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SPECIAL EDITION

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BIO INTERNATIONAL 2026
SAN DIEGO • JUNE 22-25

The IPO window is open M&A is up 32%

Pharma under pressure. AI changing R&D. Our reporters have this week covered.

$70bn
Deal value in 2025 — and M&A up 32% in Q1 2026

30%
Of the global pipeline from China

$500bn
Patent cliff shaping deals at BIO

SCRIP
ON THE GROUND

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Welcome To San Diego

ELEANOR MALONE,
Editor-in-Chief, *Scrip*

This special edition of *Scrip*, *Pink Sheet* and *In Vivo* is produced to coincide with BIO International Convention 2026.

The mood this year is the most upbeat it has been in several years. Deal value is up, the IPO market has re-opened and venture capital is flowing again, albeit on terms that have changed since the boom years of 2020-21.

Disruptive forces are strong, however. A volatile FDA and uncertain policy environment are keeping executives on their guard. Big pharma is racing to plug a $500bn patent cliff and smaller biotechs are very much in their sights. China's surging pipeline is reshaping dealmaking, presenting a competitive challenge for western biotechs, a rich hunting ground for acquirers and a powerful catalyst for global innovation. As for AI, our reporters have been tracking how it is changing every aspect of biopharma, from drug discovery and development through to dealmaking and business models, and there is plenty in these pages on that front.

But disruption has always been biotech's natural habitat: the sector was built on the conviction that the status quo in medicine is not good enough. That instinct is as alive as ever in San Diego this week.

Our reporters are on the ground throughout. We hope this edition gives you useful context – and that you find us on stand #4819.

San Diego, Deals And Reasons To Be Cheerful

Scrip's US managing editor **Mandy Jackson** has been covering biopharma for more than two decades and attending BIO International Convention for much of that time. This year the meeting returns to her home city. She's moderating two panels on dealmaking and pipeline strategy, and will be filing copy throughout. We asked her what to expect.

MANDY JACKSON,
Managing Editor,
Scrip

Mandy Jackson covers daily biopharma developments, writes features and produces *Scrip*'s Finance Watch column, regularly interviewing leaders from big pharma CEOs to biotech startup founders. She has been a business reporter since 2000.

1 You've been attending BIO for many years. What's your read on the mood going into the 2026 edition – and how does it compare to recent years?

Overall, the industry mood seems optimistic in two areas that are a big focus for BIO – dealmaking and financing. Big pharma and even many mid-sized companies are actively buying smaller drug developers and entering into lucrative partnerships. That in turn attracts investors to biotechnology opportunities, so we're seeing an uptick in initial public offerings and venture capital fundraising.

Regulatory uncertainty remains due to US FDA leadership changes and macroeconomic issues, such as the war in Iran and rising inflation, but biotech company valuations are still outperforming other sectors, for now. I expect this year's meeting to be more upbeat than it has been during the last three or four years, with some healthy cautious optimism due to regulatory and economic concerns.

2 What are the one or two issues you expect will dominate the conversation on the floor and in the sessions this year?

Dealmaking is always a big topic at BIO, since companies come to the convention to meet with potential partners. Many of the transactions that *Scrip* has reported on this year may have gotten their start with an initial conversation at last year's meeting in Boston. Panel discussions about the dealmaking environment usually draw good-sized audiences at BIO as biotech firms seek insights from potential buyers or partners. I suspect that convention attendees also will keep an ear out for information about FDA instability and policy discussions that impact drug approvals, since companies have received some mixed messages from the agency during the past year or so. Artificial intelligence also will be a big topic of conversation at BIO this year with several panels on the agenda to help biotech and pharma firms understand best use cases for AI in drug development and beyond.

3 You're moderating two panels on business development strategy – one on bold dealmaking, one on pipeline diversification. What's the question you most want your panelists to answer honestly, and do you expect them to agree?

I love to talk to executives about their companies' strategies, to really dig into the aspects that are driving a decision in their therapeutic area or understand why they pursued a specific deal, so I want the dealmakers in both of my sessions to give clear, honest answers about their strategic decision making. It's interesting to see how companies' strategies diverge and why. The nitty-gritty details of a deal are not only fascinating to me, but they help the companies' competitors and their potential partners understand 1) how to differentiate and 2) how to pitch their drug candidate or technology in a way that makes sense for a buyer or partner.

4 You spend a lot of time at BIO talking to dealmakers and BD teams. What deals are people chasing – is it all about obesity, and how much of the conversation has shifted to assets coming out of China?

There is still a lot of interest in obesity, because the market is vast and, despite the significant efficacy of approved drugs, there is a lot of room for improvement on tolerability, frequency and duration of dosing, and quality of weight loss. That said, there is also a lot of interest in differentiated oncology approaches and exponential capacity for immunology assets that treat both large indications, such as asthma and inflammatory bowel disease, and smaller indications, like hidradenitis suppurativa and vitiligo. Interest is rising for novel neuroscience drug candidates with the availability of biomarkers that may give early signs of efficacy. Big pharma and others are looking for game-changing therapies wherever they can find them, but I expect China to remain a big destination for dealmakers because government investment there has resulted in robust drug discovery and development programs.

5 The policy environment is unusually turbulent right now. Do you expect such issues to be addressed openly at BIO, or will people be more guarded than usual?

Conversations around regulatory matters are always somewhat guarded, because biopharma companies are wary of making comments that may upset regulators, but executives and investors are making their frustrations known around leadership instability at the FDA, drug pricing policy in the US and abroad, and approval pathways for gene therapies and other novel medicines. For the sake of BIO attendees seeking insight into these issues, I hope that panels covering regulatory matters will offer honest perspectives about what is happening in the US and beyond.

6 What's your one watch-out for attendees – something they might miss or underestimate at this year's meeting?

There are several panels focused on therapeutic areas – oncology, neurology, infectious diseases, cardiovascular disease. Dealmaking, finance, regulatory and now AI panels are likely to have strong interest, but these more focused panels could give BIO attendees some strong insight into where mid-sized and big pharma companies are focusing their development and dealmaking dollars within specific therapeutic areas.

7 And finally, BIO is back in your home city this year. What's your must-visit recommendation for attendees who want to escape the convention center bubble – and will we find you there?

The San Diego Padres are playing home games against the Atlanta Braves during the first three nights of BIO and a baseball game at Petco Park, across the street from the convention center, is always a fun time. Seaport Village, just past the other end of the convention center, has nice shops and restaurants, and slightly farther down Harbor Drive is the USS Midway, a Navy aircraft carrier that has been turned into a museum. Slightly farther outside of downtown, the San Diego Zoo is one of the city's crown jewels and the nearby island of Coronado has beautiful beaches. I wish I could take a break for a Padres game during BIO, but I suspect I will be too busy that week attending and covering the meeting!

