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2024 IN REVIEW:

Pharmaceutical Innovation and the Inflation Reduction Act

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A Note on Authorship

This report was researched and published by the authors during their tenure at ATI Advisory from 2023 to 2025. With continued support from Arnold Ventures, the authors carry forward this work under Verdant Research.

ATI Advisory

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Overview

We follow 19 biopharma companies that have had or are likely to have a drug selected for Medicare negotiation. In our wrap-up of 2023, we concluded that there were few signs of changes in behavior in response to the Inflation Reduction Act (IRA). In this report, we continue our evaluation through the end of 2024, with the additional context of the 2025 implementation of the Part D redesign as well as recent political, regulatory, and economic uncertainties.

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Key Findings

Amidst political and economic uncertainty, Medicare negotiation did not feature prominently as a concern during companies' 4th quarter earnings calls. Commentary on the Inflation Reduction Act (IRA) instead focused on the Part D redesign. Several companies provided estimates of the "headwind" they could experience from their increasing share of costs in the catastrophic phase starting in 2025. Despite offsetting increases in utilization from the $2,000 cap on out-of-pocket spending, estimated net impacts ranged from $0 to up to $2bn, depending on the company.

Companies continue to execute on their pipeline priorities, and R&D investment remained strong — increasing more than 10% over 2023 levels. As many of the restructuring and reprioritization programs have wrapped up, companies are focused on a more targeted set of programs and therapeutic areas.

Volume and overall value of deals declined in 2024. Among other factors, the decline may have been driven by companies focusing on pipeline reprioritization and integrating significant transactions from 2023. In contrast to 2023, transactions in 2024 generally centered on smaller and earlier-stage assets. Many believe conditions are ripe for a pickup in dealmaking, but external conditions and a high bar for investment decisions are keeping companies from rushing in.

Commercial considerations seem to be playing an increasing role in R&D decision-making as companies plan for growth from new products amidst a wave of coming exclusivity losses. In addition, China has emerged as a greater focus for dealmaking and clinical development during 2024. Biopharma companies have entered multibillion-dollar licensing and collaboration deals centered on oncology and obesity drugs.

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Many believe conditions are ripe for a pickup in dealmaking, but external conditions and a high bar for investment decisions are keeping companies from rushing in.

Overall Market Performance

Following a long-awaited rally in late 2023, overall sentiment around the sector was volatile throughout 2024 – and particularly bad in the last quarter. The industry came into 2024 with positivity, with the DRG large-cap pharma index appreciating 13% in the first quarter. That optimism was stoked by several significant deals announced in late 2023 and the hope that lower interest rates could loosen the challenging funding environment for earlier stage biotech companies.

Unfortunately, this more optimistic outlook stalled and the XBI biotech index closed the year barely above where it started (up just 1%). The DRG large-cap pharma index was down 13% during the 4th quarter and ended the year up only 2% over 2023.

Towards the end of 2024 and into 2025, industry participants appear to have grown increasingly concerned about political, financial and regulatory uncertainty, clouding the outlook for the sector and overall economy. Since the election, concerns about the Inflation Reduction Act (IRA) have increasingly been overshadowed by other considerations. During earnings calls and at the JP Morgan Healthcare conference in January, executives were restrained in their comments on risks and concerns, and were generally focused on areas of common ground with the new administration. So far, most have signaled a "wait-and-see" approach on more controversial topics, such as FDA staffing and the user-fee system, NIH funding, and the impact of Trump's international trade policies and tariffs. Administration policies in these areas all have the potential to impact R&D, the FDA review process, and manufacturing, driving uncertainty.

Company and Portfolio-Level Developments

R&D SPENDING

The intensive restructuring and reprioritization programs from 2023 have been winding down and companies are entering 2025 in "execution mode" within their targeted therapeutic areas and key programs. In 2024, we saw Roche and J&J restructure their immuno-oncology and cardiovascular divisions, respectively. Companies across the board seem to be tightening their focus and investing in therapeutic areas where they have an edge and the ability to add value to patients and their bottom lines.

R&D spending increased at a double-digit rate over last year, at an average of nearly 11% and a median of 8% (Table 1). Of the companies we follow (that reported FY results), the only one that recorded a decline in R&D was Biogen (down 14% year-over-year) following its extensive R&D restructuring program and approvals of several products in 2023. Novartis and J&J's R&D spending was down compared to 2023 during the 1st half of 2024, but both reported strong growth for the full year (8% and 12%, respectively.) All three of these companies recently reorganized their pipelines and have been targeting their investments towards priority assets.

