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Pharmaceutical Outsourcing & Services

Updating FDA Approval Analysis for 2024 Data; Strong Year for Approvals and Significant Uptick in Outsourcing Penetration

Summary: We are updating our analysis of new drugs approved by the Food and Drug Administration (FDA), which we began publishing five years ago, to incorporate 2024 approvals. With this update, our analysis now looks at 10 years of data going back to 2015. In our view, this study is relevant for our entire pharmaceutical outsourcing and services universe, as well as the bioprocessing industry. But we believe it is particularly relevant for the contract development and manufacturing (CDMO) subsector. Throughout this report we explore trends over the past 5-10 years in:

- biotech funding, number of FDA approvals, and pharma drug sales;
- the breakdown of approved therapies by therapeutic modality, dosage form, and innovator size;
- the percentage of approvals that are outsourced to CDMOs for drug substance (API) and drug product (finished dose); and
- which CDMOs were awarded the mandate to produce each approved product (if outsourced).

Key conclusions: The full analysis is discussed in slide format for easier reading, but we summarize our primary conclusions below.

Macro:

- **Biotech funding:** Approximately $75.0 billion of capital was raised by the biotech industry in 2024, up 30% compared to 2023. Except for IPOs, the increase in funding was broad based, with the $25.5 billion raised from follow-on offerings representing an increase of 40% year-over-year, the $15.4 billion raised through PIPEs representing an increase of 54% year-over-year, and the $29.4 billion raised in venture funding representing an increase of 18% year-over-year. Total IPO dollars were $4.7 billion in 2024, which is up slightly from the $4.5 billion raised in 2023.
- **FDA approvals:** 2023 represented a banner year for approvals, with the FDA giving the nod to 66 new molecules during the period. The rate of new drug approvals came back to Earth a bit in 2024, but the 59 molecules approved last year still represents a significant improvement relative to the average of 49 molecules approved annually over the prior 10 years.

- **Pharma drug sales**: Total drug sales increased 8% in 2024 and are forecast to grow at an 8% compound annual rate over the next five years (versus 6% CAGR from 2019 through 2024). The improved outlook is partly due to the industry's shift toward faster-growing biologics (50% of sales in 2024 versus 40% in 2019), but small-molecule sales are also expected to accelerate over the next five years (5% CAGR versus 3% CAGR over the prior five years). Biologics sales are expected to grow at a 10% compound annual rate from 2024 through 2029 (roughly in line with the CAGR for biologics sales observed over the prior five years), driven primarily by sustained healthy growth in sales of monoclonal antibodies, which accounted for over half of all biologics sales and over a fourth of all drug sales in 2024.
- **Therapeutic modality:** Biologics decreased as a percentage of approvals in 2024, although the 47% observed in 2024 is still above the 44% average for the last 10 years. We continue to expect biologics to account for a majority of approvals moving forward, especially as new modalities gain traction. The shift toward biologics has been a key tailwind for the CDMOs, notably Lonza (LONN-SWX CHF 583.80; Outperform), as well as companies from our coverage list with bioprocessing exposure, primarily Avantor (AVTR $17.47; Market Perform), Bio-Techne (TECH $65.56; Outperform), Danaher (DHR $211.14; Outperform), Maravai (MRVI $4.01; Market Perform), and Repligen (RGEN $164.74; Outperform). Although biologics are seemingly the focus area for innovators at present, our analysis indicates CDMOs focusing on small-molecule drugs should continue to be well positioned given a greater propensity for drug developers to outsource production of these products once approved.
- **Route of administration:** Since 2015, the route of administration for new molecules has gradually shifted toward injectables and infusion, a trend benefiting West Pharmaceuticals (WST $221.07; Outperform), Stevanato Group (STVN $21.12; Outperform), and Aptar (ATR $145.61; Outperform). In 2024, 56% of approvals used this delivery route compared to 39% for oral administration. Looking at the average since 2015, 51% of approvals have been for injectables, 44% have been for oral, and 5% have been for all other routes of administration. Since 2020, we have seen the average proportion of approvals dosed via injection/infusion tick up to 57% and given our expectation for biologics to account for majority of approvals moving forward, we expect this gradual shift to continue since these drugs are more likely to be administered via infusion/injection than small-molecule drugs.
- **Bioprocessing:** Non-COVID biologics sales are expected to grow at 10% through 2030, in line with the preceding five-year CAGR. Within biologics, new modalities are expected to grow at nearly 40% compared to the preceding five-year CAGR of roughly 25%. Given the boom-bust nature of bioprocessing and pharma packaging demand in the last several years, this serves as an important reminder of the healthy long-term demand supporting the space (roughly two-thirds of the market is tied to commercial therapies). COVID is expected to represent about 1% of biologics sales in 2025, down from 16% in 2021 and 2022.
- **Innovator landscape:** In 2024, small biotech accounted for 44% of approvals, well above the 39% observed in 2023 and 38% average going back to 2015. Despite the somewhat challenging biotech funding environment we have observed over the last couple years, we continue to expect large pharma approvals to gradually decline as a percentage of total approvals moving forward.
- **Outsourcing trends:** Looking over the drugs approved by the FDA since 2015, we analyzed the portion that rely on CDMOs for active pharmaceutical ingredients (API or drug substance) and/or finished dose (drug product) and how this tendency differs by size of the innovator. The key conclusion, in our view, is that outsourcing penetration has accelerated, particularly for API (74% outsourced in 2024 versus 56% in 2023 and 59% average since 2015). Finished dose outsourcing also spiked in 2024, with the 61% of drugs outsourced last year significantly exceeding the 42% observed in 2023 and 49% average since 2015. In addition, small and midsize innovators continue to outsource both API and finished dose production of their drugs far more often than large innovators, which when combined with our view that approvals will increasingly come from smaller innovators, appears to be a very favorable longer-term trend for CDMOs.
    - ***API manufacturing:*** Since 2015, a relatively stable average of 59% of approved therapies have outsourced API production. The 74% recorded in 2024 far exceeded this historical average and represented the highest rate in the past decade, driven by improvements in outsourcing penetration for both small molecules (87% in 2024 versus 79% in 2023 and 74% average since 2015) and biologics (61% in 2024 versus 36% in 2023 and 42% average since 2015). If we cut the same data by size of innovator, small biopharma outsourced API production for 85% of approvals (up from 69% in 2023 and 78% average since 2015), midsize pharma outsourced API production for 92% of approvals (up from 89% in 2023 and 80% average since 2015), and large pharma outsourced API production for 50% of approvals (up from 33% in 2023 and 35% average since 2015).
    - ***Finished dose manufacturing:*** Since 2015, the percentage of finished dose outsourcing has remained relatively stable around 50%. However, after two years of meaningful step-downs in finished dose outsourcing penetration, we saw a notable spike in 2024, with the 61% observed coming in meaningfully above the 42% seen in 2023 and the 49%

average since 2015. This improvement has been driven by material increases in outsourcing penetration for both small molecules (77% in 2024 versus 57% in 2023 and 60% average since 2015) and biologics (44% in 2024 versus 29% in 2023 and 35% average since 2015). If we cut the same data by size of innovator, small biopharma outsourced finished dose production for 77% of approvals in 2024 (versus 54% in 2023 and 69% average since 2015), midsize pharma outsourced finished dose production for 83% of approvals (up from 67% in 2023 and 74% average since 2015), and large pharma outsourced finished dose production at a rate of 26% (up slightly from 24% in 2023 and 25% average since 2015).

Competitive landscape: The genesis of this analysis was to get a better gauge of which CDMOs were winning the commercial mandates to produce the products approved in any given year. This is important for such a long-cycle business as the CDMO space, but the data is generally not disclosed by anyone in the industry to our knowledge. Overall, for 2024 we were able to determine *whether a newly approved drug was outsourced* in 98% of cases for API production and 97% for finished dose production. Similarly, we were able to identify the *specific CDMO(s)* in 81% of the cases for API production and 77% for finished dose production.

- One of our primary findings from this analysis is just how fragmented the industry remains, even after a spike in consolidation in recent years. For example, across the API space, the largest CDMO, Lonza, had only 7% share of approvals since 2015 (16% of biologics and 2% of small molecules). Thermo Fisher's (TMO $535.55) Patheon was tied with a 7% share of outsourced API production, and all remaining players had 4% market share or less. Looking at finished dose outsourcing, Thermo's Patheon and Catalent (recently acquired by Novo Holdings) stand out with 19% share and 15% share, respectively, since 2015. Almac is the only other player with over 5% of approvals (6% in total to be specific, including 8% in the small-molecule arena). Vetter also shows up as a significant player in large-molecule finished dose with 10% share since 2015 (but only 4% share of total finished dose).
- The three leading CDMOs continue to be Lonza, Thermo's Patheon, and Catalent. Of these three consolidators, Thermo's Patheon appears to have been most effective to date building a broad offering across API and finished dose for both small-molecule drugs and biologics. In our analysis, Patheon is tied with Lonza for first place in API with 7% market share and has the leading place in finished dose for both biologics (15% share) and small molecules (22% share). In 2024, Patheon's share of finished dose manufacturing approvals was 18%, which is nicely above the 14% seen in 2023 and roughly in line with the 17% average observed since 2017.
- Lonza continues to be the largest player in API (tied with Patheon for overall API share but the dominant No. 1 in biologics), although its share of approvals year-to-date was relatively modest (5%, up from 3% in 2023). The company is not a major player in finished dose, with little commercial presence in large scale, although in 2023 it announced the completion of its new clinical and commercial drug product manufacturing line in Visp, Switzerland, and broke ground on its large-scale, commercial drug product fill/finish facility in Stein, Switzerland, which is due to be completed in 2026.
- Catalent, which was recently acquired by Novo Holdings, commands a strong 15% share of the finished dose market and shows up as a No. 2 player behind Thermo's Patheon in both small molecules (16% share) and biologics (12% share). In 2024, Catalent's share of finished dose manufacturing approvals was 14%, in line with the 14% seen in 2023 but below the 17% average observed since 2017.

