

## US Biopharmaceuticals

## Biopharma BD Capacity and Thoughts on M&amp;A

## Industry Overview

## Business development remains a fundamental driver

Despite a step up in M&A / licensing activity since late 2023, the Biopharma industry still has ample capital to be deployed to bolster pipelines and add to intermediate / long-term growth. Indeed, by our estimates, the top 20 US / EU Biopharmas have >\$230B in BD capacity to be leveraged for deals, especially given high cash levels and a favorable capital markets backdrop (see Exhibits 1, 2). To put this into context, this capacity is more than double the current valuation of ~25 M&A targets in biotech that are strategically attractive (e.g., have de-risked / differentiated pipelines or are in “hot” therapeutic areas or have unique technology platforms; see Exhibit 4). Notably, this is after already robust share performance (+100% on average) over the last 6 months.

## Capacity is concentrated with fewer BD options

Notably, not all Biopharmas have robust deal capacity (i.e., >\$5B) as some of them, including AbbVie, Amgen, Bristol, and Pfizer, are highly levered (>2.5 net leverage) and have committed to execute on closing recent transactions and commercially in the near-term. In our view, within the US Biopharma space, Merck, J&J, and Gilead, seem most likely to deploy a significant amount of capital into M&A + licensing/ partnerships in the next two years, especially given what could be pressure on core businesses from LOEs, the IRA or competition towards the end of the decade (Exhibit 3). We’d characterize remaining M&A options as somewhat limited since many are a few years away from commercial launch and additional de-risking events are still needed to unlock value beyond what is reflected in current expectations **Continued on page 2 >>>**

**Exhibit 1: Biopharma BD capacity and company commentary**

BD remains a top priority for most Biopharmas

Company	Therapeutic Areas of Interests	Deal Size	BD Capacity (\$M)
<b>US Major Pharma</b>			
AbbVie	Eye Care, Neurology	Early stage, smaller size deals	-
Bristol Myers	Likely Oncology, Immunology, and Neuropsych	Bolt-on, partnership/ licensing deals	2,923
J&J	Pharma (Oncology, Immunology, and Neuros), MedTech (Cardio, Vision)	POC asset, different modalities, licensing & partnership	74,030
Eli Lilly	Everything with focus on I&I and Endocrinology	Earlier stage	15,095
Merck	Oncology, Vaccines, Cardiometabolic, Immunology, and Animal Health	Late ph 2, early ph 3; <\$15B size	40,923
Pfizer	Not a near term focus	Small deals or partnership	-
<b>US Biotech</b>			
Amgen	Rare disease, Inflammation, Oncology, General Medicine (Obesity/ Cardiovascular)	N/A	-
Biogen	Rare disease	Bolt-on, “< \$7B Reata”	1,841
Gilead	Virology, Oncology, and Inflammation	Later stage	10,054
Moderna	Not a priority	N/A	-
Regeneron	Not a priority	Bolt-on	27,602
Vertex	Not a priority	N/A	26,042

**Source:** BofA Global Research estimates, Company presentation, Bloomberg

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Equity  
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**Geoff Meacham**  
Research Analyst  
BofAS  
+1 646 855 1004  
[geoff.meacham@bofa.com](mailto:geoff.meacham@bofa.com)

**Charlie Yang**  
Research Analyst  
BofAS  
+1 646 855 5732  
[charlie.yang@bofa.com](mailto:charlie.yang@bofa.com)

**Alexandria Hammond**  
Research Analyst  
BofAS  
[alexandria.hammond@bofa.com](mailto:alexandria.hammond@bofa.com)

**Susan Chor**  
Research Analyst  
BofAS  
[susan.chor@bofa.com](mailto:susan.chor@bofa.com)

**John Joy**  
Research Analyst  
BofAS  
[john.joy@bofa.com](mailto:john.joy@bofa.com)

**Abbreviations:**

M&A: mergers and acquisitions

BD: business development

IRA: Inflation Reduction Act

LOE: loss of exclusivity

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## M&A Capacity

Global Biopharma still has a lot of capacity to do meaningful M&A and licensing/partnership, despite a string of recent transactions. But we think only some companies (e.g., Merck, J&J, Gilead) could execute significant transactions in the near term given a landscape of many pending deals with others making commercial execution and de-leveraging near-term priorities (e.g., Pfizer, Bristol). Additionally, for Biopharmas such as Regeneron and Vertex, larger scale BD has not been a top priority historically, even despite strong balance sheets and cash flows. Of note, looking forward, we do not anticipate the Federal Trade Commission to be a major hurdle to M&A as recent transactions in the small to medium term size (<\$20B) have closed without many surprises.