Biotech's Second Half: Resilience Under Pressure, Dealmaking On New Terms

Deal value is up and capital markets are functioning, but preclinical valuations have collapsed, China commands 30% of the global pipeline and AI is reshaping R&D faster than most companies can respond.

DAVID WILD, Senior Reporter, ***In Vivo***

The industry's challenge in second half of 2026 is not survival – the Darwinian reset has already culled the weakest – but velocity. The companies that will define the next cycle are those that can move fast enough on inorganic dealmaking, absorb China's pipeline competition without overexposing themselves geopolitically and place the right AI bets before the landscape shifts again. Discipline and decisiveness are both essential requirements in today's environment.

The biotech industry enters the second half of 2026 in a state better described as guarded momentum than outright confidence. Deal value topped $70bn in 2025, the first quarter of 2026 saw a 32% increase in M&A transaction volume over Q4 2025, and the IPO market has reopened for the right companies – those with mid-to-late-stage programs, experienced management and therapeutic areas investors want. But the backdrop – a slump in total shareholder return, a $500bn patent cliff creating intense acquisition pressure, pricing reform and an AI transformation still in its early innings – means there is little room for complacency.

"Biotech has consistently shown its resilience to successfully navigate the unknowns," said Arda Ural, EY Americas life sciences sector leader. "With valuations surpassing twice the S&P 500, the majority of approved products classified as first-in-class and a pressing secular need for biopharma to grow inorganically to offset patent expirations, I see a rather positive outlook for the biotech sector."

That optimism is grounded in real structural strengths, not least the fact that big pharma's patent cliff makes biotechs with compelling assets highly sought after. However, according to BCG, average total shareholder return across the sector was essentially flat from 2021 to 2025, against 16% for the S&P 500. The collective response – from

dealmaking to AI investment – is well underway but whether it is moving fast enough is a different question.

Pricing reform adds a further layer of complexity that is only beginning to show up in deal economics. The Inflation Reduction Act's drug negotiation mechanism has already altered how acquirers model the long-term revenue potential of small-molecule assets; the nine-year negotiation clock versus thirteen for biologics has made small molecules less attractive for bolt-on acquisitions in large-population indications, precisely the therapeutic areas the industry is pivoting toward.

Early evidence suggests the discount is being priced into valuations at the term-sheet stage rather than absorbed post-close, with buyers demanding steeper risk adjustments on assets with near-term negotiation exposure. For biotechs with late-stage small-molecule programs in cardiometabolic or other high-volume indications, that shift in buyer calculus is not theoretical, it is already reshaping which conversations happen and which do not.

The Funding And Dealmaking Equation Has Changed

For biotechs, the current environment offers real opportunity but on fundamentally different terms than the peak years of 2020-2021. BCG found that nearly half of all deal value in 2025 came from acquisitions of already-marketed products, up from roughly a quarter in the 2019-2021 period. Syneos Health's annual Dealmakers Intentions survey confirmed the trend but with a telling nuance: while appetite for marketed assets surged, interest in Phase III and programs in the process of regulatory consideration declined. The real demand from acquirers is for either marketed assets generating immediate revenue, or Phase II programs still malleable enough for buyers to shape. This seems to be good news for biotechs with compelling mid-stage data, less so for those sitting on late-stage assets waiting for a deal.

> "I see a rather positive outlook for the biotech sector."
>
> **Arda Ural, EY**

Preclinical valuations tell a different story: BCG found they have collapsed from an average of around $500m in 2021 to roughly $50m today, making the fundraising environment for early-stage companies still genuinely difficult despite the broader market recovery.

In his recent book Biotech in the Balance, industry veteran Jeremy Levin argues this risk-aversion carries a cost beyond individual company fortunes. When capital demands certainty that biology cannot provide, biotechs begin designing programs to satisfy the appearance of de-risking rather than to pursue the most important scientific questions. Bold mechanisms and first-in-class approaches are deprioritized. The pendulum swings from reckless exuberance to blanket aversion and neither extreme produces the medicines patients need.

Those that do strike deals should prepare for flexible deal structures, particularly given the added supply coming from China. Speaking at Biotech Showcase earlier this year, senior dealmakers from Novo Nordisk, Ipsen, Astellas and Flagship Pioneering were aligned that milestone-heavy licensing terms, option agreements and equity stakes are increasingly the currency of partnership over clean upfront acquisitions. For smaller biotechs, the advice from experienced dealmakers is to build relationships long before you need them and treat every pharma conversation as a feedback loop, not just a sales pitch. As Flagship Pioneering senior partner and chief business development officer Amanda Kay put it, "Sometimes the numbers are the last things in a really good collaboration that you need to be talking about."

The China Question

No development is prompting a harder reckoning across the US and European biotech ecosystem – from government funders to venture capitalists – than the rise of Chinese biotech. China-originating assets now account for roughly 30% of the global pipeline and Chinese biotechs have staked out a dominant position in certain modalities: approximately half of all new antibody-drug conjugates now originate from China, for example.

The attraction for big pharma is that innovation from China comes faster and with more de-risked data. As Flagship Pioneering's head of newco business development Neel Patel said of Chinese biotech at Biotech Showcase: "The dam has burst. Everyone is out there hunting."

That competition is increasing the value of Chinese-originating assets. No longer are these seen as discounted therapeutics, but rather they are valued for their innovation.

Geopolitical headwinds add complexity to the allure of buying Chinese assets. Executive orders from both the Biden and Trump administrations have restricted cross-border transfers of patient and genomic data, and murmurs about broader protectionist measures have not quieted. Companies seeking to reduce China exposure

without sacrificing cost efficiency or innovation quality are seeing India quietly emerge as a hedge. In 2025, Roche committed over $1.9bn in Indian R&D and commercial capabilities and Amgen invested $200m in AI and data science there.

The AI Inflection Point

Agentic AI is moving from concept to operational reality in biopharma – a shift from rule-based systems that flag anomalies or automate discrete tasks toward AI that observes context and takes autonomous action across multi-step workflows. The areas with the greatest near-term potential, according to BCG, are R&D (particularly molecule design and trial protocol development), supply chain and manufacturing and commercial functions, including field operations and patient access.

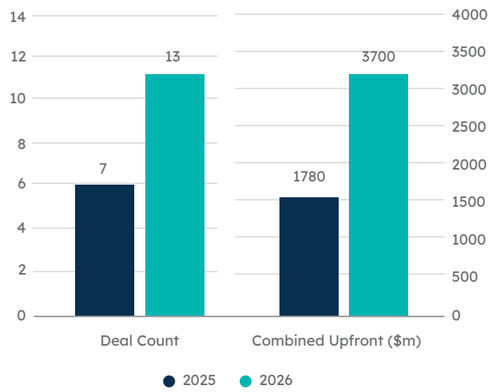
The early data on AI-assisted molecule design are striking: AI-designed molecules are clearing Phase I trials at 80-90% success rates, compared with a 40-65% industry norm for conventionally developed drugs.