The four companies with the most sizable increases in R&D are running very large phase 3 programs in obesity: NovoNordisk (+48%), Amgen (+25%), AstraZeneca (+19%) and Eli Lilly (+18%).

Companies across the board seem to be tightening their focus and investing in therapeutic areas where they have a therapeutic edge and the ability to add value to patients and their bottom lines.

Table 1. Share of company sales from products expected to lose exclusivity or face IRA negotiation

Company	% of 2024 sales LOE (2025-2029)	2024 sales of negotiated drugs ($mn)	Negotiated drugs (% 2024 US sales)	Revenue growth WW (2024/2023)	R&D growth (2024/2023)
AbbVie	52%	$1,987	5%	4%	15%
Amgen	63%	$1,247	5%	19%	25%
Astellas* (est.)	76%	$1,389	30%	4%	5%
AstraZeneca	34%	$1,182	5%	18%	19%
Biogen	63%			-2%	-15%
Boehringer Ingelheim	99%	$2,838	21%	5%	10%
BMS	87%	$4,930	14%	7%	7%
Eli Lilly	29%	$559	2%	32%	18%
Gilead	11%			6%	0%
GSK	91%	$1,064	5%	6%	8%
J&J	77%	$3,183	9%	4%	15%
Merck	90%	$252	1%	7%	11%
Novartis	65%	$1,418	7%	11%	8%
Novo Nordisk	30%	$6,464	25%	25%	48%
Pfizer	67%	$1,466	4%	7%	1%
Regeneron	66%			8%	16%
Roche	64%			5%	1%
Sanofi	51%			6%	14%
Takeda* (est.)	54%			0%	0%
AVERAGE	**62%**		**10%**	**9%**	**11%**

*Astellas and Takeda are estimates as their fiscal year results not yet reported

On average, companies' R&D growth exceeded revenue growth by 1.7 percentage points (Table 1). Notably, several companies appear to be increasing investment in R&D and manufacturing in the US rather than pulling back, including AstraZeneca, NovoNordisk and Eli Lilly.

DEALMAKING: M&A

Compared to last year, 2024 was relatively quiet on the deal front. According to IQVIA's report on Biopharma M&A, there were only 22 deals valued at over $1bn last year, compared with 27 the prior year. Perhaps more notably, total deal value declined 68% to just $48bn, and the average deal size was $2.1bn compared with $5.6bn in 2023. No deal was larger than $5bn.

The recent decline likely reflects a confluence of several factors. A number of large biopharma companies undertook significant restructuring programs in 2023 and 2024, and are either integrating the ensuing re-prioritizations or more selectively applying these filters in evaluating prospective M&A transactions. Moreover, several completed large deals over the last year or two and are still digesting and optimizing those acquisitions. A more limited supply of attractive late-stage companies and drugs may have also constrained activity, as a number of attractive and commercial-ready assets were bought up in 2023.

These trends played out in our sample of 19 biopharma manufacturers as well. This year, there were 18 acquisitions with upfront deal values of at least $1bn. The largest deal of the year was Gilead's $4.3bn acquisition of CymaBay announced in 1Q25, and there were only 5 more deals above $2bn for the remainder of the year: Lilly/Morphic ($3.2bn); Merck/Eyebiotech ($3bn); Novartis/MorphoSys ($2.9bn); AstraZeneca/Fusion ($2bn) and Sanofi/Inhibrx ($2.2bn). In contrast, these companies signed eight deals over $5bn. in 2023, including several in the 4th quarter alone.

Only 6 acquisitions surpassed $2B in 2024. In 2023, there were 8 deals above $5B—several in Q4 alone.