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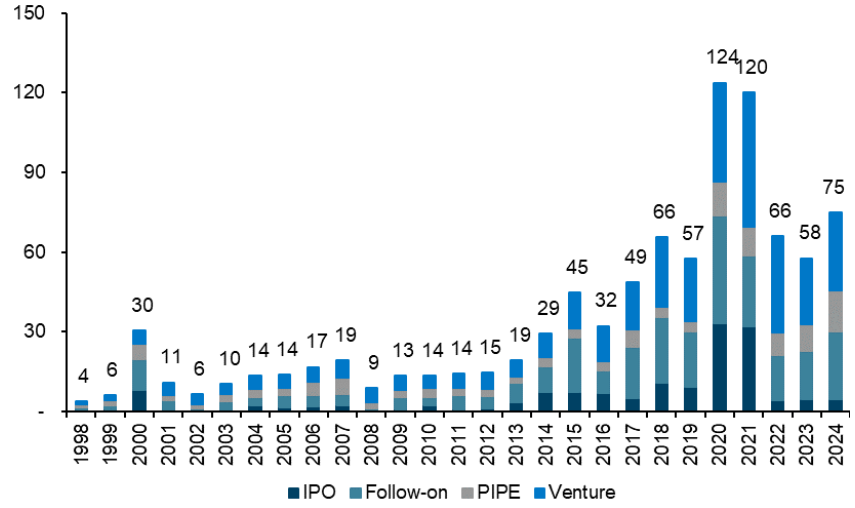
Pharmaceutical Outsourcing Industry: Industry Trends

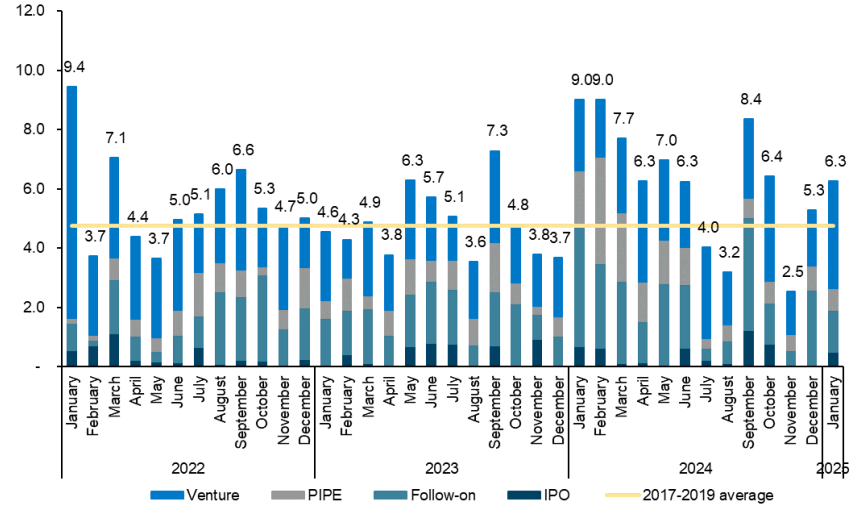
Biotech Funding

- Capital raised by the biotech industry in 2024 was $75.0 billion, which is 30% above the $57.7 billion raised in 2023 and 31% above the $57.2 billion annual average observed during the three years prior to the pandemic. Despite an encouraging step-up in total funding last year, the number of deals decreased sequentially from 1,232 in 2023 to 1,208 in 2024.
- Except for IPOs, the increase in funding was broad based, with the $25.5 billion raised from follow-on offerings representing an increase of 40% year-over-year, the $15.4 billion raised through PIPEs representing an increase of 54% year-over-year, and the $29.4 billion raised in venture funding representing an increase of 18% year-over-year. Total IPO dollars were $4.7 billion in 2024, which is up slightly from the $4.5 billion raised in 2023.

Biotech Industry Funding, 1998 to Present ($s in Billions)



Biotech Industry Monthly Funding, 2022 to Present ($s in Billions)



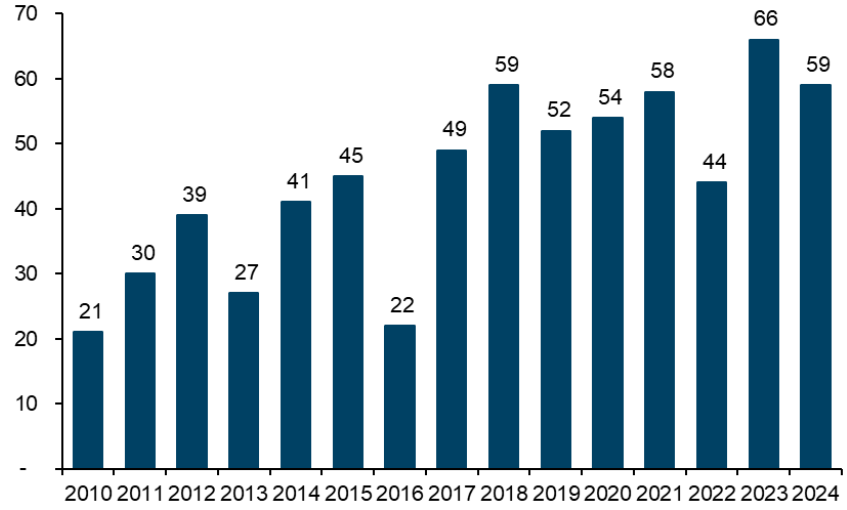
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Industry Trends

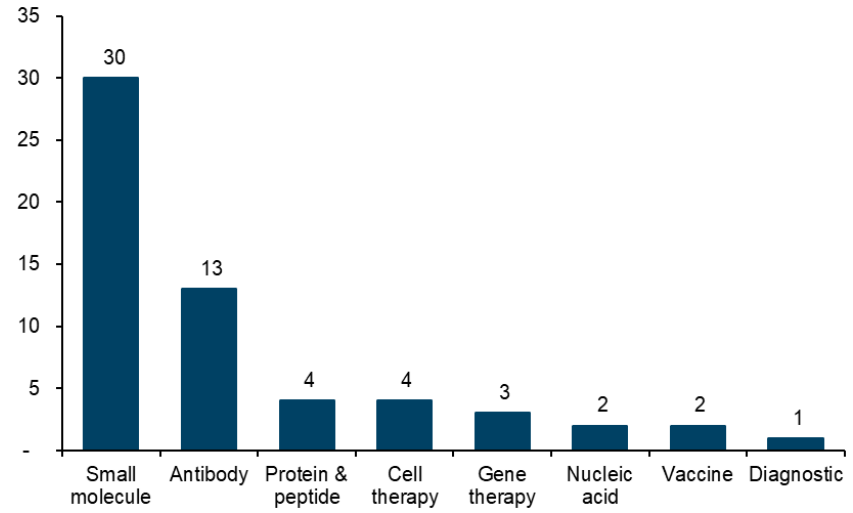
FDA Approvals

- Over the past 14 years, we have observed an overall increase in the number of molecules approved by the FDA annually, with the agency on average approving nearly 3 incremental molecules per year since 2010.
- The FDA approved 59 new molecules in 2024, representing a step-down from the record 66 new molecules approved in the 2023, but still significantly above the annual average of 49 approvals observed over the prior 10 years.
- By therapeutic modality, roughly half of approvals were for small molecule drugs, while nearly 30% of approvals were for antibodies, proteins, and peptides. There were also seven cell and gene therapies approved in 2024, a modest step-up from six cell and gene therapy approvals in 2023.

Number of FDA Approvals



2024 FDA Approvals by Therapeutic Modality



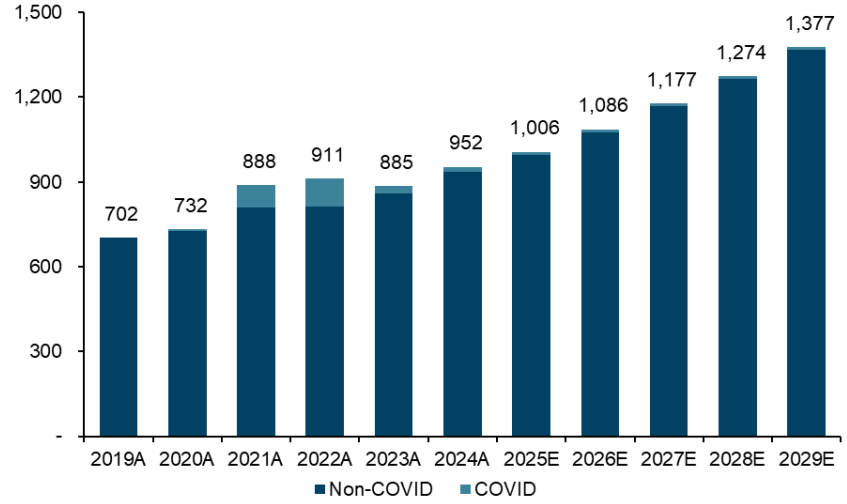
Note: Excludes products subsequently withdrawn from the market
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Industry Trends

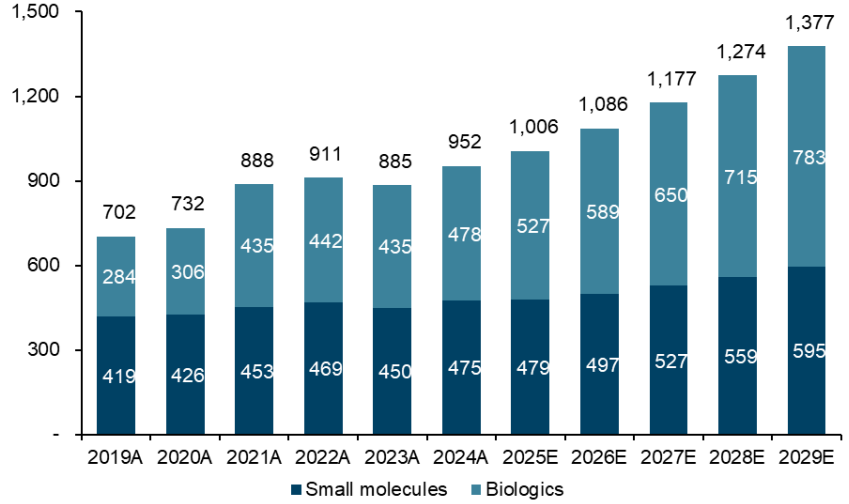
Pharma Drug Sales

- Total drug sales increased 8% in 2024 (+9% ex-COVID) and are expected to grow at an 8% compound annual rate from $952 billion in 2024 to $1,377 billion in 2029. This would represent a nice step-up from the 6% CAGR for drug sales observed from 2019 through 2024.
- In 2024, small molecule sales increased 5% year-over-year and accounted for half of all drug sales (versus 60% in 2019). Total sales from small-molecule drugs are expected to increase at a 5% compound annual rate from $475 billion in 2024 to $595 billion in 2029, a meaningful step-up from the 3% CAGR for small-molecule drug sales observed from 2019 through 2024.