### Exhibit 2: BD Capacity Remains High Overall

Global Biopharma M&A capacity remains high substantial despite recent acquisitions

\$M	Cash & Equiv.	Total Debt*	Net Debt	EBITDA (2024e)	Net Leverage	M&A Capacity (2.5x Net Leverage)	Notable M&A/BD since 2022
US Major Pharma							
AbbVie	12,816	78,486	65,670	26,030	2.5	-	ImmunoGen, Cerevel
Bristol Myers	12,644	57,764	45,120	19,217	2.3	2,923	Karuna, RayzeBio, Mirati, SystImmune, Turning Point
J&J	22,927	32,332	9,405	33,374	0.3	74,030	Ambrx, Abiomed
Eli Lilly	2,928	25,225	22,298	14,957	1.5	15,095	Dice, POINT Biopharma
Merck	7,093	38,218	31,125	28,819	1.1	40,923	Elanco's aqua biz, Harpoon, Daiichi Sankyo, Prometheus, Imago
Pfizer	12,690	75,041	62,351	22,642	2.8	-	Seagen, Global Blood, Biohaven
US Biotech							
Amgen	10,944	65,423	54,479	17,303	3.1	-	Horizon, ChemoCentryx
Biogen	1,050	7,429	6,379	3,288	1.9	1,841	Reata
Gilead	8,427	29,558	21,131	12,474	1.7	10,054	CymaBay
Moderna	8,604	1,243	(7,361)	(2,838)	2.6	-	-
Regeneron	16,241	2,703	(13,538)	5,626	(2.4)	27,602	-
Vertex	13,716	808	(12,908)	5,254	(2.5)	26,042	-
EU Pharma							
AstraZeneca	5,962	30,222	24,260	18,351	1.3	21,618	Icosavax, CinCor
Bayer	11,719	49,555	37,836	11,414	3.3	-	-
GlaxoSmithKline	6,614	23,996	17,383	13,278	1.3	15,813	Bellus, Affinivax
Novartis	14,073	28,898	14,825	18,640	0.8	31,776	Morphosys, Chinook
Novo Nordisk	4,487	20,508	16,021	20,579	0.8	35,425	Catalent, Forma
Roche	12,524	39,380	26,856	25,534	1.1	36,978	Carmot, Telavant
Sanofi	11,139	21,802	10,663	15,879	0.7	29,035	Provention Bio
<b>Total</b>	<b>\$ 125,500</b>	<b>\$ 321,525</b>	<b>\$ 196,025</b>	<b>\$ 164,782</b>	<b>1.2</b>	<b>\$ 236,185</b>	

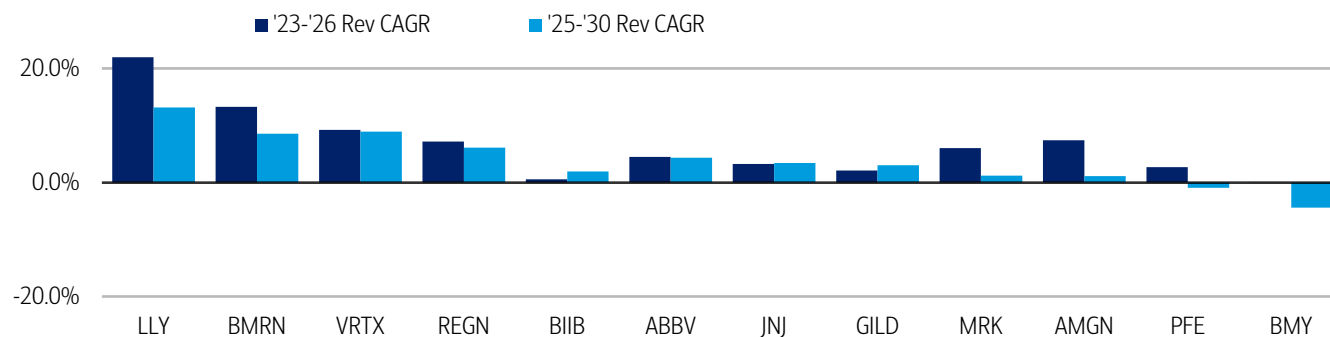
\*Includes transactions for ABBV: Cerevel, Immunogen; BMY: Karuna, RayzeBio; JNJ: Ambrx; AZN: Icosavax, Gracell; MRK: Harpoon, Elanco's aqua health business; GILD: CymaBay; NVS: Morphosys, Calypso; SNY: Inhibrx; GSK: Aiolos; NVO: Catalent; ROG: Carmot