Top Biopharma Acquisitions in 2024 (>$2B upfront)

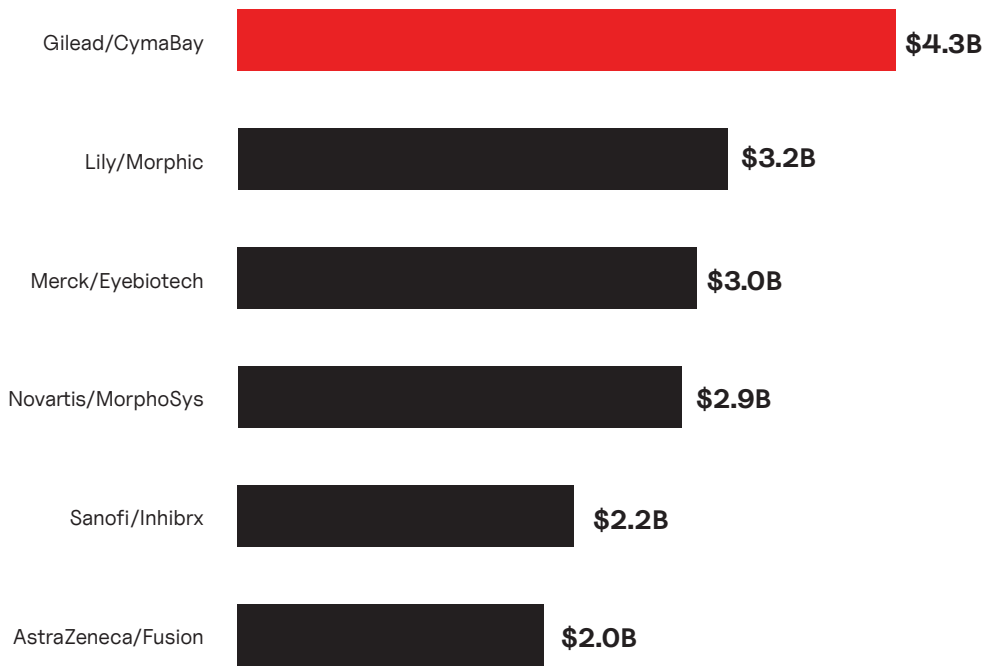

Table 2. Select M&A transactions over $1bn in total deal value

Company	Target	Key Asset(s)	Therapeutic profile	Indication	SM or Bio	Total Deal Value ($bn)
Abbvie	Aliada Therapeutics	ALIA-1758	neuroscience	Alzheimer's Disease	bio	$1.4
AstraZeneca	Amolyt Pharma	eneboparatide (AZP-3601)	endocrine	hypoparathroidism; rare endocrine diseases	SM	$1.05
	Fusion Pharmaceuticals	FPI-2265	oncology	mCRPC (castration-resistant prostate cancer)	radiopharmaceutical	$2.4
Biogen	Human Immunology Biosciences (Hi-Bio)	felzartamab	immunology		bio	$1.8
Boehringer Ingelheim	Nerio Therapeutics	PTPN1 and PTPN2 inhibitors	oncology	cancers	SM	$1.3
Eli Lilly	Morphic	MORF-057	immunology; inflammation	IBD (crohn's disease; ulcerative colitis)	SM	$3.2
Gilead	CymaBay Therapeutics	Livdelzi	rare disease; liver disease	primary biliary cholangitis	SM	$4.3
GSK	Aiolos Bio	AIO-001	respiratory	asthma	bio	$1.4
J&J	Ambrx Biopharma	ARX517	oncology	prostate, breast and renal cell carcinoma	bio	$2.0
	Yellow Jersey Therapeutics	NM26	immunology	atopic dermatitis	bio	$1.25
Merck	Eyebiotech (EyeBio)	Restoret (EYE103)	ophthalmology	diabetic macular edema	bio	$3.0
	Modifi Bio		oncology	gliomas	SM	$1.3
Novartis	Kate Therapeutics		gene therapy; neuroscience	neuromuscular diseases	bio	$1.1
	Mariana Oncology	MC-339	oncology	small cell lung cancer	radiopharmaceutical	$1.75
	MorphoSys	pelabresib	oncology	myelofibrosis	SM	$2.9
Novo Nordisk	Cardior Pharmaceuticals	CDR132	Cardiovascular	heart failure	SM	$1.11
Roche	Poseida Therapeutics	P-BCMA-ALLO1	oncology	multiple myeloma	bio	$1.5
Sanofi	Inhibrx	INBRX-101	respiratory	AATD	bio	$2.2

AATD: Alpha-1 Antitrypsin Deficiency, Bio: biologics, IBD: inflammatory bowel disease, SM: small molecule

Part of the reason for the smaller deal values is the trend toward earlier stage assets. While deals in the last couple of years centered on late-stage, "derisked" programs that were in phase 3 or close to commercialization, transactions in 2024 focused more on earlier stage assets. According to IQVIA, pre-clinical and phase 1 deals made up over 25% of M&A value in 2023, while only 8% involved commercial-stage assets (down from over 56%).