What separates AI leaders from laggards in biopharma is not the sophistication of their tools, but the discipline of their focus. BCG's benchmarking found that AI leaders concentrate on 40% fewer use cases than laggards, but scale 2.3 times faster on those applications. It is difficult to know what the state of AI will be at BIO 2027, but the biotech ecosystem is being shaped by the ongoing rise – and rapid change – of these technologies. Automated labs, increasingly advanced synthetic biology capabilities, and clinical trial technologies that are guided by AI are accelerating innovation and time-to-market.

What The Science Is Telling Us

Beneath the strategic maneuvering, biological innovation continues to deliver. In oncology – still the dominant arena for dealmaking – a new wave of first-in-class mechanisms is generating serious investor and acquirer interest well ahead of approval. *In vivo* CAR-T, which promises autologous CAR-T's efficacy at a fraction of the cost by reprogramming T cells inside the body rather than in the manufacturing facility, has triggered a wave of big pharma dealmaking that has substantially outpaced the maturity of the clinical data – a pattern that suggests broad conviction about the mechanism's commercial potential. Additionally, pan-RAS and pan-KRAS inhibition, synthetic lethality approaches broadening beyond PARP, and CALR-mutant targeted therapies in blood cancers round out a pipeline that indicates oncology's innovation cycle is far from exhausted.

Big Pharma Deals For Chinese-Originating Assets



Source: Evaluate, Jan-May 2025 vs. Jan-May 2026

The broader therapeutic mix is also shifting. After a decade dominated by specialty biologics targeting rare diseases, the success of GLP-1s for obesity and monoclonal antibodies for Alzheimer's has reshaped expectations about where blockbuster-scale returns can come from. While rare disease remains of interest to biotechs and pharma, the direction of travel is toward large-population indications, including cardiometabolic and inflammatory and immune-related diseases.

The View From BIO

The mood at BIO 2026 reflects the complexity of the moment. There is forward momentum, backed by data: deal value is up, the capital markets are functioning again and the science is delivering. But the pressures are real and converging: the patent cliff demands inorganic action at speed; China is competing for deals and talent with a seriousness that was unimaginable five years ago; and AI's transformation of drug development is creating new winners and losers before anyone has fully mapped the terrain.

The companies best positioned for the second half of 2026 are those that have learned the lesson of the Darwinian reset – lean operations, disciplined portfolio management and milestone-based thinking – while moving decisively on the opportunities those habits create. Maintaining a focus on innovation, cost discipline and building resilience against multiple geopolitical and policy scenarios is essential. In a period of convergent pressures, there is no safe middle ground.

Behind China Deals: If The Trials Are More Fly, Then You Must Buy

Multinationals are developing new deal patterns with Chinese originators which enable them to tap into China's strengths in early-stage clinical studies.

DEXTER JIE YAN, Senior Reporter, ***Scrip, Pink Sheet***

High-flying are those Chinese biopharmas and biotechs that have struck mega deals, characterized by preclinical assets out-licensed en bloc, with multinational partners over the past few months.

Since late 2025, multinationals have been quickening the pace of preclinical-focused "bulk orders" for new assets in China.

The trend reached its zenith so far around mid-May this year, when Bristol Myers Squibb announced the in-licensing of four wholly owned and five jointly discovered and developed preclinical assets from Jiangsu Hengrui Pharmaceuticals, an established Chinese drug maker. For its part, Hengrui will bear the full responsibility of advancing these programs into early clinical development until the proof-of-concept stage.

"The BMS/Hengrui deal signifies the multinationals' R&D arrangements in China to completely externalize certain preclinical programs to Chinese firms," Jun Bao, founding and managing partner of Apuri BioVenture, told *Scrip*. Apuri is a Shanghai-based venture capital firm funding early-stage discoveries at Chinese universities.

"In effect, with the help of these deals, they [MNCs] are tapping into Chinese partners' highly efficient infrastructure in China," Bao added, referring to local firms' strong capabilities to run world-competitive domestic trials in operational and financial terms, as well as the country's vast clinical resources in the form of large patient populations.

> "You can enroll trials faster just because of bigger numbers."
>
> **Geoff Meyerson, Locust Walk**

Bao is best known for having reached two licensing deals, one focused on the anti-PD-L1 x VEGF-A bispecific antibody pumitamig, with BioNTech when he was chief business officer at Chinese firm Biotheus. In the wake of the partnerships, Biotheus was acquired by BioNTech for $800m upfront in 2025.

Notably, it was also Hengrui that first included the component of early-stage trial responsibility into any big pharma alliance that lumped in multiple preclinical assets. Under a collaboration with GSK revealed in July 2025, Hengrui will lead the development of as many as 11 programs, to which GSK will gain exclusive optional rights, up to completion of Phase I trials both inside and outside China.

Following suit have been similarly structured deals signed by Harbour BioMed and Innovent Biologics with BMS and Eli Lilly in December 2025 and February 2026, respectively. (*See table for further details.*)

China's 'Magic Formula' For Cheaper, Faster Trials

While it's widely acknowledged that China's rise as an early-stage trial powerhouse is based on its huge patient population, drug developers from the country have also developed over the years a "magic formula" for running such work cheaper

and faster, which could be exclusive to them on their home turf.

"You can enroll faster just because of bigger numbers," Geoff Meyerson, CEO of Boston, MA-based Locust Walk, a life sciences-focused investment bank, told *Scrip*.

On top of higher patient numbers nationwide, China also has more concentration of patients compared to the US as there are fewer major centers to run clinical trials, according to Meyerson. Conversely, the higher patient concentration helps Chinese sponsors cut the spending per patient when conducting a domestic trial.

"When you reduce the cost per patient because the costs are cheaper [in Chinese trials], you can enroll faster," the CEO noted.

As for the clinical development of early-stage assets, which involves far fewer enrollees than in Phase III trials, China-based trials also plays more strongly to the advantage of local firms.

"When you add that all up and then when China has a regulatory regime that allows early clinical trials for certain types of modalities, that actually makes it quicker to get from a PCC [preclinical compound candidate] to the patient," Meyerson noted.

Last but not least, Chinese principal investigators are more incentivized to enroll more patients. "All those things just compound," he observed.

Recent Preclinical Deals With Early-Stage Clinical Responsibility In China

	GSK/Hengrui	BMS/Harbour BioMed	Eli Lilly/Innovent	BMS/Hengrui
	July 2025	December 2025	February 2026	May 2026
Number of preclinical assets	up to 11	NA	NA	13 incl. 4 from BMS
Therapeutic areas	respiratory, immunology & inflammation, oncology	NA	immunology, oncology	oncology/hematology, etc.
Early clinical responsibility	Hengrui	Possibly Harbour BioMed	Innovent	Hengrui

Source: Company Press Releases

Impact Of China's New Data Protection On Deals, Corporate Strategies

New data protection measures released by China's drug regulator could influence future licensing deals for innovative assets originating in the country, particularly royalty terms, a law firm predicts.

