs are being developed, getting FDA approval, and manufactured every year. And right now, the biggest new drugs are **biologics**.

Biologics are new, high-tech therapies aimed at cancer, heart ailments, and rare diseases. Crucially, they're often created from living materials – like humans, animals, and other micro-organisms.

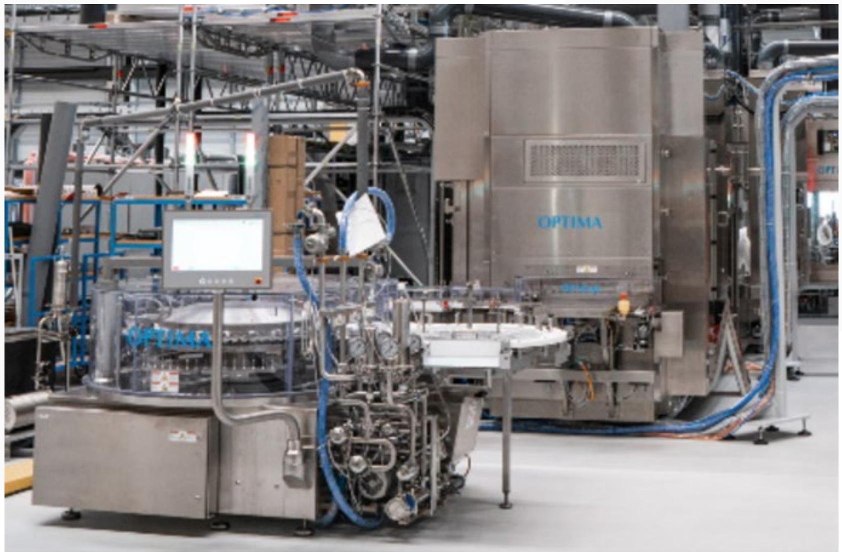
These cutting-edge medicines cover a wide range of products – vaccines (like for COVID-19), DNA gene therapies, and special manufacturing of biologic drug substances. They offer newfound hope for treatment of diseases with no current cure. And they can be targeted to a specific disease within a specific person – like the chimeric antigen receptor T-cell ("CAR T-cell"), a personalized drug that re-engineers a patient's own immune-system cells so they attack only cancer cells.

In 2000, only 7% of total FDA-approved drugs were biologics. In 2022, 41% were.

In 2002, Catalent committed to building a large biologics business. Since 2017, the company has invested more than $4 billion in biologics.

This $4 billion includes investment in new technology, research and development, and biologic-related acquisitions across the globe. The company has new facilities in New Jersey;  Dusseldorf, Germany; and Oxford, England.

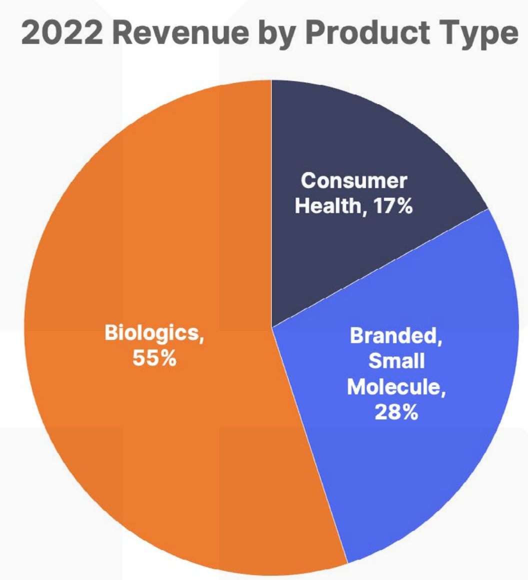
Pictured here is high-speed, vial-filling equipment for manufacturing the COVID-19 vaccine, located at the company's Bloomington, Indiana, facility. Post-pandemic, it's been repurposed for other liquid vial-filling needs.




Here is another piece of Catalent's high-tech equipment: a stainless-steel bioreactor – a system that supports a biologically active environment for manipulating organisms or biologic substances. They are used to make pharmaceuticals, vaccines, or antibodies. It also converts raw materials into useful byproducts.

Both of these pictures illustrate the type of technology present in Catalent's facilities across the globe.

As expected, these investments have paid off. Over half of Catalent's revenue comes from the biologics business. In fiscal 2020, which ended June 30, prior to the company's push into the COVID-19 vaccine, 32% of EBITDA came from biologics. In 2022, this rose to 62% as vaccine production added to biologics financial contribution. In 2024, biologics is expected to account for 49% of EBITDA, since there will only be a small amount of COVID-19-vaccine revenue. It is down as a percentage of overall profitability, but is still essentially half.




As comparison, in 2016, revenue from biologics was only 17%, about $314 million. In 2022, biologics contributed $2.7 billion – a 745% increase in only six years.

Catalent has grown its biologics revenue over 42% per year since 2016. Longer term, the company believes biologics will see annual growth of 10% to 15%. Although based on what we expect for the next crop of biologic drugs, this forecast may be woefully conservative.

What's driving the massive growth in biologics? Another pandemic – global obesity.