Total Drug Sales ($s in Billions)



Drug Sales by Therapeutic Modality ($s in Billions)



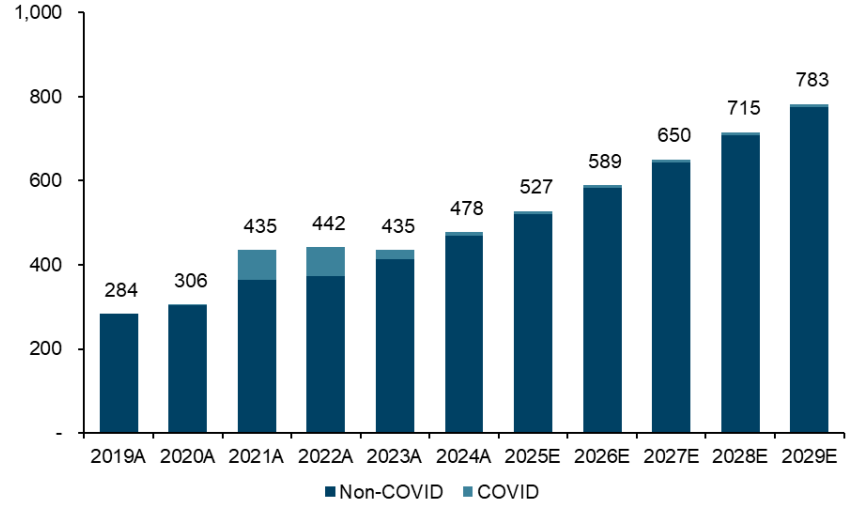
Sources: Evaluate Pharma and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Industry Trends

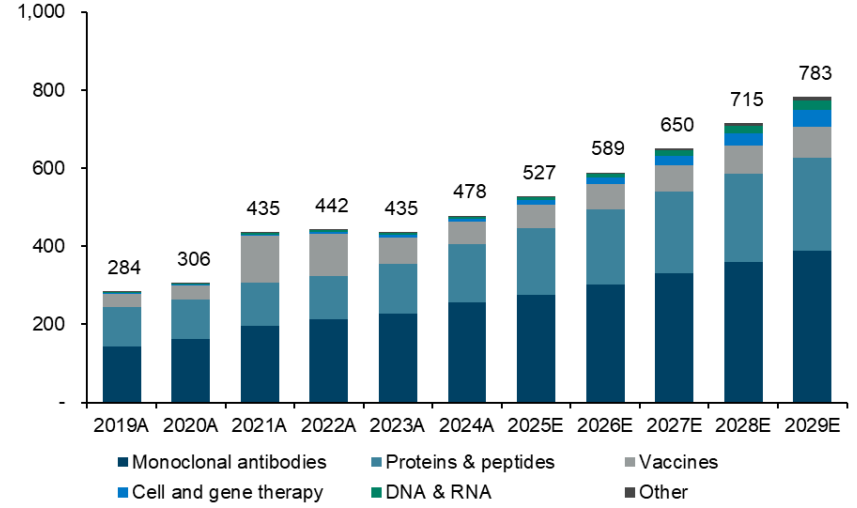
Pharma Drug Sales

- In 2024, biologics sales increased 10% year-over-year and accounted for 50% of all drug sales (versus 40% in 2019). Total sales from biologics are expected to increase at a 10% compound annual rate from $478 million in 2024 to $783 billion in 2029 (11% ex-COVID). This would be roughly in line with the CAGR for biologics sales observed from 2019 through 2024.
- Monoclonal antibodies (mAbs) are still the single-largest class of biologics today, accounting for 54% of biologics sales and 27% of total drug sales in 2024. Sales of mAbs grew at a 12% compound annual rate from 2019 through 2024 and are forecast to grow at a 9% compound annual rate over the next five years.

Biologics Drug Sales ($s in Billions)



Biologics Drug Sales by Therapeutic Modality ($s in Billions)



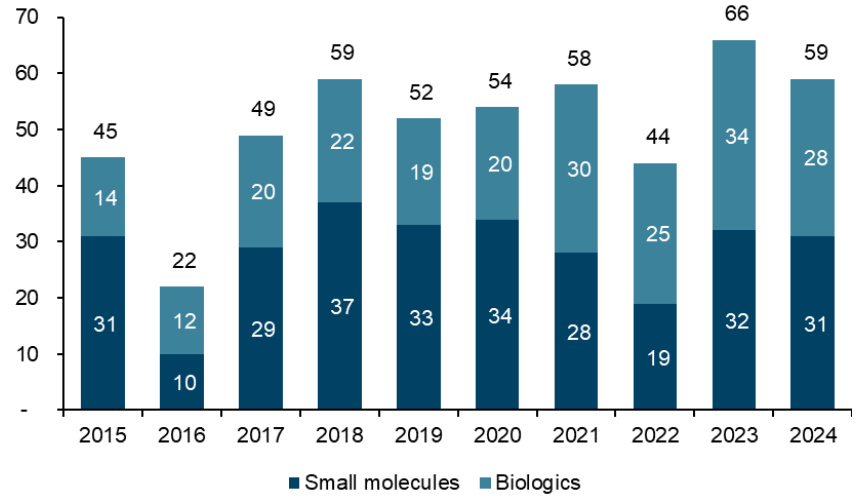
Sources: Evaluate Pharma and William Blair Equity Research

Pharmaceutical Outsourcing Industry: FDA Approvals

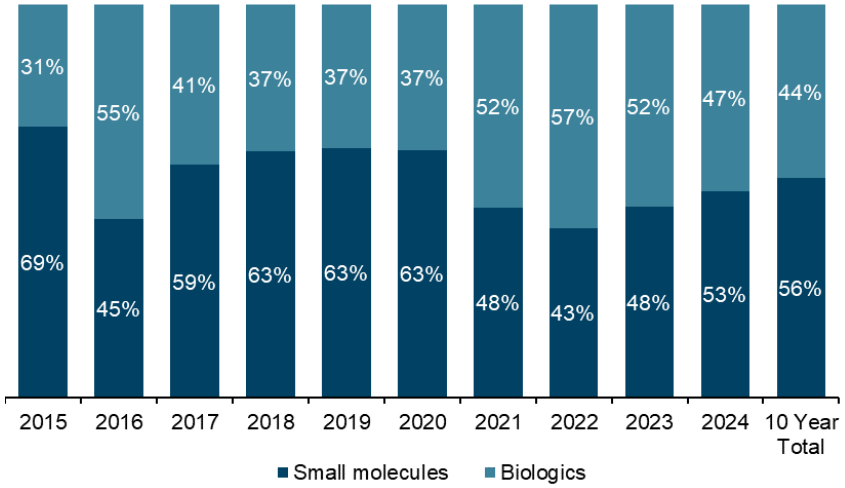
Small Molecules Versus Biologics

- 2024 marks the second consecutive year small-molecule drugs increased as a percentage of approvals, although the 53% observed in 2024 remains below the 56% average for the last 10 years.
- Biologics composed 47% of drug approvals in 2024. This represents a 5-percentage-point decrease compared to 2023, but a 3-percentage-point increase compared to its 10-year average of 44%. We expect biologics to account for a majority of approvals moving forward, especially as newer modalities (e.g., cell and gene therapies) gain traction.

Number of FDA Approvals



Percent of FDA Approvals



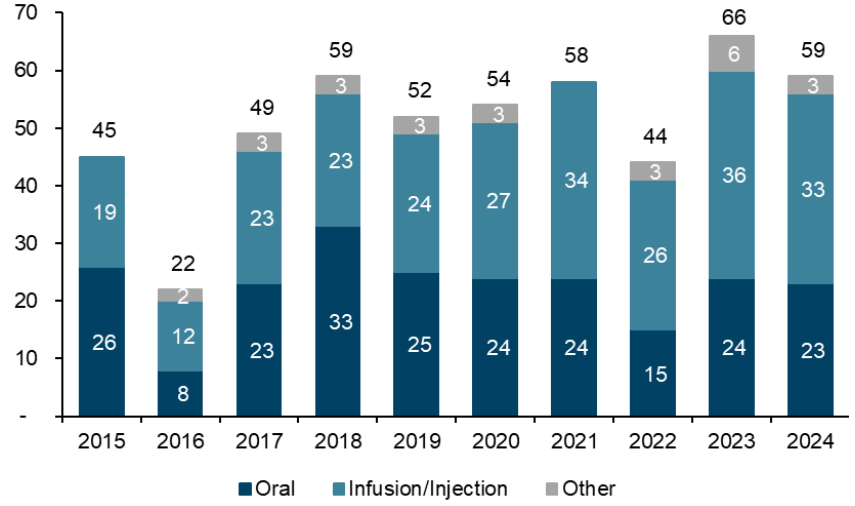
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: FDA Approvals

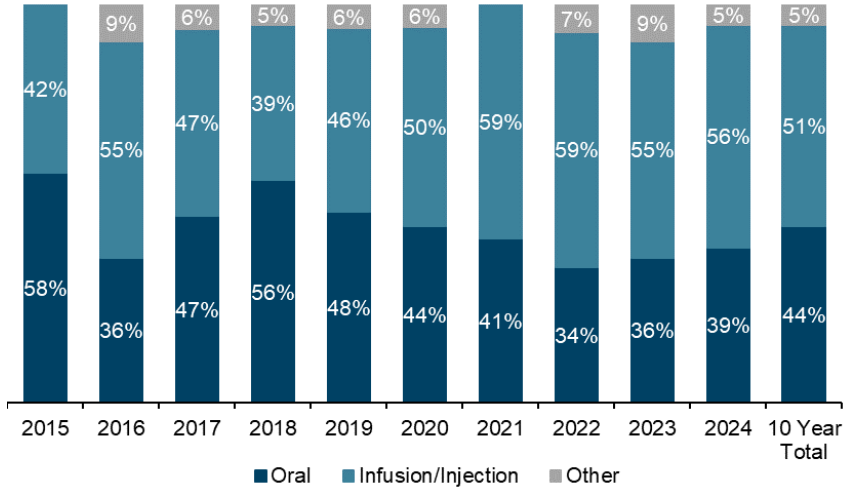
Approvals by Route of Administration

- Since 2015, we have seen the percentage of drugs dosed via injection increase from 42% to 56%. Given our expectation for biologics to account for the majority of approvals moving forward, we expect this gradual shift to continue as these drugs are more likely to be administered via infusion/ injection than small-molecule drugs.
- However, it should be noted that although injectables are becoming a more important component of the overall biopharma industry, oral drugs remain a large and resilient category, accounting for nearly 40% of drug approvals in 2024 (only slightly below the category average of 44% over the last 10 years).