Source: BofA Global Research estimates, Bloomberg, Company presentation

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### Exhibit 3: US Biopharma Revenue CAGR Growth

Revenue growth from '23-'26 and '25-'30



Source: BofA Global Research, Visible Alpha

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Continued on page 3 for Biotech Companies in the Therapeutic Areas of Interests>>

**Exhibit 4: Biotech Companies in the Therapeutic Areas of Interests**

Screened based on share performance (>50% since July 2021, >10% since July 2023) and 2035e consensus sales >\$1B, including recent IPOs with robust performance

Company	Ticker	Mkt cap (\$M)	6mo Stock Perf.	2035e Total Rev (\$M)	Lead Indications	Modalities	Key Assets	Stage
<b>Immunology &amp; Inflammation</b>								
Biohaven	BHVN	4,594	190%	7,316	obesity, SMA, epilepsy, RA, MG,	Fusion protein, small molecule, bispecific	taldefgrobep alpha (myostatin); BHV-7000 (Kv7); BHV-1300 (IgG degrader)	Phase 2
Apogee	APGE	3,850	217%	6,166	atopic dermatitis, asthma, COPD	Antibody	APG777 (IL-13); APG808 (IL-4Ra)	Phase 1
Alpine Immune	ALPN	2,389	210%	3,555	IgAN, SLE	Fusion protein	povetacicept (APRIL/ BAFF)	Phase 2
Vera	VERA	2,378	160%	1,518	IgAN, LN	Fusion protein	atacept (APRIL/ BAFF)	Phase 3
Kyverna	KYTX	1,290	37%	N/A	LN, systemic sclerosis, MS	Cell therapy	KYV-101 (CD19)	Phase 2
<b>Oncology</b>								
Nuvalent	NUVL	5,445	77%	3,208	Lung cancer	Small molecule	zidesamtinib (ROS1+), NVL-665 (ALK+)	Phase 2
Arcellx	ACLX	3,660	271%	1,768	Multiple myeloma	Cell therapy	CART-ddBCMA (BCMA)	Phase 2/ Pivotal
Ideaya	IDYA	3,375	141%	1,940	Uveal/cutaneous melanoma, solid tumors	Small molecule	Darovasertib (PKC), IDE397 (MAT2A)	Phase 3
Merus NV	MRUS	2,660	89%	2,407	HNSCC, NRG1+ cancer	Bispecific	Petosemtamab (EGFRxLGR5); zenocutuzumab (HER2xHER3)	Phase 2
CG Oncology	CGON	2,371	88%	N/A	bladder cancer	Oncolytic adenovirus	cretostimogene grenadenorepvec (GM-CSF)	Phase 3
Janux	JANX	1,936	110%	3,166	Prostate cancer, solid tumors	Bispecific	JANX007 (PSMAxCD3); JANX008 (EGFRxCD3)	Phase 1
Cargo	CRGX	1,195	106%	N/A	Heme malignancies	Cell therapy	CRG-022 (CD22)	Phase 2
<b>Neuro/Psych</b>								
Biohaven	BHVN	4,594	190%	7,316	obesity, SMA, epilepsy, RA, MG,	Fusion protein, small molecule, bispecific	taldefgrobep alpha (myostatin); BHV-7000 (Kv7); BHV-1300 (IgG degrader)	Phase 2
Xenon	XENE	3,338	21%	1,857	epilepsy, MDD	Small molecule	XEN1101 (Kv7 ion channel)	Phase 3
<b>Cardiovascular</b>								
Cytokinetics	CYTK	6,649	83%	3,671	HCM, heart failure	Small molecule	aficamten (cardiac myosin inhibitor)	Phase 2
Keros	KROS	2,431	92%	2,488	PAH, heart failure, MDS, myelofibrosis, obesity	Fusion protein	KER-012 (ActRIIB); KER-050 (ActRIIA); KER-065 (ActRII)	Phase 2
New Amsterdam	NAMS	2,092	121%	2,817	LDL-C lowering	Small molecule	obicetrapib (CETP)	Phase 3
<b>Metabolic/ Endocrinology</b>								
Viking	VKTX	7,313	366%	5,578	obesity, NASH/ MASH	Peptide, small molecule	VK2735 (GLP-1/GIP agonist); VK2809 (TR $\beta$ agonist)	Phase 2
Madrigal	MDGL	5,226	41%	2,454	NASH/ MASH	Small molecule	resmetirom (TR $\beta$ agonist)	Phase 3
Biohaven	BHVN	4,594	190%	7,316	obesity, SMA, RA, MG	Fusion protein, small molecule, bispecific	taldefgrobep alpha (myostatin); BHV-7000 (Kv7); BHV-1300 (IgG degrader)	Phase 2
<b>Rare Disease</b>								
Krystal	KRYS	5,063	46%	1,880	DEB	Topical gene therapy	Vyjuvek (COL7A1 gene)	Commercial
Crinetics	CRNX	3,060	34%	2,434	acromegaly, carcinoid syndrome, Cushing's, CAH	Small molecule	paltusotine (SST2 agonist); CRN04894 (ACTH antagonist)	Phase 3
Rhythm	RYTM	2,392	61%	2,297	genetic obesity	Peptide	Imcivree (MC4 agonist)	Commercial / Phase 3
<b>Ophthalmology</b>								
EyePoint	EYPT	1,067	95%	1,520	wAMD, NPDR, DME	Small molecule/ device implant	EYP-1901 (VEGF)	Phase 2
<b>Infectious Disease</b>								
Vaxcyte	PCVX	7,764	42%	3,608	pneumococcal disease	Vaccine	VAX-24 (PCV24), VAX-31 (PCV31)	Phase 2