Even companies that have the ability and willingness to do more substantial deals stuck to small transactions. For example, AbbVie reported "the investment opportunities for us in terms of business development are really about the early stage" – emphasizing that they are primarily focused on growth into the next decade. Even Lilly, which is flush with capital from the success of Mounjaro and Zepbound, remains in this camp. With regard to its recent $2.5bn Scorpion Therapeutics deal announced in January: "It […] exemplifies the kind of dealmaking that Lilly likes to do […] Our strategy is to go a bit earlier than competitors, to take some molecule or scientific risk, but to focus on targets that have a very high level of scientific conviction or validity." Other factors that may have contributed include the inability to reach financial terms for assets that met their needs and increased discipline with regard to capital allocation. Moreover, disappointing clinical readouts from several recently acquired assets may be contributing to more stringent due diligence or risk aversion on the deal front.

Based on recent comments from R&D executives, companies still do not seem interested in mega-mergers, even for deals focused on later-stage or commercialized assets; rather, the target range for acquisitions still seems to cap out at around $15bn. For example, following the January announcement of its $14.6bn acquisition of IntraCellular Therapeutics (which has a commercialized lead asset), J&J emphasized that "larger deals are more outliers. The majority of the value that we create is through smaller deals and tuck-ins, where we can use our scale." Merck struck a similar note on its earnings call, stating that they consistently focus on "science-first" and deals are likely to be in the $0-$15bn range.

As in previous years, oncology remains the leading therapeutic area, representing seven of the 18 largest transactions, followed by immunology with three acquisitions. Nine had biologics as lead assets, whereas seven had small molecules and two were radio-pharmaceuticals (Table 2). The percentage of deals centered on small molecules is smaller than in 2023, when they accounted for 11 out of 19 M&A transactions over $1bn.

DEALMAKING: PRODUCT LICENSING AND COLLABORATIONS

While the number and size of acquisitions declined in 2024, product licensing and collaboration deals took on greater importance. Last year, the companies we follow executed 16 transactions with upfront payments of at least $100mn and total potential deal value of over $1bn (Table 3). In 2024, the most highly valued product deal was Merck's November licensing deal with LaNova for its phase 1 PD-1/VEGF oncology program, which has potential value up to $3.2bn but only $588mn upfront. Novartis led on the number of licensing agreements, with six large transactions totaling over $15bn in potential deal value. It was also the only company to pay $1bn upfront, in its agreement with PTC Therapeutics.

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As in M&A, product licensing deals trended towards earlier stage programs than we saw last year. Given the higher level of risk, deal structures continue to have a relatively small percentage of total deal value paid upfront, with substantial payments for achievement of regulatory and commercial milestones. For the companies we follow, five were for pre-clinical assets while one is already approved (SNY/NovaVax Covid-19 vaccine). Upfront payments reflected only 16% of the total deal value, comparable to 17% in 2023.

Oncology remained the dominant therapeutic area—particularly more novel modalities such as bispecific and precision therapeutics, as well the emergence of licensing deals for "molecular glue" drug candidates, such as Novartis/MonteRosa, Biogen's/Neomorph, Pfizer/Triana and Takeda/Degron Therapeutics. Neuroscience/CNS assets were the 2nd largest therapeutic area for product-specific deals while immunology ranked third. There were also a couple of smaller deals announced within the obesity and metabolic space, though recent transactions have been relatively small compared with recent years—and generally centered on pre-clinical programs.

Table 3. Select product licensing deals and collaborations with over $100mn upfront value