XU HU,
Senior Reporter,
Scrip, Pink Sheet

The recently finalized measures for data protection issued by China's drug regulator, the National Medical Products Administration (NMPA), send a strong signal the country is strengthening measures to support innovation and looking to provide commercial benefits for novel drugs.

This may contribute to more acquisitions of, or in-licensing deals for, China-originated assets by foreign companies, including multinationals, in the view of legal experts from Han Kun, a China-headquartered multinational law firm.

In addition to increasing the commercial value of clinical trial and other data for innovative drugs submitted to the NMPA, the implementation of the new data protection terms and measures could also impact royalty terms under future transactions for such assets compared to previously, when protection measures were both unclear and challenging to implement, according to the law firm.

On top of this, the new protection framework may affect product lifecycle management and approaches to market access in China under corporate strategies, particularly the sequence of regulatory filings to the NMPA for different indications, Han Kun told the *Scrip*.

The NMPA released on May 15 the final version of the measures for data protection after a nearly nine-year period since 2017, when China's State Council first included the concept of data protection in policy incentives for regulatory reforms for drugs and medical devices and to improve food and drug safety.

The revised protections apply to all data used to demonstrate product efficacy, safety and quality for drug registration purposes in China, with protection periods ranging from three to six years.

Impact On Licensing Deals

The data protection measures will likely be seen as an incentive for companies to seek more and larger licensing deals, and encourage overseas drugs to enter the China market, the lawyers predicted.

The main reasons are that the provisions may help increase the predictability of product revenue and reduce market risks associated with patent instability, creating a more secure environment for asset transactions, particularly for those that may lack strong patent protection, they explained.

More specifically, of the 15 items in the data protection measures, three items particularly – which specify data protection periods and related measures for innovative original and improved drugs not approved globally, as well as for original and improved products already launched overseas but not yet approved in China – establish a robust data exclusivity regime, the Han Kun lawyers pointed out.

They expect this to strategically impact transactions for innovative drug assets in three respects: prolonged royalty terms, a reduced impact from any patent cliff, and early data access for domestic developers of generics, they predicted.

For data related to innovative drugs submitted to the NMPA, these measures will have a positive impact on deals involving such data, regardless of whether the licensing agreement is between Chinese firms or cross-border, due to enhanced asset value from the data exclusivity.

For instance, a licensor may look to maintain a higher royalty rate for a longer period of time to generate increased total revenue from a deal. Conversely, this could not be leveraged should an agreement cover only global assets and markets outside China, the lawyers noted.

As for generics, the new data protection measures mean the original data holder may license early access to proprietary data to a generic developer prior to the protection expiration date in exchange for financial benefits, the law firm explained.

Pillar Of Lifecycle Management

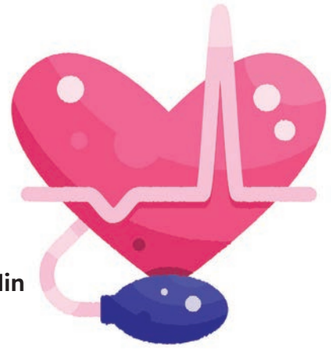
The Han Kun lawyers see the new China data protection framework serving as a "core pillar" for drug developers when it comes to product lifecycle management and market access strategies.

> Measures are an incentive for companies to seek more and larger licensing deals.

Companies will level up the quality of their data packages, clinical trial design and the curation of "indication launch" strategies to secure the longest data protection periods, they believe. This is because the NMPA grants different protection periods based on the value of trial data and according to the filing sequence for different indications.

For example, an original drug not approved in China will receive six years of data protection for its first indication, but only four years for subsequent indications, the lawyers explained.

Novartis On The Future Of CV In A World Of GLP-1s



CV, renal and metabolic R&D leaders **Ruchira Glaser** and **Shaun Coughlin** talked to *Scrip* about investments and catalysts in the therapeutic area.

JESSICA MERRILL,
Senior Editor,
Scrip

Novartis has a deep heritage in cardiovascular disease and has been working to extend that expertise into renal disease through a series of recent acquisitions. But while the company has a long-term goal to prevent cardiovascular events, Novartis missed out on the early obesity market and hasn't jumped into the space like some rivals.

In an interview, the R&D leaders charged with overseeing the company's cardiovascular and renal renaissance said they see a long-term opportunity in the two disease areas despite the success of GLP-1s on some cardiovascular and renal outcomes.

Shaun Coughlin, Novartis

"Obviously, they're incredible medicines," global head, cardiovascular and metabolism, biomedical research Shaun Coughlin said. "But the LDL-lowering that's achieved is typically 5%-10% and the blood pressure reductions are typically 5mL of mercury, on that order, so that's certainly not going to obviate the need for other therapies to reduce those important risk drivers."

"They're kind of a fundamental medicine for a number of aspects of cardiovascular disease, but I don't think they're going to obviate the need for the rest of our pipeline," he added.

Ruchira Glaser, Novartis

Global head, cardiovascular, renal and metabolic development Ruchira Glaser pointed out that improved health outcomes driven by the broad use of GLP-1s could even lay a foundation for individuals to take more initiative with their health.

"It's also actually done something really positive for cardiovascular health because, with the GLP-1s … there's been much more appreciation for the importance of risk factor modification and longevity in cardiovascular health in general," Glaser said.

"I see more people asking about what other risk factors they may have, whether that be inflammation, hypertension, hyperlipidemia, genetic risk factors like Lp(a) and what they can do to continue to modify those," she added.

Metabolic Interest But Not GLP-1s

While Novartis is interested in metabolic disease as a therapeutic area, the company's top leadership has said it does not have interest in trying to play catch up in the GLP-1 space. That appears to remain the case, perhaps a valuable lesson learned by the company's botched attempt to catch up late in the game in the PD-1/L1 immuno-oncology race.

As Coughlin put it: "We are certainly looking for different, differentiated opportunities, differentiated mechanisms, and we're not interested in kind of me-too entries."

Glaser added, "We certainly would look at interesting orthogonal mechanisms to the current incretin approach to obesity, particularly with the lens of the cardiovascular health and synergies to our own pipeline."

Coughlin predicted that new opportunities will continue to emerge in obesity as the therapeutic area evolves.

"I've heard victory declared in ASCVD [atherosclerotic cardiovascular disease] with statins and in hypertension with ACE/ARBs, and in anticoagulation with warfarin and then the [factor] Xas, and those fields have certainly progressed and evolved in wonderful ways, and I think the same thing will happen in obesity," he said.