Number of FDA Approvals



Percent of FDA Approvals



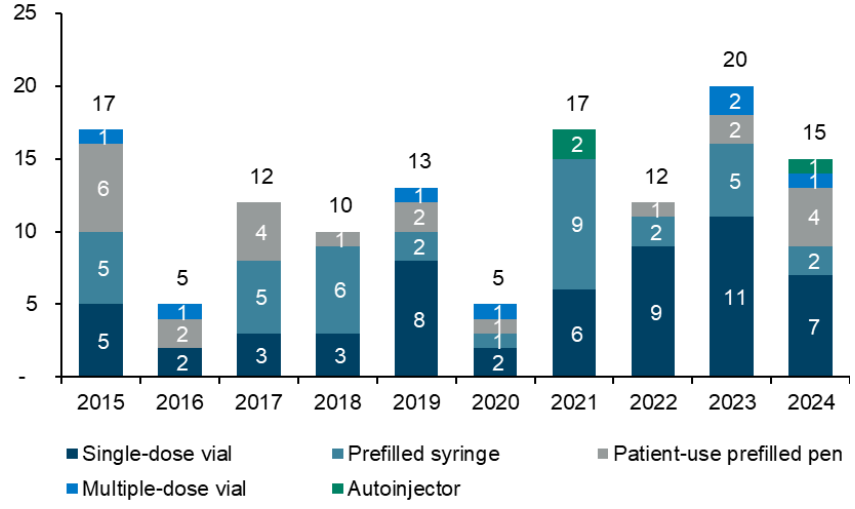
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: FDA Approvals

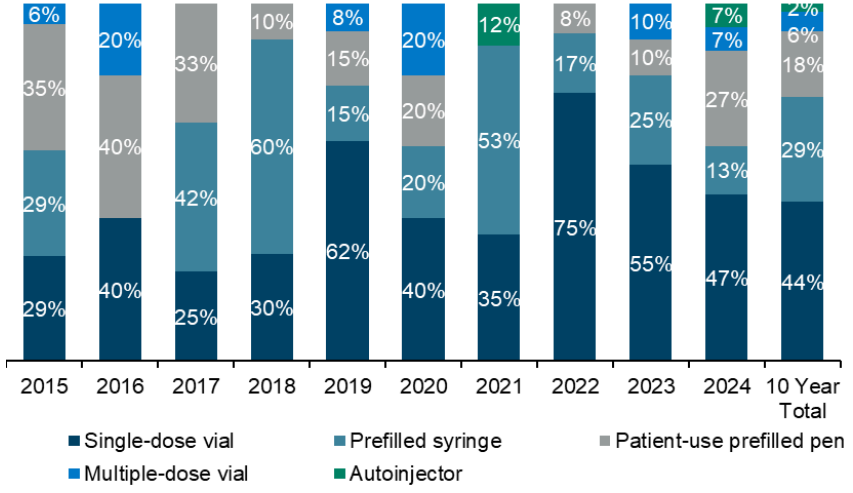
Injectables Approvals by Dosage Form

- Since 2015, we have seen the percentage of injectables approvals dosed in single-dose vials increase from 29% to 47%. The 10-year average is 44%, with an average of 59% in the last three years compared to 31% for 2015 through 2017. Notably, the percentage of approvals using prefilled pens has averaged below 20% over the last 3 years compared to accounting for more than a third of approvals a decade ago.
- We note that these data points reflect initial approval dosage form and do not account for molecule and dosage management strategies employed over the lifetime of a drug to make delivery easier, safer, and/or more convenient for patients.

Number of FDA Approvals



Percent of FDA Approvals



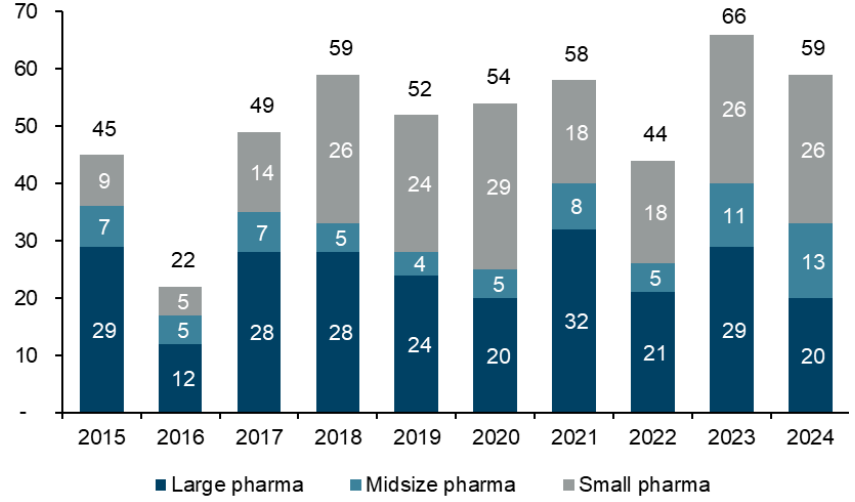
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: FDA Approvals

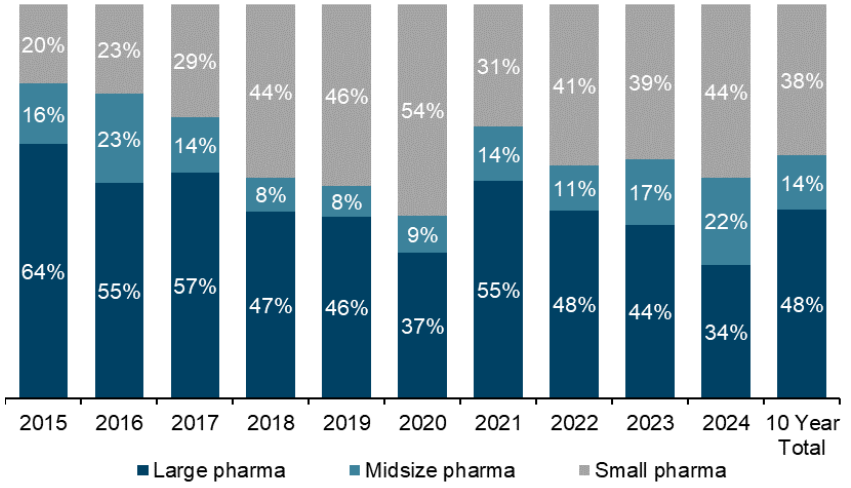
Approvals by Innovator Size

- Since 2015, we have observed an increase in average approvals from small biopharma in absolute numbers and as a percentage of total approvals. Smaller innovators accounted for 44% of approvals in 2024, a notable step-up compared to 39% in 2023, 20% in 2015, and the 10-year average of 38%.
- Large pharma has accounted for a declining number of approvals over the past 10 years, accounting for just 34% of total approvals in 2024, the lowest share of approvals for this cohort that we have observed in the past decade. This compares to 64% in 2015 and a 10-year average of 48%.

Number of FDA Approvals



Percent of FDA Approvals



Note: Developer is entity that controlled molecule three years prior to approval; market capitalization categorization: Small: <$2.5B, Mid: >$2.5B and <$10B, Large: >$10B
Sources: FDA.gov, FactSet, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

API Approval Analysis Capture Rate

- Across the 10-year sample, we were able to determine whether a drug's API production was outsourced 84% of the time (left table).
- Over the same 10 years, for those drugs using CDMOs for API production, we were able to identify the specific CDMO selected 71% of the time (right table).

% of Approvals for Which API Outsourcing Status Is Known

Year	Total FDA Approved Drugs	Total Known API Products (Outsourced and Inhouse)	Capture Rate of API Products
2015	45	36	80%
2016	22	18	82%
2017	49	33	67%
2018	59	41	69%
2019	52	32	62%
2020	54	51	94%
2021	58	54	93%
2022	44	40	91%
2023	66	62	94%
2024	59	58	98%
2015-2024	**508**	**425**	**84%**

% of Approvals With Outsourced API With Known Manufacturer

Year	Total Known Outsourced API Products	Total Known API CDMOs (Per Drug Basis)	Capture Rate of API CDMOs
2015	22	22	100%
2016	8	7	88%
2017	15	5	33%
2018	27	19	70%
2019	17	10	59%
2020	30	19	63%
2021	30	16	53%
2022	24	19	79%
2023	35	27	77%
2024	43	35	81%
2015-2024	**251**	**179**	**71%**

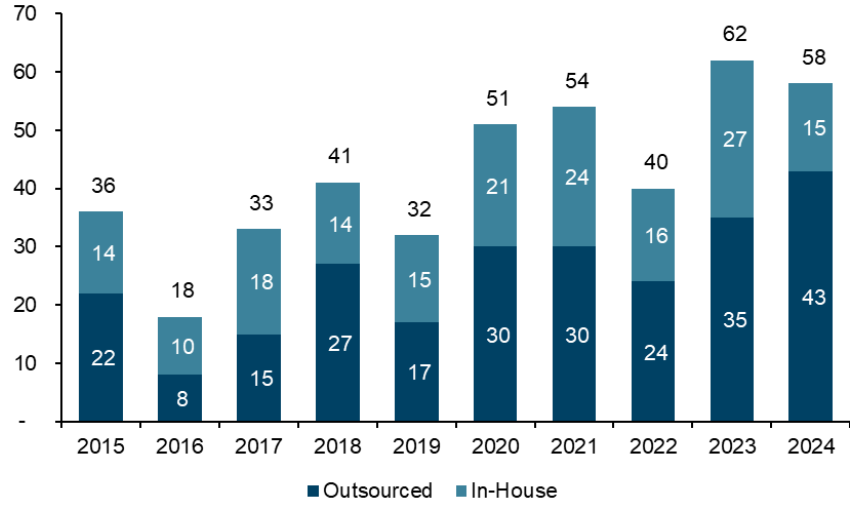
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

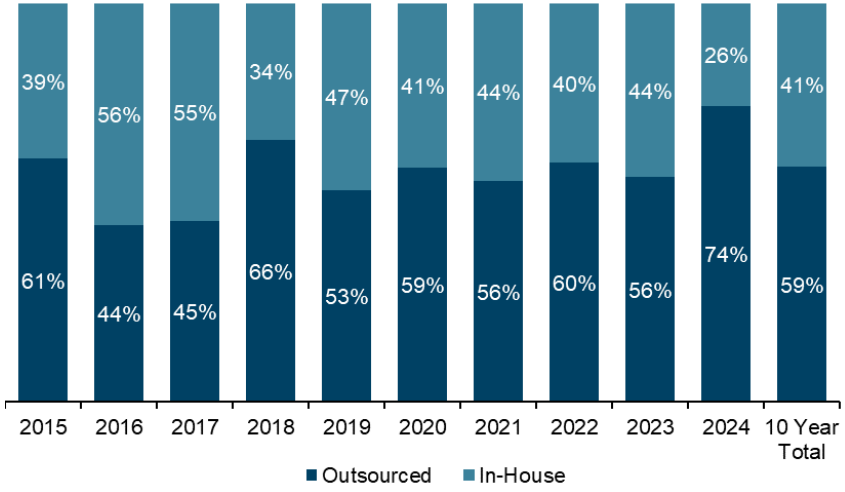
API Outsourced Manufacturing for Recent FDA Approvals

- Over the past 10 years, the percentage of FDA approvals that used outsourcing partners for API production has averaged 59%, with a notable uptick in 2024 to 74%, the highest outsourcing penetration rate observed across our dataset.
- Consistent with prior years, the percentage of 2024 approvals that rely on CDMOs for API production is solidly above the percentage of approvals that rely on CDMOs for finished dose production (61%, as shown on page 21).