Company	Target	Key Asset(s)	Therapeutic profile	Indication	SM or Bio	Upfront value ($mn)	Total deal value ($bn)
Abbvie	FutureGen	FG-M701	immunology	IBD	bio	$150	$1.7
AstraZeneca	CSPC Pharmaceutical Groups	YS2302018	Cardiovascular	dyslipidemia	SM	$100	$1.9
Bristol Myers Squibb	BioArctic	BAN1503; BAN2803	neuroscience	Alzheimer's Disease	bio	$100	$1.25
GSK	CureVac	GSK4396687	infectious disease	influenza and COVID-19	vaccine	$431	$1.6
Merck	Curon Biopharmaceutical	CN201	oncology; immunology	B-cell associated cancers and diseases	bio	$700	$1.3
	Hansoh Pharma (Jiangsu)	HS-10535	obesity	obesity	SM	$112	$2.0
	LaNova	LM-299	oncology	various tumor types	bio	$588	$3.2
Novartis	Arvinas	ARV-766	oncology	prostate cancer	SM	$150	$1.2
	Monte Rosa Therapeutics	MRT-6160	immunology	auto-immune conditions	bio	$150	$2.2
	PTC Therapeutics	PTC518	neuroscience	Huntington's Disease	SM	$1,000	$1.9
	Shanghai Argo Biopharmaceuticals	RNAi therapeutics	Cardiovascular	CV conditions	SM	$185	$4.4
	Voyager	TRACER capsids for GT	rare diseases; gene therapy	Huntington's disease; spinal muscular atrophy	bio	$100	$1.3
Sanofi	Novavax	Covid Vaccines	Infectious disease	Covid-19	vaccine	$500	$1.2
Takeda	AC Immune	ACI-24.060	neurology	Alzheimer's Disease	vaccine	$100	$2.2
	Ascentage Pharma Group	Olverembatinib	oncology	CML	SM	$100	$1.3
	Kumquat Biosciences		oncology		SM	$130	$1.3

Bio: biologics, CML: chronic myeloid leukemia, CV: cardiovascular, IBD: inflammatory bowel disease, SM: small molecule

Consistent with the recent shift toward earlier stage clinical programs, we saw a pick up this year in research collaborations. These allow partners to gain a better understanding of clinical attributes and potential risks of platforms and assets. GSK, Pfizer and NovoNordisk each signed collaboration agreements with Flagship Pioneering to jointly fund research on multiple novel medicines and vaccines. Separately, Novartis signed a collaboration agreement with Generate: Biomedicines, a Flagship Pioneering company using AI to generate drug targets.

China has emerged as a significant source of clinical development and product transactions. Deal-flow and clinical data readouts increased dramatically for Chinese assets. Six of the 18 largest licensing deals in 2024 centered on Chinese assets, including three by Merck alone. This is consistent with a recent Stifel report that one in three licensing deals last year were centered on assets from China.

Table 4. Significant China-related transactions in the last 18 months

Company	Target/ Lead Asset (TA)	Date	Terms	Comments
Merck	Hansoh Pharma/ JS-10535 (obesity)	12/18/2024	$112mn upfront, with total pot'l deal value of $2bn	Global license agreement for preclinical oral GLP-1 receptor agonist
	LaNova/ LM-299	11/14/2024	$588mn upfront; up to add'l $2.7bn in potential milestone payments	Bispecific antibody; similar mechanism to Summit Therapetuics' ivonescimab, which is viewed as threat to Keytruda
	Curon Biopharmaceutical/ CN201 (oncology)	8/9/2024	$700mn upfront with total pot'l deal value of $1.3bn	Bispecific antibody for NHL and ALL
	CSPC Pharma Group / YS2302018 (cardiovascular)	10/7/2024	$100mn upfront; up to $1.9bn in milestones	Licensing agreement for preclinical lipid-lowering therapy
	Eccogene / ECC5004 (obesity)	11/2023	$185mn upfront; up to $1.8bn in milestones	Product licensing agreement to develop and commercialize small molecule GLP-1 receptor agonist
Roche	Regor Pharmaceuticals /RGT4198 (oncology)	09/30/24	$850mn	Product acquisition; breast cancer SM (phase 1)
AbbVie	FutureGen/ FG-M701 (immunology)	6/13/2024	$150mn upfront; up to additional $1.56bn in milestones and royalties	Inflammatory Bowel Disease
BMS	Biokin Pharma and SystImmune/ BL-B01D1 (oncology)	12/2023	$800mn upfront; up to $8.4bn	Product licensing agreement to develop and commercialize ADC/ bispecific for lung and breast cancer
GSK	Hansoh/ HS-20089 (oncology)	10/2023	$1.33bn	Product licensing agreement for global development and commercialization rights

TA: therapeutic area

Transactions between large US biopharma companies and China aren't new, but we're seeing more of them, with 10 out-licensing deals each in 2023 and 2024. The total value of these deals was $3.9bn in 2024 compared with just $800bn in 2022. One of the earliest successful collaborations between US and Chinese pharma companies was J&J's collaboration agreement with Legend Biotech for the development the CAR-T cell therapy, Carvykti, in 2017. Carvykti was approved in 2022 and generated nearly $1bn in 2024.