Novartis Highlights Phase II/III Pipeline

Glaser and Coughlin talked to *Scrip* after a media briefing hosted by the company on May 21 to showcase its pipeline across four core therapeutic areas, including oncology, immunology and neuroscience, in addition to cardiovascular, renal and metabolic disease.

On the cardiovascular front, Novartis said it is advancing a broad portfolio of assets with the goal to prevent heart attacks, strokes and early death, relying on both established mechanisms and next-generation opportunities.

"We're really seeking, on the cardiovascular side, to have broad coverage of the cardiovascular risk factors: we have lipids, inflammation and blood pressure," Glaser told *Scrip*. "Beyond that, we also have exciting work in Shaun's shop around rhythm disorders and in the late stage around the prevention of thrombosis."

Novartis is looking to replenish its cardiovascular portfolio as its heart failure blockbuster Entresto (sacubitril/valsartan) – the company's top-selling drug last year – fades due to generic competition. The PCSK9 inhibitor Leqvio (inclisiran) for high cholesterol has slowly grown into a blockbuster, generating $1.2bn in 2025, but the class of drugs is poised to face new competition from the first oral competitor, Merck & Co.'s enlicitide, soon.

The company's lead CV pipeline asset is the Lp(a) inhibitor pelacarsen, for which Phase III data is expected midyear, positioning Novartis in the lead of what is expected to be a competitive category.

The company is also developing the Factor XI inhibitor abelacimab for atrial fibrillation and the prevention of stroke and systemic embolism, with late-stage trials expected to read out in 2027. In Phase II, the company's key CV assets include pacibekitug, an anti-IL-6 antibody for ASCVD targeting inflammation that Novartis acquired with the $1.4bn buyout of Tourmaline Bio last year, and QCZ484 for resistant hypertension.

"Pacibekitug really has a potential to redefine how we treat cardiovascular risk, bringing a very long overlooked driver of disease right into the heart of patient care," Glaser said during the media briefing.

QCZ484 is a siRNA therapy being developed as a twice-yearly medication that works by inhibiting angiotensinogen.

"What's so energizing to me about QCZ is it's a great example of the future of how we do drug development because it's the convergence of strong biology and a dosing profile that's built for the real-world life," Glaser said.

"When you pair a validated mechanism with twice-yearly adherence, you're not just lowering blood pressure in the office or on a chart, but you're really giving patients a genuine chance at cardiovascular protection over the long term," she added.

AbbVie Leverages Successes And Setbacks To Grow In Neuroscience

Scrip spoke with **Sean Kelley,** AbbVie vice president of neuroscience asset leadership, about the company's strategy for its second-largest and fastest-growing business.

MANDY JACKSON,
Managing Editor,
Scrip

AbbVie is known for its powerhouse immunology portfolio, but neuroscience is its second-largest and fastest-growing business, with several opportunities for expansion in the coming years, starting with tavapadon for Parkinson's disease, which is awaiting US Food and Drug Administration approval later this year.

Scrip spoke with Sean Kelley, vice president of neuroscience asset leadership, about AbbVie's plans for the portfolio over the next decade and beyond.

The neuroscience portfolio generated $10.77bn in 2025 sales, while the company's immunology drugs brought in $30.41bn – 17.6% versus a whopping 49.7% of AbbVie's $61.16bn in total revenue last year. However, neuroscience revenue grew 19.6% in 2025 from 2024 compared with 14% for immunology. And 2026 is off to a good start, with the portfolio of neuropsychiatry, migraine and Parkinson's disease drugs bringing in $2.88bn in first quarter revenue, up 26% year-over-year versus 16.4% growth for immunology.

The neuroscience portfolio got a big boost in 2020 when AbbVie closed its $63bn purchase of Botox (onabotulinumtoxinA) maker Allergan, which came with a significant number of approved and investigational neuroscience assets. In addition to Botox for aesthetic and therapeutic indications, including migraine prevention, AbbVie gained another blockbuster drug, the atypical antipsychotic Vraylar (cariprazine) for schizophrenia, bipolar 1 disorder depression and manic episodes, and major depressive disorder, and the CGRP inhibitors Ubrelvy (ubrogepant) for acute treatment of migraine and Qulipta (atogepant) for migraine prevention. Botox

Therapeutic, Vraylar, Ubrelvy and Qulipta each delivered more than $1bn in sales in 2026.

Going forward, Kelley said, AbbVie is playing to its strengths by focusing on psychiatry, migraine and movement disorders, including Parkinson's disease, while also aiming to grow its neuroscience portfolio in the area of neurodegenerative disorders, including Alzheimer's disease.

"In three of those four areas … we have already established on-market credibility," he said. "We've got Vraylar, which is the no. 1 one most-prescribed branded antipsychotic in the market. We've got Ubrelvy, Qulipta and Botox, all in the migraine space, all leading assets. And then in Parkinson's, both Vyalev and Duopa on market."

The FDA approved Vyalev (foscarbidopa/foslevidopa) to treat motor fluctuations in advanced Parkinson's disease in 2024, nine years after the agency approved Duopa, an enteral suspension formulation of carbidopa and levodopa. Tavapadon, a first-in-class partial agonist of the D1/D5 dopamine receptors, is an oral therapy that has shown efficacy in Parkinson's disease across the Phase III TEMPO-1, -2 and -3 clinical trials.

Kelley said AbbVie is a leader in a number of neuroscience areas and the company is doubling down on its existing expertise. "We're focusing to make sure we maintain that leadership position in those three pillars and playing to our strengths," he said. "We've built capabilities both in clinical trial execution, in precision medicine and other areas to improve the probability of success in the psychiatric space, for example, and to help drive transformative treatment in Parkinson's earlier in the Parkinson's journey."

Cerevel Deal Provided Neuroscience Surprises, Lessons

Tavapadon came from AbbVie's $8.7bn acquisition of Cerevel Therapeutics, which the company announced in December 2023. Emraclidine, a positive allosteric modulator of the muscarinic M4 receptor, was the prime asset behind the purchase, but tavapadon's blockbuster potential was better understood after the product began generating Phase III results, a balm for the company since emraclidine failed in its potentially pivotal Phase II studies in schizophrenia. AbbVie has gone back to the drawing board with emraclidine, with dose-escalating Phase I and II trials ongoing in Alzheimer's disease psychosis and schizophrenia.

"Before the Cerevel acquisition, we looked at [tavapadon] and said, 'A new oral treatment in Parkinson's disease, there's a lot of those. Does it have an opportunity?' But when you saw the TEMPO-1 to -3 data, it was surprisingly good," Kelley said.

Having a broad neuroscience portfolio gives AbbVie the space it needs to learn from setbacks, he noted, such as the failed EMPOWER studies of emraclidine.