API Outsourced vs. In-House Production



API % Outsourced vs. % In-House Production

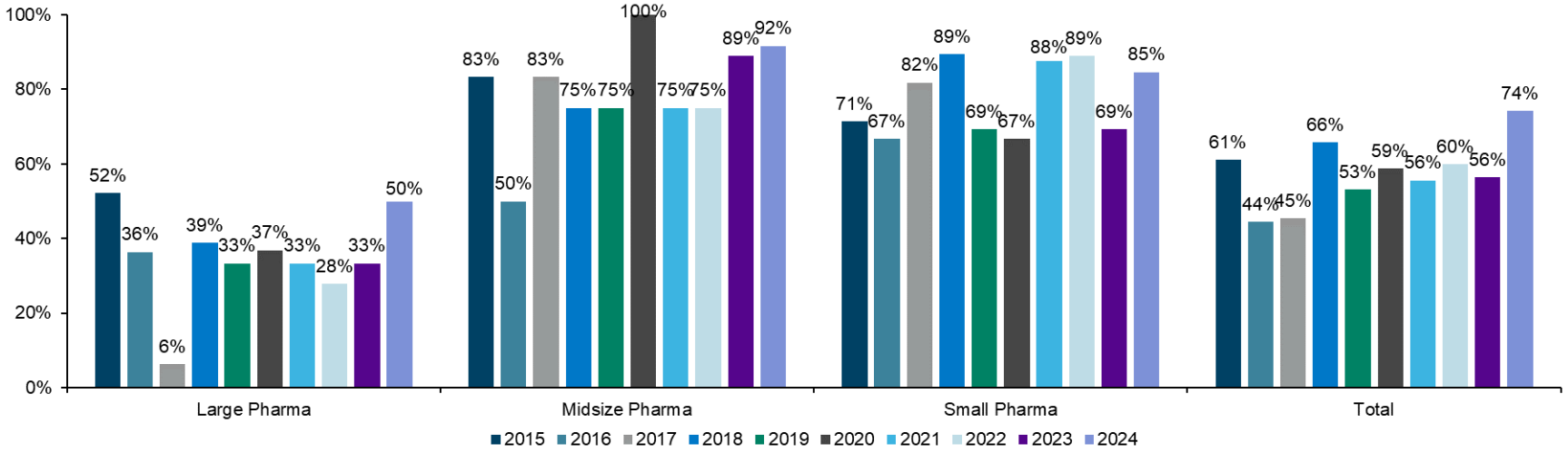


Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

API Outsourcing by Pharma Size

- Small biopharma's outsourcing rate for API over the last 10 years has averaged 78%. This increased to 85% in 2024, returning the cohort's outsourcing penetration rate to above 80% after it ticked below 70% in 2023.
- Midsize pharma's outsourcing rate for API since 2015 has averaged 80% but increased meaningfully in 2024 to 92%. Large pharma's outsourcing rate for API was 50% in 2024, above its 35% average since 2015.
- As smaller sponsors increasingly account for a larger portion of drug approvals, we assume the overall average portion of API that is outsourced should increase moving forward.



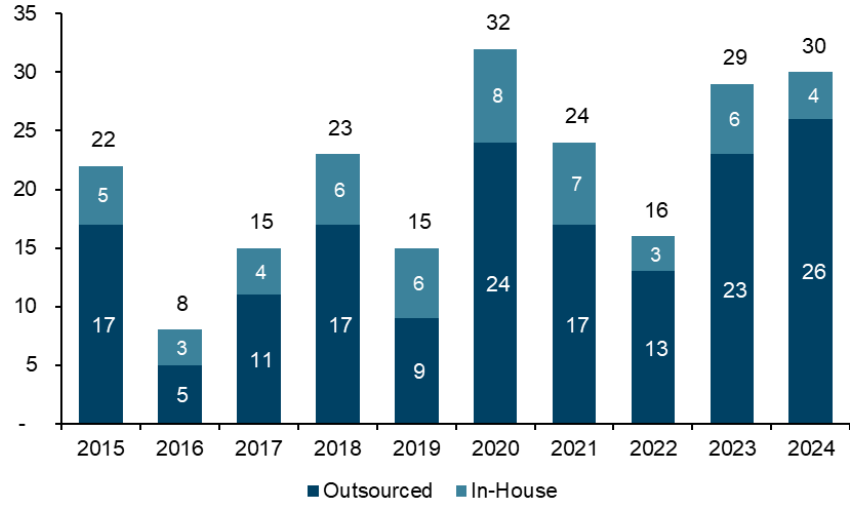
Sample size: 2015: 36, 2016: 18, 2017: 33, 2018: 41, 2019: 32, 2020: 51, 2021: 54, 2022: 40, 2023: 62, 2024: 58
Note: Developer is entity that controlled molecule three years prior to approval; market capitalization categorization: Small: <$2.5B, Mid: >$2.5B and <$10B, Large: >$10B
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

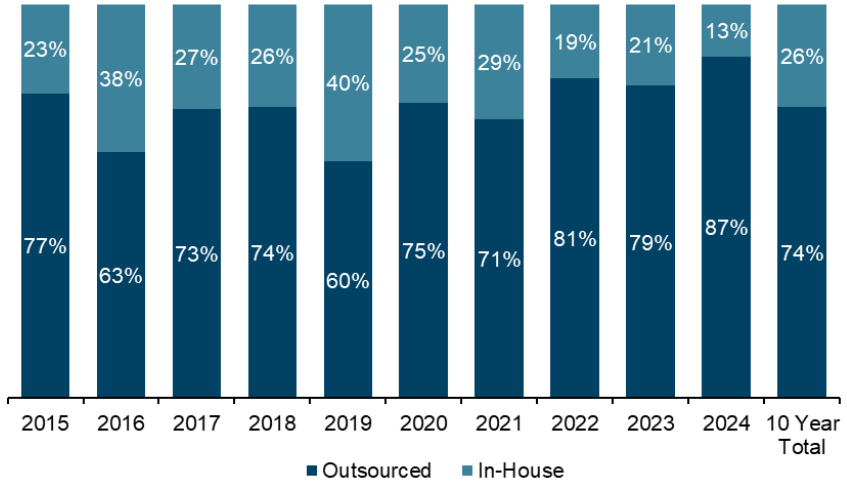
Small Molecule – API Outsourced Manufacturing for Recent FDA Approvals

- Since 2015, we have observed a relatively consistent outsourcing rate of about 74% for the API manufacturing of small molecules, with a nice uptick in 2024 to 87%.
- The 87% outsourcing rate observed in 2024 is highest rate of small-molecule API outsourcing penetration on record, representing an impressive 8-percentage-point increase over the 79% recorded in 2023.

Small Molecule – API Outsourced vs. In-House Production



Small Molecule – API % Outsourced vs. % In-House Production



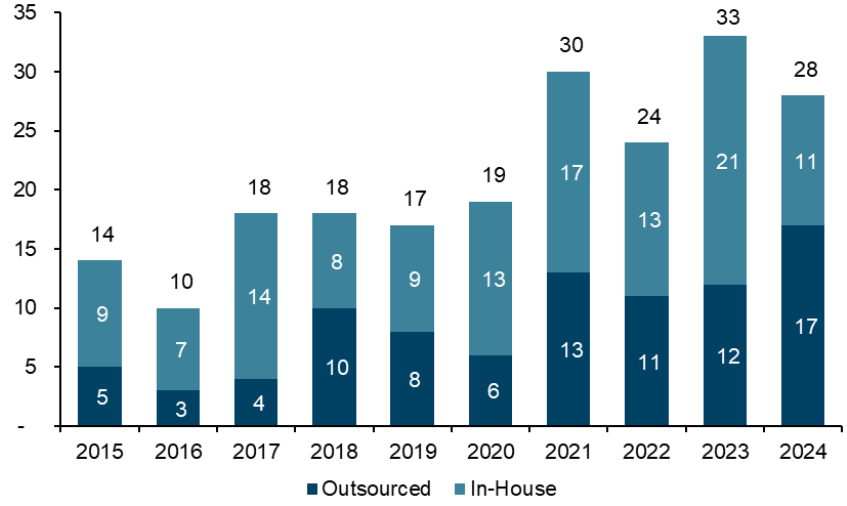
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

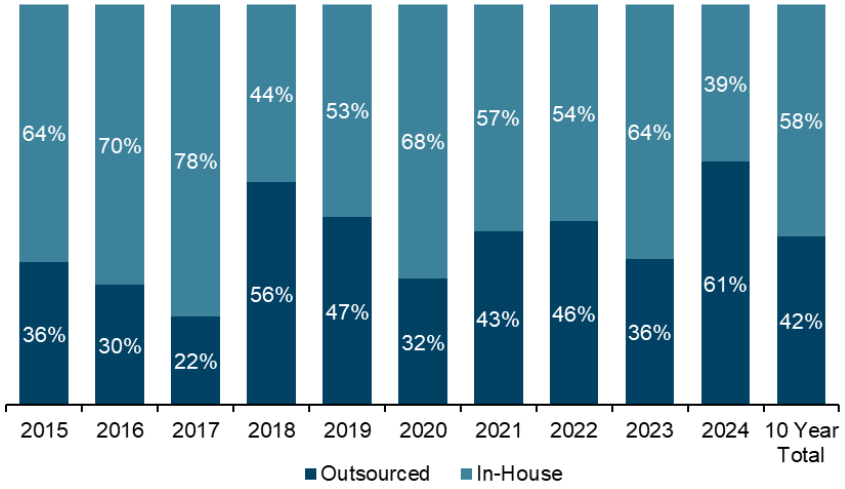
Biologics – API Outsourced Manufacturing for Recent FDA Approvals

- Since 2015, we have observed an average outsourcing rate of 42% for the API manufacturing of biologics, with a significant uptick in 2024 to 61%.
- The outsourcing rate has been volatile over the past 10 years with no clear trend. Despite the volatility, it is clear innovators continue to outsource biologic drug API production less often than they do for small molecules. We would assume the outsourcing rate for biologic drugs will trend higher over time given they are increasingly being sourced by smaller innovators.