Abbreviation:

LN: lupus nephritis; MDD: major depressive disorder; GM-CSF: cytokine granulocyte-macrophage colony stimulating factor; RA: rheumatoid arthritis; SMA: spinal muscular atrophy  
wAMD: wet age-related macular degeneration; NPDR: non-proliferative diabetic retinopathy; DME: diabetic macular edema; MG: myasthenia gravis; MS: multiple sclerosis  
CAH: congenital adrenal hyperplasia; HS: hidradenitis suppurativa; PsA: psoriatic arthritis; CSU: chronic spontaneous urticaria; PN: prurigo nodularis  
NASH/ MASH: non-alcoholic steatohepatitis/ metabolic dysfunction-associated steatohepatitis; HNSCC: head and neck squamous cell carcinoma  
HCM: hypertrophic cardiomyopathy; DEB: dystrophic epidermolysis bullosa; BPD\* bipolar depression; COPD: chronic obstructive pulmonary disease

Source: BofA Global Research, Bloomberg, Visible Alpha, Company presentation

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## Company Commentary

**Abbvie:** “So our BD efforts continue to be focused on identifying assets really that can drive growth in the next decade across immunology, oncology, neuroscience, aesthetics, and eye care. But we have what we need in our current portfolio to deliver on growth expectations in this decade, so our external efforts are really aimed at early stage opportunities, which are typically smaller size deals.

As we look across the growth areas, so just think about immunology, Skyrizi and Rinvoq will drive robust growth into the decade. So our focus in immunology in terms of BD is really looking for new mechanisms of action that can elevate standard of care, whether monotherapy or in combination. I’d say there’s a lot of interest in combination.

In oncology, ImmunoGen really nicely complements our efforts with ADCs. It gives us a head start, an entry in the solid tumor space that we’re not in today. But in addition to ADCs, we’re focused on bispecifics, multispecifics, immuno-onc agents. We also recently announced a collaboration with the Umoja, studying in-situ CAR-T therapy. So a lot of focus in oncology, but these again would be earlier stage, smaller sized deals.