"That was a disappointment out of the Cerevel acquisition, but the signals that we saw in that suggested that we were underdosing emraclidine," Kelley said. "And so, we've been seeing the data from the emraclidine multiple ascending dose studies. We are seeing evidence that gives us greater confidence with emraclidine and the highest dose cohort is beginning. And so, we'll be able to wrap that up and get started with Phase II work with emraclidine at those higher doses later this year."

AbbVie has learned a lot from emraclidine's development about what to look for in dosing psychiatric treatments. For example, the company has introduced electroencephalograms into its studies to help with decision-making around appropriate dosing. AbbVie has also focused on how to manage placebo responses within psychiatric studies, because those were "exceedingly high" at some trial sites in the EMPOWER trials of emraclidine, Kelley explained.

Kelley noted that emraclidine was a highlight at the time of the Cerevel acquisition, because AbbVie had a leading commercial position with Vraylar in the psychiatric market, but "we didn't have a lot behind it." Buying Cerevel gave the company emraclidine and other M4-targeting assets in neuropsychiatry as well as icalcaprant (CVL-354/ABBV-1354) for depression.

"While the highly publicized impact with emraclidine was kind of the most prominent issue with the Cerevel acquisition, it gave us a pretty robust psych pipeline that is encouraging looking forward. And it had tavapadon, which has been a nice surprise," he said.

R&D Portfolio Growing Internally, With External Partners

Kelley described several areas where AbbVie intends to build on its first three pillars in neuroscience while adding the fourth pillar in neurodegenerative diseases.

"We're pretty late with advanced Parkinson's right now, but we think there's opportunity to drive earlier in that journey," he said. "And then in migraine, roughly 50% of people have a 50% reduction in migraine frequency. And that's a responder, but that's far from good enough, so we're aiming for migraine freedom and that means different mechanisms, potentially combining mechanisms."

AbbVie has a monoclonal antibody targeting protease-activated receptor 2 (PAR-2) – ABBV-2002, which it acquired from AstraZeneca – in Phase II for migraine prevention with data expected in 2027.

"We are continuing to look for other migraine and pain assets potentially as monotherapies or in combination with CGRPs because we think that stacking therapies may be necessary in order to get to migraine freedom," Kelley said.

In neurodegeneration, AbbVie has the amyloid-beta-targeting candidate ABBV-1758 in Phase I for Alzheimer's disease and it is developing agents to prevent tau propagation, while keeping an eye on areas such as neuroinflammation. "That's further down the road and a growth opportunity, but in the near term, we want to double down and strengthen where we're already strong," Kelley said.

AbbVie paid $1.4bn in 2024 to buy Aliada Therapeutics, bringing in ABBV-1758, which uses Aliada's blood-brain barrier-crossing technology to deliver the drug into the brain of Alzheimer's patients.

"We don't explicitly balance internal discovery versus external discovery efforts," Kelley explained. "We focus on where those core diseases are and we put together profiles of what we believe a transformative treatment could be in those spaces, and then we look for the best innovation to deliver against that profile. So, if external innovation is most likely to drive transformation and address unmet need in a timeline that's better than we can deliver, we are certainly going to pursue that external innovation. And I think if you look at our pipeline, you could see a fair amount of it comes from external partnerships."

AbbVie added a mid-stage depression drug candidate to its pipeline, the serotonergic psychedelic bretisilocin, by committing up to $1.2bn to its partner Gilgamesh Pharmaceuticals in August 2025. Additional Phase II data are expected for the drug this year in major depressive disorder (MDD). If those results meet the company's bar for success, bretisilocin will move into Phase III for acute treatment of depression and Phase II for recurrent MDD and post-traumatic stress disorder (PTSD).

All Modalities On The Table In Neuroscience

In terms of future deals, Kelley noted that bretisilocin is an example of how AbbVie has not ruled out any specific modalities in neuroscience. In MDD, its takes six weeks or more for patients to start benefiting from standard-of-care generic antidepressants and those drugs have relatively low remission rates.

"It's slow response, but it's a daily oral and people like taking a daily oral," Kelley said. "If you launch something like bretisilocin with roughly a two-hour in-office experience, but 80%-90% of people get remission and it's as early as the first week, that modality may be less convenient and requires some infrastructure in the US or elsewhere to support it, but the outcome is so dramatically different that I think the market could support it. So, we look at the modality relative to the benefit it could offer, and then we see if we believe that has a place in the market."

AbbVie monitors innovation round the globe in its core therapeutic areas within neuroscience, evaluating 10 to 20 times as many deals as it actually closes each year, Kelley estimated.

"There's not lots and lots that's transformative or meets a very high bar, but the deals we do are both for assets and for technology platforms," he said. "Blood-brain barrier shuttles, psychoplastogens, next-gen psychedelics, neuroplastogens and non-psychedelic treatments, the genetic medicine platforms – those are external deals that could enable more internal discovery and progress, improving our development as well."

With what AbbVie believes is "a very strong growth proposition into the 2030s with the assets we have in market today and those that we have in the late-stage pipeline," Kelley said, "what we're trying to fill is that second half of the '30s. And so the assets that we mainly are looking for externally would fit that profile, that you'd anticipate them being replacements beyond the life cycle we have with our current programs."

AbbVie's Upcoming Neuroscience Milestones

2026

Ex-US approvals for Qulipta in migraine; US approval for tavapadon in Parkinson's disease; Phase III data for Qulipta and Ubrelvy in menstrual migraine prevention; Phase II data for ABBV-932 in bipolar depression, bretisilocin in major depressive disorder (MDD) and emraclidine in schizophrenia; and Phase I results for emraclidine in Alzheimer's disease psychosis

2027

EU approval for Qulipta in menstrual migraine prevention; US approval for Ubrelvy in menstrual migraine prevention; US regulatory submission for Ubrelvy in menstrual migraine prevention; and Phase II data for ABBV-932 in generalized anxiety disorder, ABBV-1354 in MDD and ABBV-2002 in migraine prevention

Against Specialist Tide: Anthropic Backs A Generalist Claude For Biopharma's R&D Stack

Anthropic is betting that a generalist Claude trained on biology, backed by a $400m biotech acquisition, an in-house wet lab and a Novartis-CEO board seat, can become biopharma's end-to-end AI partner for drug discovery.

DAVID WILD,
Senior Reporter,
In Vivo,

Anthropic has built its public identity around the risks of frontier artificial intelligence. At SynBioBeta this month, the company made its clearest case yet for the upside and laid out a markedly different biopharma strategy compared with Isomorphic Labs, Xaira, Recursion, and the wave of structure- and molecule-design specialists – a single generalist Claude, trained heavily on biology, can do more for drug discovery end-to-end than any specialized model operating alone.

The company made clear that its largest area of investment after coding is in life sciences. It is a position Anthropic has backed since October 2025 with the launch of Claude for Life Sciences, an April 2026 acquisition of stealth biotech Coefficient Bio for $400m, and the appointment of Novartis CEO Vas Narasimhan to its board the same month.