Biologics – API Outsourced vs. In-House Production



Biologics – API % Outsourced vs. % In-House Production



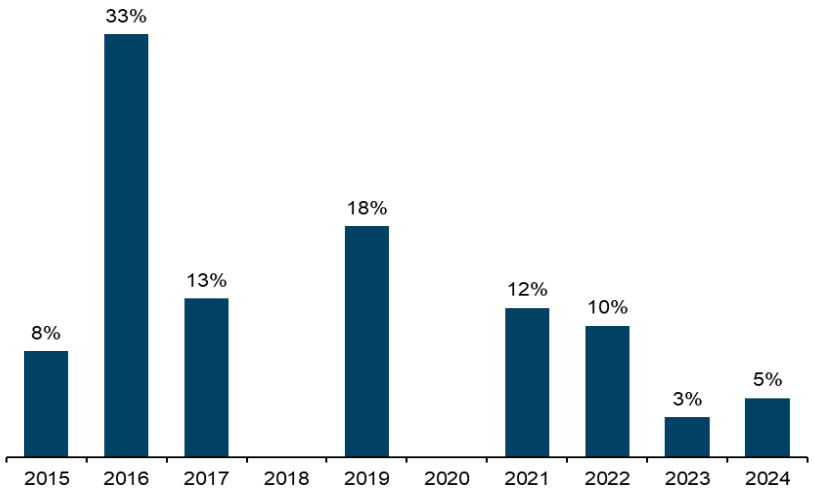
Sources: FDA.gov, BioCentury Inc., and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

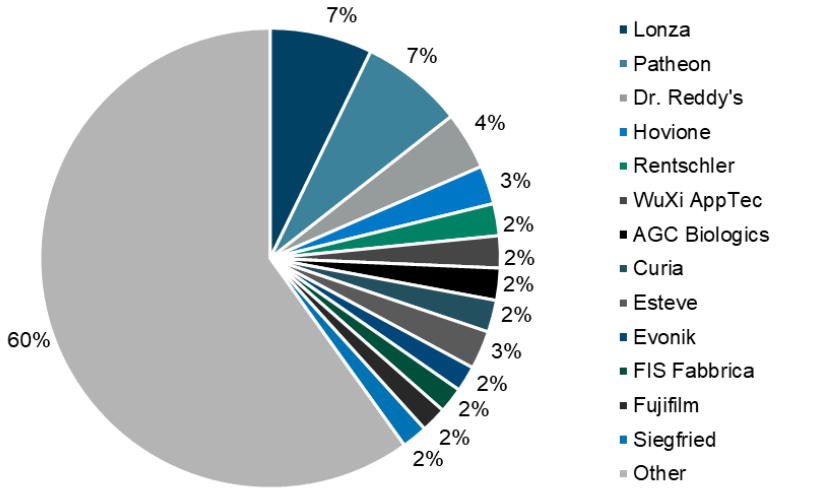
CDMO Market Share

- The top 13 CDMOs since 2015 only account for 40% of approvals. The remaining 60% of approvals are supported by CDMOs with less than 2% market share each, which illustrates how fragmented the API CDMO market remains.
- Lonza remains the leader in API manufacturing, particularly in the large-molecule space, although its share of newly approved drugs only rebounded modestly in 2024. Thermo Fisher/Patheon remains the only company with a comparable share of the API manufacturing market.

Lonza's Share of Outsourcing[1]



API CDMO Landscape 2015-2024[2]



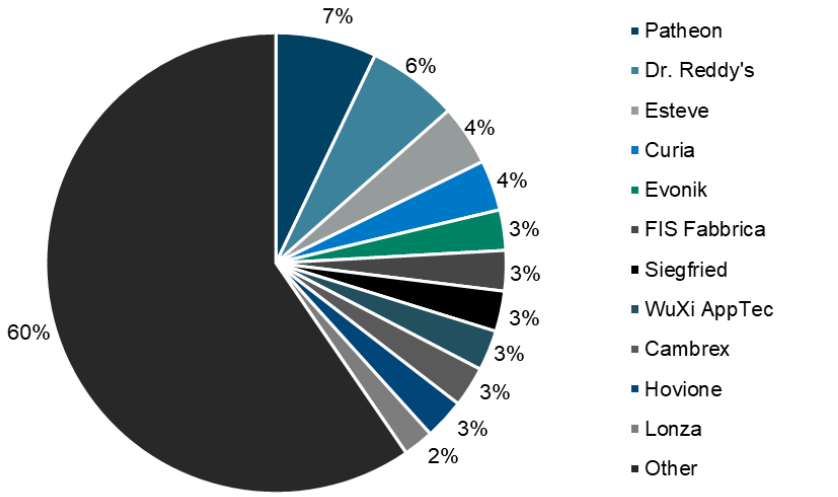
Sample size[1]: 2015: 24, 2016: 9, 2017: 8, 2018: 27, 2019: 11, 2020: 22, 2021: 17, 2022: 29, 2023: 32; 2024: 43; Sample size[2]: 222
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: API – Trends in Manufacturing Outsourcing

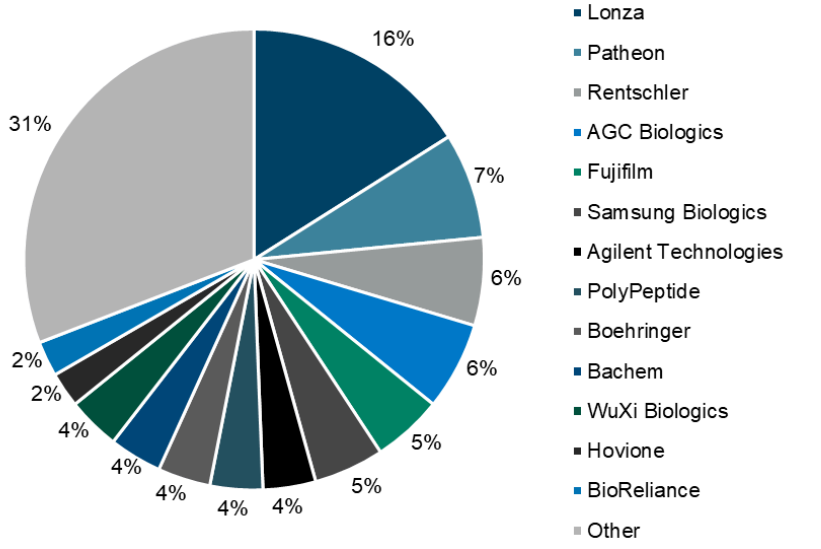
CDMO Market Share by Molecule Type

- Since 2015, the top 11 CDMOs have accounted for 40% of small-molecule API approvals. The remaining 60% of approvals are supported by CDMOs with less than 2% market share each.
- Lonza is the clear leader in the large-molecule API category, accounting for 16% of biologic drug API approvals since 2015. Thermo Fisher/Patheon, Rentschler, and AGC Biologics have each received more than 5% of biologic drug approvals, though we note that the sample size of biologics approvals is only around half of our small-molecule API sample size.

Small-Molecule API CDMO Landscape 2015-2024[1]



Biologics API CDMO Landscape 2015-2024[2]



Sample size[1]: 141; Sample size[2]: 81
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

Finished Dose Approval Analysis Capture Rate

- Across the 10-year sample, we were able to determine whether a drug's finished dose production was outsourced 96% of the time (left table).
- Over the same period, for those drugs using CDMOs for finished dose production, we were able to identify the specific CDMO selected 79% of the time (right table).

% of Approvals for Which DP Outsourcing Status Is Known

Year	Total FDA Approved Drugs	Total Known DP Products (Outsourced and Inhouse)	Capture Rate of DP Products
2015	45	43	96%
2016	22	22	100%
2017	49	47	96%
2018	59	56	95%
2019	52	49	94%
2020	54	53	98%
2021	58	57	98%
2022	44	40	91%
2023	66	64	97%
2024	59	57	97%
2015-2024	**508**	**488**	**96%**

% of Approvals With Outsourced DP With Known Manufacturer

Year	Total Known Outsourced DP Products	Total Known DP CDMOs (Per Drug Basis)	Capture Rate of DP CDMOs
2015	17	17	100%
2016	9	8	89%
2017	24	22	92%
2018	26	24	92%
2019	21	16	76%
2020	28	17	61%
2021	33	23	70%
2022	18	14	78%
2023	27	19	70%
2024	35	27	77%
2015-2024	**238**	**187**	**79%**

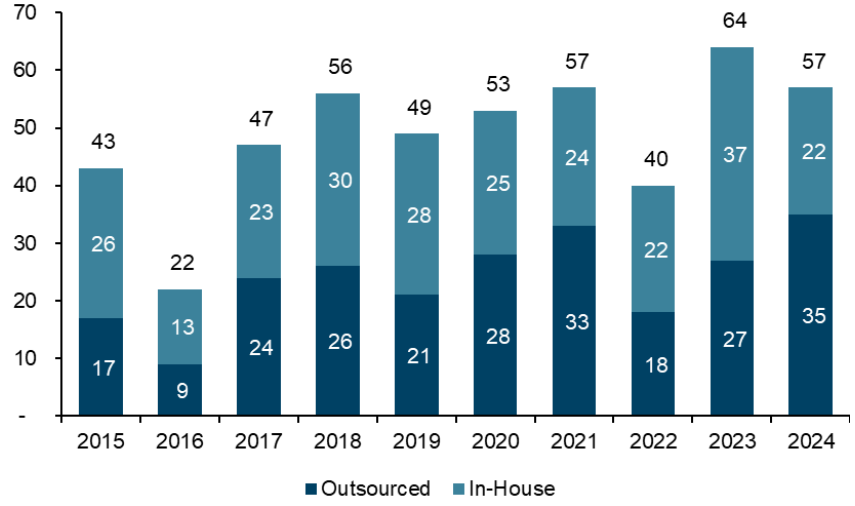
Note: DP = drug product, which is used interchangeably with finished dose
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

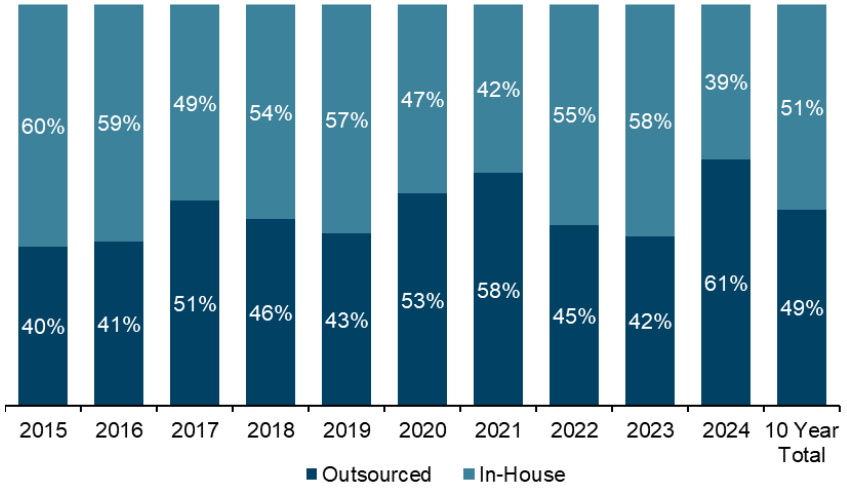
Finished Dose Outsourced Manufacturing for Recent FDA Approvals

- While the percentage of finished dose outsourcing has remained relatively stable around 50% since 2015, there was a notable uptick in 2024, with 61% of drugs approved leveraging third-party manufacturers.
- The uptick in fill-finish outsourcing observed in 2024 breaks a streak of two consecutive periods of year-over-year declines, and the 61% of approved drugs leveraging third-party manufacturers represents the highest outsourcing rate we have observed in the 10-year period.