In neuroscience, Cerevel adds depth to our neuropsych pipeline, but we also have a focus on migraine and neurodegeneration.

In eye care, we’re extremely excited about the REGENXBIO program in wet AMD and diabetic retinopathy, but we continue to look for innovation in glaucoma and retinal disease. So we certainly have an interest there.

And then in aesthetics, it’s always about looking for innovation that can drive new consumers into our providers’ practices.

So our BD group is still very active. We certainly have the financial wherewithal to pursue those opportunities to further bolster our pipeline, but those are the areas that we’re most interested in.”

**Amgen:** “In summary, we continue to execute on our multiple capital allocation priorities. First, we continue to prioritize investments in both internal and external innovation. Our increased spending in non-GAAP R&D of 8% in ‘23 over ‘22, coupled with the acquisition of Horizon Therapeutics, continues to broaden and strengthen our balanced portfolio across therapeutic areas. With our strong late-stage innovative pipeline moving forward through development, we expect our non-GAAP R&D to continue to increase in 2024.

Second, we continue investing in our business for long-term growth, including our state-of-the-art manufacturing facilities in Ohio and North Carolina. Amgen, Ohio, our new advanced assembly and final product packaging plant, has just received licensure from the FDA for commercial production in January, roughly two years after we broke ground.

And our innovative drug substance plant under construction in North Carolina is expected to be operational by 2026. In addition, we’ve positioned the organization to accelerate investments in innovation, including leveraging the power of generative artificial intelligence.

And third, we return capital to shareholders through growing dividends, including \$2.13 per share in the quarter. This represented a 10% increase over that paid in each of 2022’s four quarters.”

**Bristol-Myers Squibb:** “As we’ve discussed previously, as we think about capital allocation, business development continues to be a top priority for us. Obviously, we’ve just executed a number of deals towards the end of last year, and we’ve got to stay focused on executing those deals. Having said that, we certainly are going to continue to be interested in bringing innovation into the company that makes strategic and financial sense to do. So I would characterize those a bit more as bolt-on opportunities at this

point. We're also, of course, continuing to look at partnerships and licensing deals as well. But that's how I would characterize it."

**Gilead Sciences:** "This is Dan. Maybe I'll start and then ask others to add, but I appreciate the question. I think just to reinforce our M&A strategy, I mean, nothing has changed from a business development perspective, and particularly that's against the context of the background of nearly doubling our clinical trials underway over the past four years, multiple late-stage results. As you know, we're expecting more than 20 results still this year, and against the backdrop of no significant patent expirations in our business until early parts of the next decade.

So I think we'll continue to be opportunistic about pursuing business development in the three areas that we are focused on, which is obviously virology, oncology, and inflammation. We'll be driven by the science. We continue to articulate that, building our late research early development pipeline is probably one of our biggest focuses, and we'll continue to look at later-stage deals as they fit into our portfolio and our range.

It might also be important to note that we are back to pre-Immunomedics levels now relative to our leverage ratios, and so we're comfortable with our ability to put capital to work.

But nothing has changed, and we feel we have everything within Gilead right now to achieve our ambitions over the second half of this decade."

**Johnson & Johnson:** "M&A and external innovation has been the core of our pharma portfolio growth and transformation. As I said initially, we are agnostic to sector. In the case of pharma, our preferred mode has been trying to go to assets that were around proof-of-concept. So generally speaking, from a size perspective, it's been about deals that have been either of a smaller size or have been different modalities like licenses or partnerships. Just last year, we completed overall at Johnson & Johnson more than 50 deals. The thing is that the headlines are only made by the ones that are M&A. So we've done multiple deals in our pharmaceutical side in order to be able to enhance our existing portfolio, and our bias is to go for transactions that are going to enable us to create more value by leveraging our clinical development strength, our manufacturing capabilities and our commercial reach. So hence, why the majority of the deals that you see in our pharmaceutical side are at an earlier stage.