## The Biggest-Selling Drugs of All Time

These new weight-loss drugs have been making headlines as Hollywood celebrities use them to shed pounds for roles and red carpets. They have names like Ozempic, Wegovy, and Mounjaro.

These new GLP-1 diabetes and weight-loss drugs will be the biggest-selling meds of all time. As mentioned, GLP-1 is a special type of biologic medication that mimics the hormones in the blood that regulate the stuff that should and shouldn't be there.

Ozempic and its counterparts are great diabetes drugs as they lower A1C (sugar) levels in people with Type-2 diabetes without using insulin. But they have an even greater side-effect: sustained weight loss.

As shown in the table below, these drugs created 6% to 22% weight loss in clinical trials.

### The New Weight Loss Drugs

| GLP-1 Medications | Ozempic (diabetes) | Wegovy (weight loss) | Mounjaro (diabetes) |
|---|---|---|---|
| Manufacturer | Novo Nordisk | Novo Nordisk | Eli Lilly |
| Active Ingredient | Semaglutide | Semaglutide | Tirzepatide |
| FDA Approval | Dec-17 | Jun-21 | May-22 |
| Dose duration | 52 weeks | 68 weeks | 72 weeks |
| **Average weight loss** | **6.1%** | **14.9%** | **22.5%** |
| Expected Sales (billions) | | | |
| 2023 | $17.3 | | $3.4 |
| 2024 | $23.1 | | $6.5 |
| 2025 | $27.9 | | $9.3 |

*Source: Clinical trial results, Factset*

According to FactSet Research, Novo Nordisk is expected to sell $17.3 billion worth of Ozempic and Wegovy in 2023; $23.1 billion in 2024; and $27.9 billion in 2025. Eli Lilly's Mounjaro is expected to sell $3.4 billion, $6.5 billion, and $9.3 billion in those years.

It's important to note, Mounjaro is FDA-approved to treat diabetes only. But that will soon change. Eli Lilly is expecting the FDA to approve Mounjaro as a weight-loss drug later this year, just as it did for Wegovy.

As of today, these drugs are expected to sell almost $90 billion from 2023 to 2025. That's in only three years.

For comparison, as of 2021, rheumatoid-arthritis drug Humira was the best-selling drug of all time. In the 19 years from its December 2002 FDA approval to 2021, sales were about $198 billion – just more than double what these GLP-1 drugs will do in three years.

And here's the crucial part...

As of April 2023, *Catalent was the sole manufacturer of Ozempic and Wegovy*. This established the company as a key partner with Novo Nordisk. However, given massive demand and some manufacturing hiccups, other partners are expected to be added. A second is up and running while a third is still in negotiations. But given demand, there will be enough manufacturing capacity for everyone.

This one piece of business is a key asset that Elliott and Corvex are looking to expand with their activism.

## Where Catalent Stock Is Headed Next

At the end of Q2 2023, sales of Wegovy were about $100 million higher than expected. This translates directly to Catalent's financial outlook.

And given the success of Ozempic and Wegovy, expectations are high for Mounjaro.

In the two years after Ozempic and Wegovy were approved, sales rose 251%. For Mounjaro, the same two-year forward look estimates 164% growth. And remember – Mounjaro is a better drug for weight loss. Should Mounjaro grow like Ozempic and Wegovy, sales will be $3.4 billion higher than current estimates.

Ely Lilly has said it will rely on manufacturing partners to make the drug, and Catalent is a longtime partner. We expect Lilly to engage Catalent in manufacturing Mounjaro.

## The Bottom Line

Catalent has all the makings of a great, activist-led, special-situation investment.

Consider the four components ideal in profiting from a special-situation investment:

**A corporate action** – Elliott Investment Management and Corvex Management are leading the ongoing push for a shake-up of the current Catalent board. In fact, just recently Catalent and Elliott agreed on adding four new independent board members... two by Elliott. Its new slate will push for operational and potential leadership change. This is a great sign as the activists now have a front-row seat to board decision making.

**An undervalued security** – In our view, Catalent shares are trading well below their potential given pending operational changes and sizable opportunities, such as the manufacturing of weight-loss drugs.

**A return can be forecast** – Applying recent-year EV/EBITDA multiples to estimated profits in 2025 suggest a two-year return over 100%.

**A minimal investment risk** – Shares plummeted 72% to recent lows in May. Currently, shares have shown an uptrend but remain down 41% over the prior year.

What could go wrong?

As will all special situations, the biggest risk is failure of the activists to make positive changes. These are called special situations for a reason… something "special" is occurring.

That said, we believe Catalent is very attractive right now. The worst operational issues appear to have been fixed and new financial guidance has been established. Moreover, the potential for new business driven by robust global drug development – including new weight-loss drugs in massive demand – is very real.

What's more – the positive direction of things at Catalent could reignite Danaher's interest in an acquisition. That would create even more demand for the shares, moving its price higher.

Sandra Boyd and the FDA should be pleased with the improvements they instigated.

**Action to Take:** Buy Catalent (NYSE: CTLT) up to $100 a share.