Finished Dose Outsourced vs. In-House Production



Finished Dose % Outsourced vs. % In-House Production

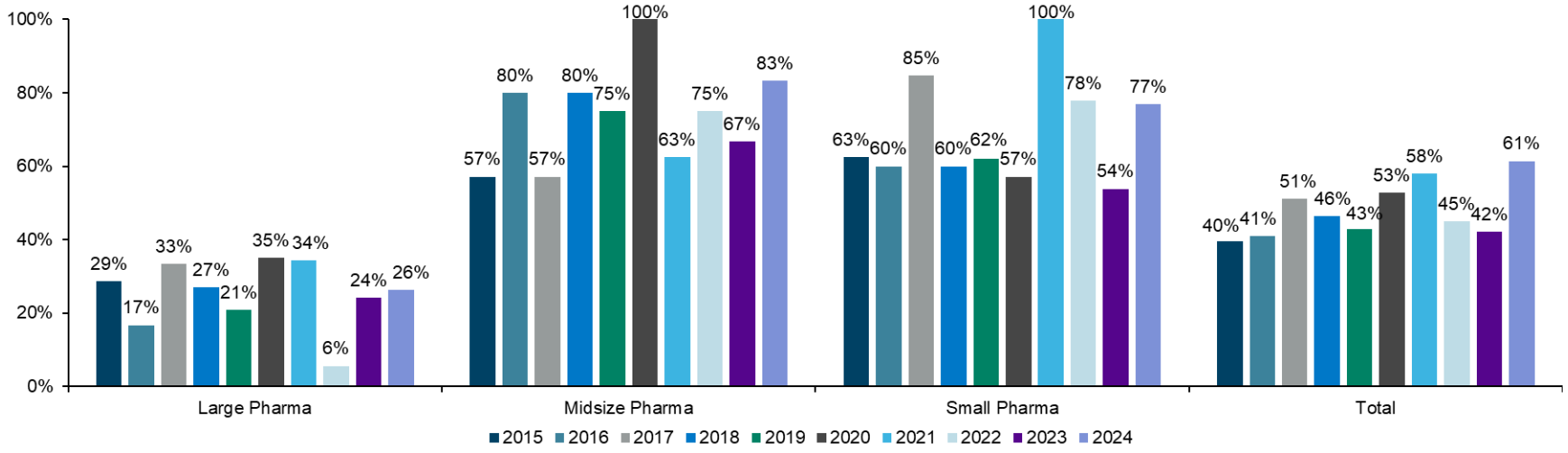


Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

Finished Dose Outsourcing by Pharma Size

- Small biopharma experienced a significant increase in finished dose outsourcing penetration in 2024, with the 77% observed representing the fourth highest outsourcing rate observed since 2015. Outsourcing penetration for midsize pharma of 83% was nicely above its 74% average observed since 2015, while outsourcing penetration for large pharma was roughly in line with its 25% average since 2015.
- Despite volatility in finished dose outsourcing penetration for the different innovator size categories since 2015, in aggregate, there remains a clear pattern that smaller innovators outsource finished dose production at a much greater rate than large pharma.



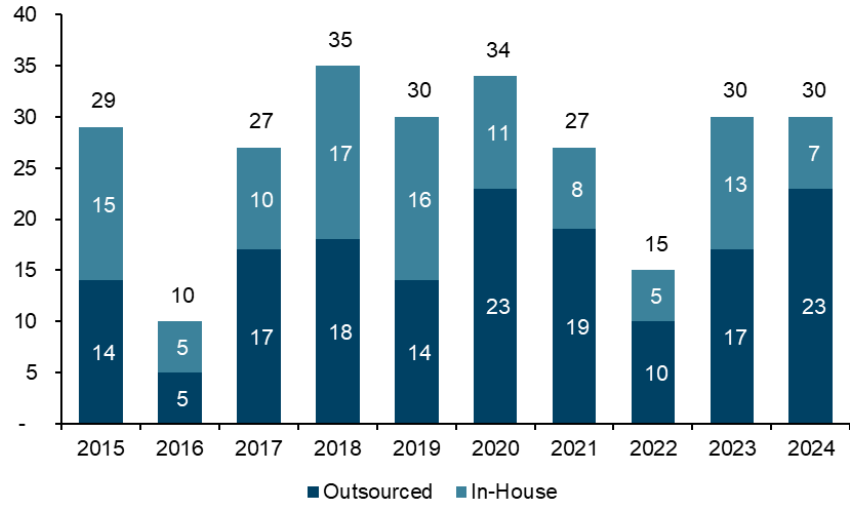
Sample size: 2015: 43, 2016: 22, 2017: 47, 2018: 56, 2019: 49, 2020: 53, 2021: 57, 2022: 40, 2023: 64, 2024: 57
Note: Developer is entity that controlled molecule three years prior to approval; market capitalization categorization: Small: <$2.5B, Mid: >$2.5B and <$10B, Large: >$10B
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

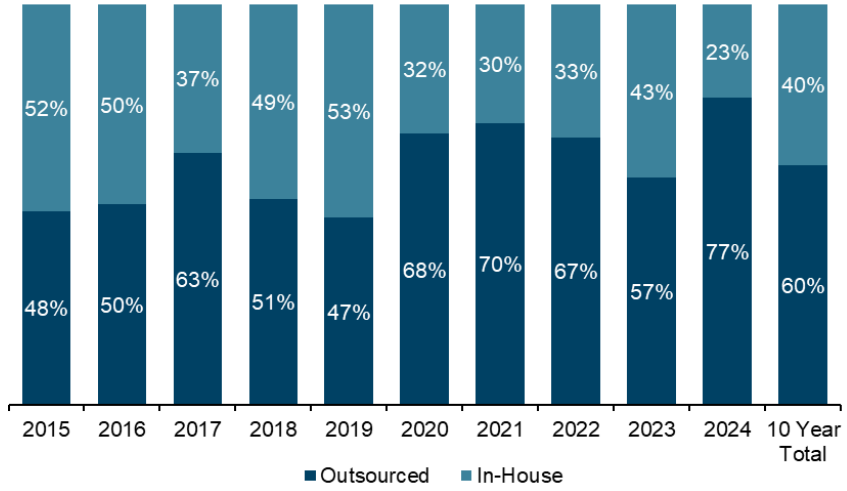
Small Molecule – Finished Dose Outsourced Manufacturing for Recent FDA Approvals

- Looking at the small-molecule portion of approvals since 2015, we have seen outsourcing rates historically vary between roughly 50% and 70% of approvals outsourced for finished dose production.
- In 2024, 77% of new small-molecule approvals used outsourced finished dose manufacturing, which is up materially from the prior year and well above the 10-year average of 60%. We assume there will be some upward drift in the portion that is outsourced over time as more approvals come from smaller innovators.

Small Molecule – DP Outsourced vs. In-House Production



Small Molecule – DP % Outsourced vs. % In-House Production



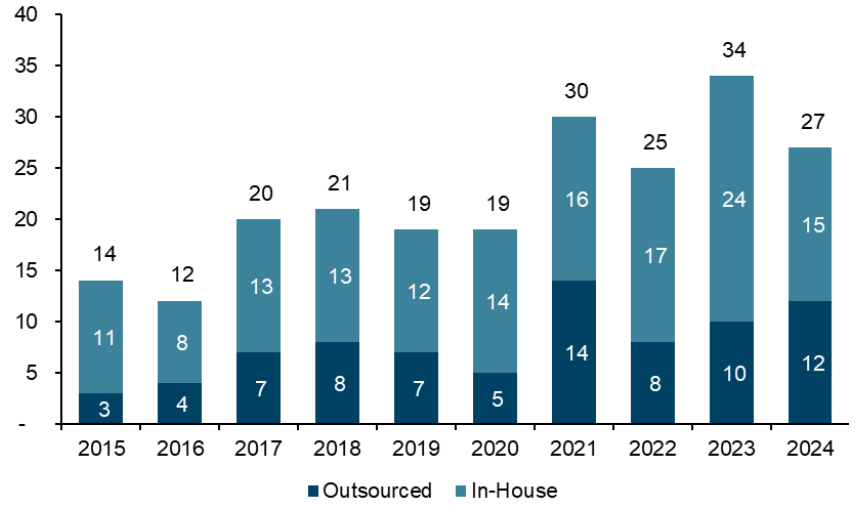
Note: DP = drug product, which is used interchangeably with finished dose
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

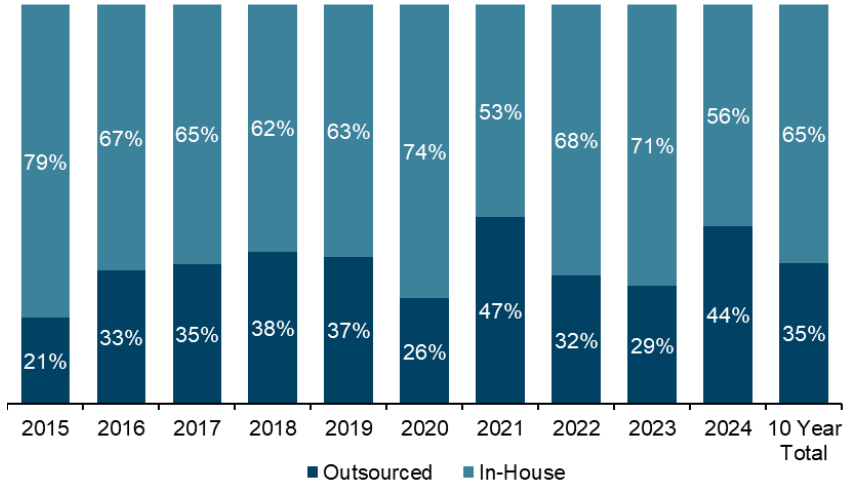
Biologics - Finished Dose Outsourced Manufacturing for Recent FDA Approvals

- Looking at only large-molecule approvals since 2015, the average outsourcing rate for biologics finished dose is 35%, with the rate in 2024 coming in well above this average at 44%.
- We assume the rate of outsourcing will continue to drift higher over time as we move further beyond the disruption from the pandemic and companies gain comfort in outsourcing newer biologics modalities (e.g., cell and gene therapies).