Are we looking broader than that? Yes, we do, but mainly, we find more opportunities to create value at an earlier stage. For example, this year we did a number of deals that went less publicized. We did, as I commented before, a deal with CBMG, now called AbelZeta, in CAR-T with CD19 and CD20, which we believe could be best-in-class CAR-Ts in this area that could launch in this decade. Or at the end of the year, we also did another deal in antibody drug conjugates with a Korean company called LegoChem, which was underreported. We continue to work in identifying deals in our pharmaceutical space that enables us to be able to put all our capabilities to work in the clinical development side, in manufacturing and in commercial, and that's been the source of very significant value creation in products that all of you know, like DARZALEX or CARVYKTI, that come from that type of approach of going earlier on into the development process."

**Eli Lilly:** "On Slide 13, we provide an update on capital allocation. Looking forward to 2024 and beyond, we have confidence in our existing commercial portfolio bolstered by the recent launches of Mounjaro, Jaypirca, Omvoh, and Zepbound, and the potential launches of donanemab and lebrizumab, all of which we expect to serve as drivers for continued growth through the balance of the decade.

On Slide 14, you'll see a summary of our outlook outlining our capital deployment decisions in relation to achievement of our strategic deliverables. We will invest in our current portfolio and in the future innovation through R&D, business development, and a comprehensive manufacturing expansion agenda designed to drive revenue growth and

speed life-changing medicines to patients. We will continue to return capital to our shareholders through dividend increases in line with earnings growth over time and share repurchases with excess capital.”

**Moderna:** “In our Q3 earnings call, I provided our Moderna operating principles, which largely centered around a very disciplined approach to capital allocation. Our Number 1 priority has been and will continue to be reinvesting in the business. In addition to the investment into our pipeline, we expect capital expenditures in 2024 to be approximately \$0.9 billion as we mostly complete the construction of our facilities across the globe. Our teams are laser-focused on operational improvements for both expense management and working capital. As a result, we expect to end 2024 with approximately \$9 billion in cash.”

**Merck:** “Now turning to capital allocation, where our strategy remains unchanged. We will prioritize investments in our business to drive near and long-term growth. We are excited by the significant progress our team has made to advance and augment our innovative pipeline in 2023. In 2024, we will increase this investment, including the initiation of more late-stage clinical trials across multiple novel candidates, each of which has significant potential to address important unmet medical needs. We remain committed to our dividend and plan to increase it over-time. Business development remains a high-priority. We maintain ample capacity, given our strong investment-grade credit rating and cash-flow, to pursue additional, science-driven, value enhancing transactions going-forward. We will continue to execute a modest level of share repurchases.”

**Pfizer:** “And then, once we bring our de-levers to the levels that we are aspiring, we will start also moving into share buybacks, and of course, M&A, which means that for ‘24, we will see everything in existence, because we never say never to business development opportunities could come. But our strategy, it is that you will not see anything major in business development in terms of dollars.”

**Regeneron Pharmaceuticals:** “And with regards to business development, I mean, just because we can, it doesn’t mean we’re going to force something, it has to be right, it has to be a franchise, has to be modality, you’ve heard George mentioned that it has to be kind of incremental to what we currently have in the clinic here with regards to RGC and the targets we develop and all of that.”

**Vertex:** “Our priorities for cash deployment remain unchanged as we continue to prioritize investment in innovation including external innovation via business development. During 2023, we completed 10 transactions and recognized over \$500 million of AIPR&D. We also deployed over \$400 million to repurchase 1.3 million shares over the course of 2023.”

**Royalty Pharma:** “As it relates to the second question around \$4 billion, is that the new norm? We’re not changing our capital deployment guidance that we gave last year at our Analyst Day meeting of \$10 billion to \$12 billion over five years. I think what it does highlight is there’s a strong momentum. You can absolutely see it in our funnel and obviously the deals we’ve announced. We see it every day, that Royalty financing, and that can come in a lot of different ways, obviously synthetic and existing royalties, all kinds of different ways, is an absolutely growing trend within the sector. So, we’re super excited about the opportunity set, but we’re not changing our long-term guidance.”

## Special Disclosures

BofA Securities is acting as a financial advisor to Elanco Animal Health Inc, in connection with its sale of its aqua business to Merck Animal Health, which was announced on February 5, 2024.

BofA Securities is currently acting as Co-Advisor to Gilead Sciences Inc. in connection with its proposed acquisition of Cymabay Therapeutics, which was announced on Monday, February 12, 2024.



# Disclosures

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