Oncology has had the most China-related deal activity, particularly in ADC therapies and bispecific therapies. AstraZeneca and Merck have in-licensed oral obesity candidates that have also attracted attention.

Product-Level Developments and Updates

DISCONTINUATIONS AND TERMINATED PROGRAMS

Based on data from Evaluate Pharma, the 19 companies we follow have fewer programs in clinical development than past years. Companies had 1,644 programs in development in 2024, a 7% decrease from 1,766 in 2023.[1] This marks the 2nd year in a row that number of pipeline projects has declined. On an absolute basis, Roche and Bristol-Myers cut the most programs, while Biogen, Boehringer Ingelheim, and Takeda cut the most as a share of their pipelines. As we've noted before, this likely reflects efforts to double down on priority assets. Biogen, Roche, Takeda, and Bristol-Myers were actively implementing R&D restructuring and pipeline rationalization initiatives during much of 2024. Each of these companies is reinvesting savings in existing or newly acquired high-priority assets.

Although companies are not required to disclose discontinued products and programs unless the cut is deemed financially material, we systematically track discontinuations that are announced in quarterly filings and calls. In the four quarters since 2023 FY earnings were announced, we counted a total of 73 discontinued products, a decline from the 84 terminated in 2023. Many terminations have been due to failure to meet clinical endpoints. Several companies have also "raised the bar" for advancing pipeline candidates and we are seeing more discontinuations being attributed to higher thresholds to justify further development. For example, Roche recently set the standard that 80% of its pipeline assets be "best-in-disease" or "first-in-class", trimming the number of drugs in development while increasing resources behind the programs for which it has the most conviction.

1 Accessed March 2025. Evaluate data track pipeline programs including additional indications rather than individual products.

Table 5. Selected products and research programs terminated for strategic or competitive reasons

Company	Product or Indications	Comments
Novartis	Omnusarib (PIII; lung cancer)	Decision made "in light of increasing options available to patients with KRAS G12C-driven cancers".
AbbVie	ABBV-916 (PII: Alzheimer's Disease monotherapy)	Terminated because "emerging efficacy and safety profile in this study is similar to what has been demonstrated by approved agents".
Amgen	AMG786 (PI; obesity)	Not better than its other candidates in development.
GSK	HPV vaccine (PII)	Expected not to be "best in class".
BMS	Alnuctamab (PII; multiple myeloma)	Company cited existing competition and priority on "investing in opportunities where it can deliver the highest return for patients and stakeholders."
BMS	Cendakimab (PIII; immune disorders)	They are going to "prioritize investments and opportunities where [they] have a competitive advantage. We can deliver the highest return for the company in areas where we believe that we have an opportunity to deliver potentially transformational outcomes for patients."
BMS	Ezobresib (PII; oncology)	"does not meet the threshold to be a driver for their growth potential"

While none of the product terminations was attributed to the IRA, we took a closer look at small molecules, oncology products, and orphan drug candidates, which some have argued will be disadvantaged under Medicare negotiation.

Key Insights

- Of the 88 discontinued products, 8 were vaccines, including 3 from GSK (Hepatitis B and HPV) and 2 from Sanofi (an mRNA flu vaccine and the E.coli vaccine it was co-developing with J&J).
- 31% (27 products) were in oncology—well below the roughly 40% of total pipeline assets represented by oncology.
- Of the 11 products that were dropped from late-stage development (phase 3 or filed), three were oncology assets, and the rest from a variety of other therapeutic areas. Two of the oncology products were discontinued based on "strategic" decisions rather than disappointing clinical data: Novartis' KRAS inhibitor opnurasib (mentioned above) and Bristol's alnuctamab.
- There were 43 discontinued biologic products compared with 36 small molecules. (Last year was more evenly split, with 40 biologics and 38 small molecules.)