Biologics – DP Outsourced vs. In-House Production



Biologics – DP % Outsourced vs. % In-House Production



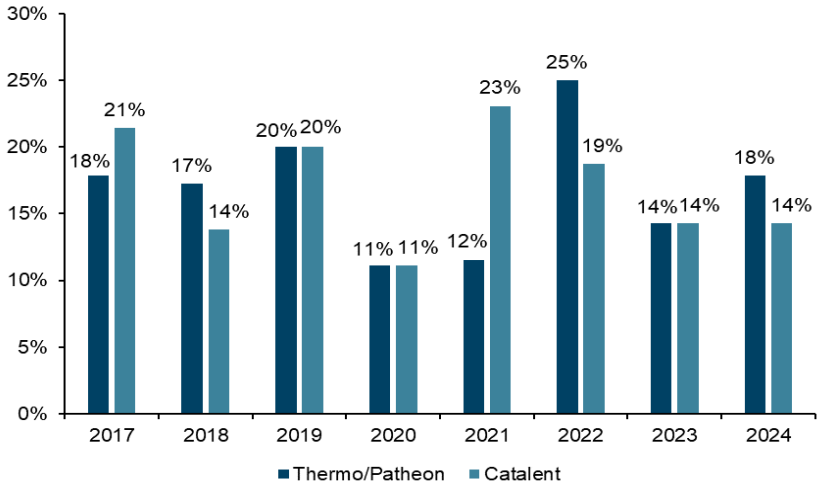
Note: DP = drug product, which is used interchangeably with finished dose
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

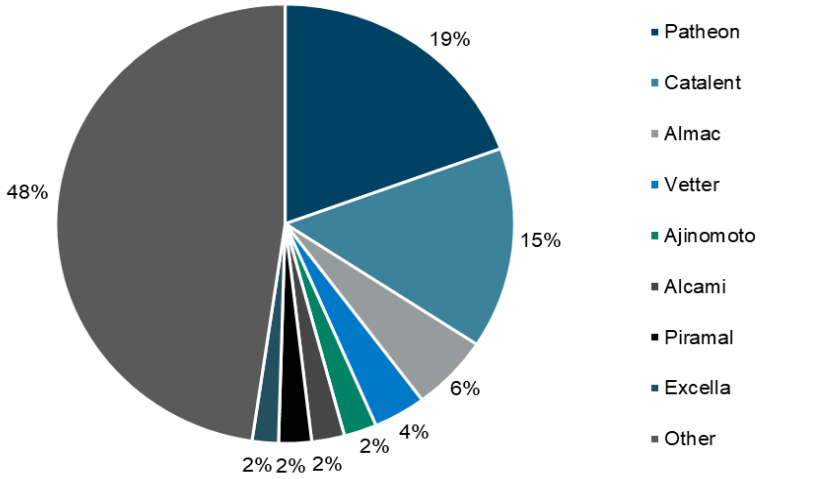
CDMO Market Share

- The finished dose CDMO market remains fragmented, although less so in comparison to the API CDMO market. The top three companies have an impressive 40% share of this market since 2015—Thermo Fisher/Patheon leads the pack, with Catalent (recently acquired by Novo Holdings) in second place, and U.K.-based Almac as the third biggest by share.
- These three companies are followed by a cluster of other CDMOs with market share of 4% or less, including Vetter, Ajinomoto, Alcami, Piramal, and Excella.

Thermo/Patheon & Catalent Share of Outsourcing[1]



Finished Dose CDMO Landscape 2015-2024[2]



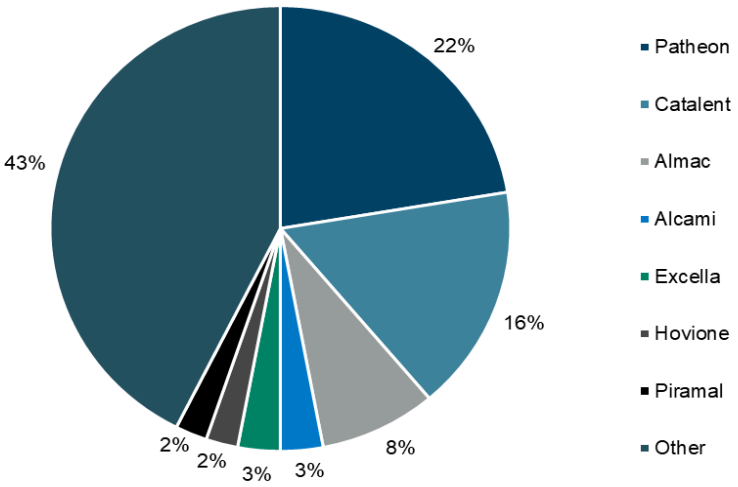
Sample size[1]: 2017: 28, 2018: 29, 2019: 20, 2020: 18, 2021: 26, 2022: 16, 2023: 21, 2024: 28; Sample size[2]: 216
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: Finished Dose – Trends in Manufacturing Outsourcing

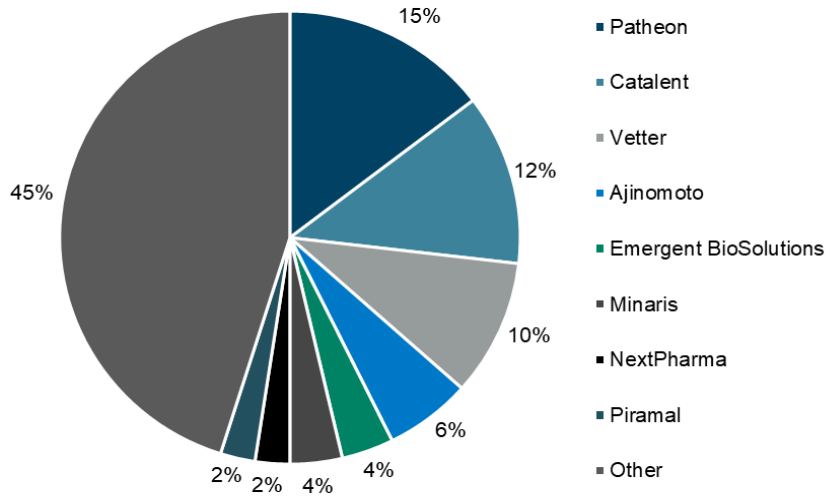
CDMO Market Share by Molecule Type

- Small-molecule finished dose is dominated by three players: Thermo Fisher/Patheon, Catalent (recently acquired by Novo Holdings), and Almac, which combine for nearly 50% of the market. The other half of the market remains relatively fragmented.
- Large-molecule finished dose is dominated by four players: Thermo Fisher/Patheon, Catalent, Vetter, and Ajinomoto, which together account for 43% of approvals. The remainder of the market remains fragmented, similar to the market for small molecules.

Small-Molecule Finished-Dose CDMO Landscape 2015-2024[1]



Biologics Finished-Dose CDMO Landscape 2015-2024[2]



Sample size[1]: 134; Sample size[2]: 82
Sources: DailyMed – National Library of Medicine, FDA.gov, company filings, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: CDMO Landscape – Small-Molecule Capabilities

Company	Capability	
	API	Finished Dose
Aenova	✓	✓
Alcami	✓	✓
Almac	✓	✓
Ajinomoto Bio-Pharma*	✓	✓
Bachem*	✓	
Simtra BioPharma Solutions (Baxter)		✓
BioVectra	✓	
Cambrex	✓	✓
Catalent (Novo)	✓	✓
Cenexi		✓
CordenPharma	✓	✓
Curia Global	✓	✓
Delpharm		✓
Evonik*	✓	✓
Esteve	✓	
Eurofins*	✓	✓
Famar		✓

Company	Capability	
	API	Finished Dose
Fareva Excella	✓	✓
FIS Fabbrica	✓	
Hovione	✓	✓
Johnson Matthey*	✓	
Jubilant*	✓	✓
Lonza*	✓	✓
NextPharma		✓
Quotient Sciences		✓
PCI Pharma Services		✓
Piramal*	✓	✓
Porton*	✓	✓
Recipharm	✓	✓
Seqens	✓	
Siegfried*	✓	✓
Societal CDMO		✓
Sterling Pharma Solutions	✓	✓
Thermo Fisher (Patheon)*	✓	✓
Vetter		✓
WuXi*	✓	✓
Yuhan*	✓	

Note: * denotes publicly traded company
Sources: Company reports, PharmSource, and William Blair Equity Research

Pharmaceutical Outsourcing Industry: CDMO Landscape – Biologics Capabilities

Company	Capability			
	API	Finished Dose	Gene Therapy	Cell Therapy
Alcami		✓		
AGC Biologics	✓	✓	✓	✓
Ajinomoto Bio-Pharma*	✓	✓		
Avid Bioservices	✓	✓	✓	✓
Simtra BioPharma Solutions (Baxter)		✓		
BioNTech*	✓		✓	✓
BioVectra	✓			
Boehringer Ingelheim (BioXcellence)	✓	✓		
Catalent (Novo)	✓	✓	✓	✓
Cell & Gene Therapy Catapult			✓	✓
Cenexi	✓	✓		
Charles River (Cognate BioServices)*			✓	✓
CordenPharma	✓	✓		
Curia Global	✓	✓	✓	✓
Delpharm		✓		
Eurofins*	✓			
Merck KGaA (Exelead)*	✓	✓		

Company	Capability			
	API	Finished Dose	Gene Therapy	Cell Therapy
Fareva Excella	✓	✓		
Forge Biologics			✓	
Fujifilm*	✓	✓	✓	✓
Jubilant*		✓		
Lonza*	✓	✓	✓	✓
NextPharma		✓		
PCI Pharma Services		✓		
Piramal*		✓		
Porton*	✓	✓	✓	✓
Recipharm	✓	✓		
Rentschler	✓	✓	✓	✓
Resilience	✓		✓	✓
Resonac*	✓		✓	✓
Samsung Biologics*	✓	✓		
Thermo Fisher (Patheon)*	✓	✓	✓	✓
Vetter		✓		
WuXi*	✓	✓	✓	✓

Note: * denotes publicly traded company
Sources: Company reports, PharmSource, and William Blair Equity Research

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DOW JONES: 43433.10
S&P 500: 5956.06
NASDAQ: 19075.30

Additional information is available upon request.

Current Rating Distribution (as of February 27, 2025):

Coverage Universe	Percent	Inv. Banking Relationships *	Percent
Outperform (Buy)	70	Outperform (Buy)	9
Market Perform (Hold)	29	Market Perform (Hold)	1
Underperform (Sell)	1	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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