"We believe the greatest opportunities to benefit human life at the largest possible scale are in life sciences," Eric Kauderer-Abrams, who heads Anthropic's life sciences team, told attendees.

The generalist approach positions Anthropic against the prevailing assumption inside biopharma that the most valuable AI for drug discovery will be domain-specific, like the descendants of AlphaFold of Google DeepMind and RoseTTAFold from the lab of David Baker (co-founder of Xaira Therapeutics).

Kauderer-Abrams conceded that those models "have a lot of value and a place in the ecosystem," but argued the more impactful role for Claude is to do what a scientist does end-to-end: design molecules, run bioinformatics, plan synthesis, optimize candidates, reason over literature, and connect those tasks together.

"Our philosophy is to invest as heavily as possible in training our base Claude models," he said. "The same Claude that everyone uses day-to-day, we're training it to be skilled at everything we can think of in the life sciences."

Putting Capital Behind The Thesis: Coefficient Bio And In-House Wet Lab

Two operational moves discussed at the conference give the strategy substance beyond model training. In April, Anthropic acquired Coefficient Bio – a stealth biotech only eight months old – for $400m, in a deal aimed at extending Claude's reach from the technical core of discovery up into program-level decisions, including which targets to pursue, which modalities to combine with which targets, and how to plan and manage programs end-to-end.

"Our work in life sciences so far has largely focused on the technical core," Kauderer-Abrams said. "With Coefficient Bio, our thinking was to accelerate the other side: helping biotech operators and decision-makers…so we can deliver a more complete, useful picture of what's needed."

Anthropic is also setting up its own wet lab, currently focused on basic research. The rationale, Kauderer-Abrams said, is partly practical.

"If we're serious about doing biology, there's no substitute for being in the lab," he said.

The lab will serve as a training feedback loop with scientists using Claude daily, identifying gaps that flow back into model training and product design. It also positions Anthropic to begin closing what he called one of the field's biggest needs: connecting "atoms to bits," so that real-world experimental results become learning signals for the model.

Kauderer-Abrams made it clear that the wet lab component was not an indication that Anthropic will develop its own pipeline, but rather it is in service of accelerating discovery for the ecosystem.

Those moves sit alongside a more visible signal of pharma engagement, namely the addition of Novartis CEO Vas Narasimhan to its board in April. Biopharma representation at frontier-AI companies now includes Aarti Shah, former Eli Lilly chief information and digital officer, on NVIDIA's board of directors, and Sue Desmond-Hellmann, former president of product development at Genentech and current CEO of the Bill & Melinda Gates Foundation, on OpenAI's board.

"Vas brings something rare to our board," Anthropic co-founder and president Daniela Amodei said at the time, citing his oversight of more than 35 novel medicine approvals. Anthropic has also disclosed that Claude is used by "most Sanofians daily," according to Sanofi chief digital officer Emmanuel Frenehard.

From 'Grad-School Chunks' To Long-Horizon Workflows

Opus 4.7, which Anthropic describes as its second model with extensive dedicated biology training, is said to have "structural biology reasoning [that] has more than doubled" and the ability to read chemical structures, technical diagrams and complex experimental data.

Asked about the training roadmap, Kauderer-Abrams described a shift in how Anthropic is refining Claude. Until recently, models were trained on "chunks" of problems – discrete, grad-school-style tasks such as running a bioinformatics workflow or planning a chemical synthesis. There are thousands of such tasks, he said, and models are close to saturating that space.

The next phase, he said, is end-to-end problems where the output is a meaningful work product, such as taking a therapeutic hit through to an optimized lead, proposing a new target worth pursuing, or completing a genomics analysis from raw data to interpretation.

"We're moving from bite-sized problems to long-horizon workflows with real output," he said.

Three other themes stood out from what Kauderer-Abrams shared. The first is a focus on accelerating what has historically been the longest and most expensive phases of drug development: clinical trials and regulatory approval.

"Design is flashier, but clinical and regulatory are full of problems where AI can help," he asserted.

The second theme is using Claude for hypothesis generation. Here, he said, while models have moved from "not very good" to roughly PhD level on most life-science evaluations, genuinely novel idea generation is a shortcoming Anthropic is now explicitly measuring and training for.

Developing and refining new modalities is another priority for Anthropic, with Kauderer-Abrams pointing to "amazing clinical readouts" for macrocyclic flu inhibitors, antibody drug conjugates and proteolysis targeting chimeras (PROTACs), and arguing that AI can move the design of these complex modalities "from a more alchemical art into a more rational engineering discipline."

Commercial Terms Biopharma Will Want To Note

Responding to questions from meeting attendees, Kauderer-Abrams said Anthropic has no plans to move away from token-based pricing in life sciences, despite industry speculation about outcome-based or clinical research organization-style models. "We think a meaningful share of the thinking in life sciences can be expressed in tokens," he said.

He also reassured attendees about IP ownership. "If you use our models as part of your process, you own the IP," he said, noting that such concerns are a common reason cited for not using frontier-AI models in scientific discovery.

The Competitive Backdrop

Anthropic's push comes as the rest of the frontier-AI field intensifies its own pharma activity. In April, Novo Nordisk announced a strategic partnership with OpenAI to deploy AI from drug discovery through commercial operations, while, in October 2025, Eli Lilly committed with NVIDIA to invest $1bn over five years in a co-innovation lab in the San Francisco Bay Area. Novartis has been an active AI dealmaker, including striking a multi-program collaboration for immuno-dermatology targets with Relation worth more than $1.7bn, much of it tied to milestones.

A Jefferies survey in February found that most biopharma executives expect AI to account for more than 10% of their R&D budgets by 2030. Against that backdrop, Anthropic's pitch – for a generalist model trained heavily on biology, an orchestration-friendly stance and explicit customer ownership of IP – is a differentiated offer that could please biopharma companies.

What To Watch

Kauderer-Abrams set an ambitious medium-term marker to watch for.

"What we really want to see is a noticeable deflection in the trajectory of the total number of high-quality new therapeutics developed each year," he said. He acknowledged that some elements of drug discovery and development are rate-limiting – cells will not grow faster and clinical trials may not accelerate ten-fold – but he argued the cumulative effect across the R&D spectrum should be tangible. Whether biopharma agrees – and whether a generalist Claude can hold its own against the specialist models and infrastructure-heavy partnerships gaining ground elsewhere – is the question the industry will look to answer over the next 12 months.

Venture Funding Keeps A Steady Pace In Q1

Mid-Sized Financings Rise From Q4

At $7.94bn, the first quarter of 2026 fell only slightly below the $8.04bn in venture capital raised by biopharma companies in Q4 of 2025, which was the biggest quarter in years.