Table 6. Product discontinuations by therapeutic area and molecule size

Companies	Therapeutic areas	Small molecule: biologic*	No. of products
Amgen	Oncology, metabolic	1:1	2
Astellas	Oncology, rare diseases	0:2	2
AstraZeneca	Cardiovascular, gastrointestinal, oncology, rare diseases, neurology/CNS	3:2	5
Biogen	Neurology/CNS	4:4	8
Bristol Myers Squibb	Oncology, inflammation	1:5	6
Eli Lilly	Cardiovascular, immunology, metabolic, oncology, neurology/CNS	4:4	9
Gilead	Oncology	0:1	1
GSK	Infectious disease, rare diseases	4:0	7
J&J	Infectious disease, oncology, neurology/CNS	3:1	4
Merck	Oncology	0:1	1
Novartis	Cardiovascular, immunology, oncology	3:1	4
Novo Nordisk	Cardiovascular, metabolic	3:0	3
Pfizer	Infectious disease, rare diseases, respiratory, vaccine, RSV, neurology/CNS	2:3	7
Roche	Oncology, neurology/CNS, respiratory, infectious disease	7:14	21
Sanofi	Oncology, vaccine, inflammation	0:2	4
Takeda	Oncology, immunology, neurology/CNS, infectious disease	1:2	4
TOTAL		36:43	79

*Excluding vaccines and programs with undisclosed technologies
Note: Counts reflect unique products, and do not reflect discontinuations at the indication level. Counts based on disclosures by companies based on materiality thresholds and are not comprehensive.

Time from launch to peak sales

Time from market entry to peak sales has become a common area of focus in earnings calls and panels, where executives frequently discuss shortening the time it takes for a drug to attain "peak sales". For example, AstraZeneca's CFO Aradhana Sarin noted during an Endpoints panel in January that it used to take 7-8 years to get peak sales whereas the average time is now four years.

Recent analyses show the average amount of time required for a drug to accrue 80% of their lifetime sales has declined 35 months in the last 20 years, with biologics decreasing significantly more than small molecule assets. Of the 20 top-selling drugs that launched since 2014, it took an average of 5 years to generate $1bn or more in sales. It took an average of 5.5 years for 15 drugs that surpassed $5bn in sales to reach that threshold, and an average 6.6 years for the remaining five drugs that reached $10bn or more to hit that marker. These metrics support industry's argument that the disparity in timelines should be

addressed; however, they offer merit to suggestions that parity could occur closer to nine years than 13. As biologic drug development has accelerated in the last decade, there is less justification for the differential vs small molecules or for such lengthy periods of exclusivity.

Elevating commercial considerations sooner in the R&D process

Several companies have moved towards greater collaboration between R&D and commercial functions in pipeline decision-making. Pfizer, Bristol Myers, and Novartis have been explicit about considering commercial and financial analyses earlier in product development. For example, we may start hearing more decisions to discontinue development attributed to commercial and strategic, rather than only clinical reasons. Pfizer's CEO recently reflected that the company's R&D productivity is in the top quartile in terms of the volume of products that get to the finish line and their success rates. "However, when I see the dollars that are coming out from new launches that came out from our pipeline, I see that we could have done way better." Biogen CEO Chris Viebacher said the company had stopped a few internal programs which "gave room to bring in other assets." The goal "was not to save costs, but to prioritize" more compelling pipeline programs.

ESTIMATED FINANCIAL IMPACT OF PART D REFORM

Fourth quarter earnings were the first time many companies provided quantitative estimates of the impact of Part D redesign on their top-line sales. (Prior commentary characterized it as "pushes and pulls" that would vary across different products). Pfizer was the first to do so, estimating a $1bn net negative impact – about a 1.6% top-line hit on forecast sales of $61-64bn in 2025.

Other companies quantified impacts ranging from minimal and manageable up to $2bn. Although most did not break down the revenue decline to the product level, several named the drugs they expected to drive this effect. Not surprisingly, these tended to be high-priced products, with a heavy concentration of oncology and immunology drugs.

> "When I see the dollars coming out from new launches that came from our pipeline, I see that we could have done way better."
>
> — Albert Bourla, Pfizer CEO

Table 7. Estimated impact of Part D reform on 2025 sales

Company	Estimated Impact	Products expected to be most affected	Comments
Pfizer	$1bn.	Ibrance, Xtandi, Xeljanz, Vyndaquel	Net impact from $1.5bn in incremental rebates offset by ~$500mn benefit from increased utilization due to OOP cap.
J&J	$2bn.	Stelara, Darzalex, Carvykti	Improved patient adherence could partially offset this impact; already in their short and long-term growth projections
BMS	$2bn.	Eliquis, Opdivo, Revlimid, Pomalyst	High Medicare share for Eliquis and oncology drugs; Eliquis
AbbVie	$1.1bn.	Humira, Imbruvica, Rinvoq, Skyrizi; Vraylar	Project 3-4 percentage pt. impact on top line; didn't quantify potential volume offsets
Gilead	$1.1bn.	Biktarvy	$900mn of impact will be in HIV
Merck	$400mn.	Winrevair, Lynparza, Lenvima, Welireg	Will be partially offset with some volume benefits
Sanofi	~500mn euro	Dupixent, vaccines	Some potential offsets in volume; less exposure overall due to business mix
Eli Lilly	$300mn to 500mn	Trulicity, Mounjaro, Verzenio	
GSK	400 to 500 GBP	HIV, Vaccines	
Novo Nordisk	$200mn to $400mn	Ozempic	~30% of Ozempic sales are Medicare
AstraZeneca	Undisclosed, but "manageable"	Tagrisso, Farxiga, Enhertu	

Conclusions

Increased R&D spending in 2024 – often driven by costly late-stage clinical trials – reflected industry-wide responses to expected LOEs and the need to get priority assets to market quickly. For the companies we follow, products with LOEs in the next 5 years comprise 62% of total worldwide revenues, whereas products included in the first two rounds of Medicare negotiation represent an estimated 10% of US sales.

While certainly driven by the urgency to replace revenue from products facing LOE, anticipated competition around certain targets, modalities and mechanisms of action (MOA) likely also plays a role. During a January panel discussion on the 2025 Dealmaking Outlook, AstraZeneca's CFO Aradhana Sarin described a "herding" trend, particularly affecting antibody-drug conjugates (ADCs), bispecifics, PD-1s, and GLP-1s. She noted that it used to take six years to get three products with the same mechanism of action into the market; the same now occurs in three years. Along with the push from upcoming LOEs and Medicare negotiation, this may be driving interest in the development of novel MOAs, entailing more scientific risk but also incentivizing more innovation.

The IRA was not among the top concerns discussed in end-of-year earnings calls, even though the next 15 drugs to be negotiated were announced in early 2025. To the extent that the IRA did come up, it mostly centered on the effects of Part D redesign, as several companies quantified the expected net financial liability for the first time. Nevertheless, companies continue to advocate for legislative changes to negotiation, such as extending the time before small molecules can be selected.

Although company executives continue to argue that the law's differential treatment of small molecules and biologics is harmful, pipeline decisions since the IRA's passage don't suggest a significant change in behavior. Among the 37 deals struck in 2023 and 2024 that exceeded $1bn, 19 (51%) had small molecules as lead assets. Over the same timeframe, companies discontinued 79 products, of which 36 were small molecules.

In communications with investors, company management continues to emphasize the value of small molecules. For example, when discussing J&J's high-profile immunology program for psoriasis and IBD, CEO Joaquin Duato said "availability of an oral can be a game changer. Generally speaking, patients prefer orals." As a signal of patients' preference, he pointed to the fact that the clinical trial for J&J-2113 recruited in a third of the time of a biologic. Similar comments were made about the prospect for oral obesity drugs, such as Lilly's orforglipron. Merck's Dean Li expressed similar sentiments about developing an oral PCSk9 as a small molecule, with the added

"It used to take six years to get three products with the same mechanism of action into the market; the same now occurs in three years."

— Aradhana Sarin, AstraZeneca CFO

prospect of “appropriate combinations” made possible by small molecules offering additional value.

The recent trend to in-license from Chinese companies remains an important trend to watch. This approach is an alternative to relying on small domestic VC-funded biotech companies acquiring assets and later out-licensing to large companies. Although average deal value for Chinese assets is going up, it is still more cost-effective for pharma companies to acquire directly, rather than giving up some of the economics to the biotech company or investors.

Despite 2025’s inauspicious beginnings, there is still significant potential for additional business development as companies continue addressing the challenge of nearly $200bn in upcoming LOEs. Many companies have plenty of cash and, in some cases, a stated interest in further boosting pipelines through external development. The jury is out as to whether they will be successful in identifying acquisition or licensing targets that are strategically compatible, clinically compelling, and financially attractive.

Appendix

Companies included in our analysis

1	Abbvie	11	Johnson& Johnson
2	Amgen	12	Merck
3	Astellas	13	Novartis
4	AstraZeneca	14	NovoNordisk
5	Biogen	15	Pfizer
6	Bristol Myers Squibb	16	Regeneron
7	Boehringer Ingelheim (private)	17	Roche
8	Eli Lilly	18	Sanofi
9	Gilead	19	Takeda
10	GSK		

ATI Advisory

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Arnold Ventures

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