MANDY JACKSON, Managing Editor, ***Scrip***

Venture capital invested in biopharmaceutical companies kept up a relatively steady pace between the fourth quarter of 2025 and the first quarter of 2026, with a strong showing for mid-sized and earlier-stage financings, according to new data from Evaluate and Biomedtracker. VC fundraising totaled $7.94bn in Q1, down just $100m from the Q4 total of $8.04bn – the largest quarter for drug developer venture rounds since Q1 of 2022.

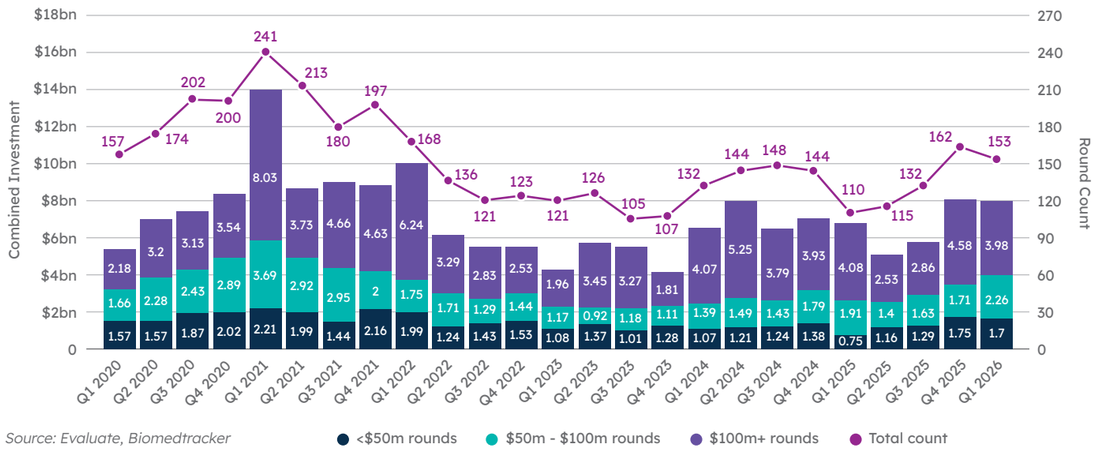
VC investment boomed in 2020-2021 and declined in 2022-2023. The recovery that started in 2024 is ongoing, and Q1 fundraising offers some glimmers of hope for drug developers seeking their next round of private financing. While the number of mega-rounds of $100m or more fell from 29 in Q4 to 20 in Q1, the average raised in that category rose from $157.9m to $199m.

Also, the number of mid-sized VC rounds between $50m and $100m grew from 21 that raised $81.4m on average in Q4 to 28 that raised an average of $80.7m in Q1. The number of VC financings of $50m or less dropped from 112 to 105, but the average raised grew from $15.6m to $16.2m.

Venture capital fundraising has been particularly difficult during the past few years for start-ups seeking their first financings and for early-stage companies looking to raise their next round of funding, with investors favoring firms with drugs in clinical trials or nearing the clinic – a trend that was expected to mostly continue in 2026 even with rising investor confidence in the biopharma sector at the start of the year.

That confidence has been shaken more recently, especially on the public company side, as investors

Quarterly Biopharma VC Rounds



Source: Evaluate, Biomedtracker

grapple with the implications of the war in Iran, changes in US Food and Drug Administration leadership and uncertainty around policy changes under the Trump administration, including a recent announcement of 100% tariffs on certain imported pharmaceutical products and ingredients.

The relative stability in the amount of VC money raised in Q1 versus Q4 may be a result of investor optimism observed at the start of 2026, although that enthusiasm may subside as geopolitical and industry concerns continue beyond the first quarter.

However, the Q1 increase in the number of mid-sized VC rounds and in the average size of smaller venture financings may reflect a shift in VC investor priorities identified by venture investors and advisors at BIO's Investor and Growth Summit in early March. They noted multiple green shoots, such as an emergence of new investors at the seed financing stage, the potential for investors to see better returns from mid-sized financings than from mega-rounds, and the amount of capital raised by VC firms in 2022 and 2023 that they still need to invest.

Big Mega-Rounds Lead Q1's Top 5 Deals

Nevertheless, mega-rounds are here to stay as investors focus on big investments in clinical-stage drug developers, artificial intelligence platforms and companies developing therapeutics for large indications, such as obesity. The top 5 financings in Q1 ranged from $250m to $787m.

Earendil Labs emerged in March with $787m raised across multiple rounds to fund its AI-enabled drug discovery and development programs. The company is developing biologics, including monoclonal, biparatopic, bispecific and trispecific antibodies for autoimmune diseases as well as bispecific and biparatopic antibody-drug conjugates, T-cell engagers and a fusion protein for cancer. Lead development candidate HXN-001 is a Phase II-ready, half-life-extended anti-TL1A antibody for inflammatory diseases.

The second-largest financing in Q1 was a $305m series F round announced by Parabilis Medicines in early January. The company formerly known as FogPharma is using its new funding to advance FOG-001 (zolucatetide), which targets a downstream node within the Wnt/ß-catenin pathway, toward a registrational trial in desmoid tumors. The cash will also support evaluation of FOG-001 in other tumor types and drug discovery programs, including a prostate cancer franchise.

At the no. 3 spot in Q1, Corxel Pharmaceuticals raised a $287m series D1 round in late January to fund its cardiometabolic disease pipeline, including lead drug candidate CX11, a Phase II-ready oral small molecule GLP-1 receptor agonist for obesity and type 2 diabetes. The company previously known as Ji Xing Pharmaceuticals is also developing JX10 for acute ischemic stroke and JX09 for hypertension.

Coming in at no. 4, Cellares revealed a $257m series D round in late January to fund construction of new manufacturing sites in the US and other countries. The cell therapy integrated development and manufacturing organization (IDMO) counts Bristol Myers Squibb and Kite Therapeutics among its global customers.

Orca Bio's $250m financing in early January, including a series F round and another equity investment, rounds out the top five financings in Q1. The cell therapy developer will use the proceeds to fund commercial preparations for Orca-T, an allogeneic T-cell immunotherapy under consideration for FDA approval with a July 6 action date, which recently was pushed back from April 6. The product's first potential indication would be as a treatment for hematological malignancies, including acute myeloid leukemia, acute lymphoblastic leukemia and myelodysplastic syndromes.

Company	Investment	Financing Round	Specialty
Earendil	$787m	Multiple rounds	AI-enabled antibody design
Parabilis	$305m	Series F	Novel cancer drugs
Corxel	$287m	Series D1	Cardiometabolic diseases
Cellares	$257m	Series D	Cell therapy integrated development and manufacturing organization
Orca Bio	$250m	Series F/Other equity	Cell therapy

Source: Scrip, Evaluate, Biomedtracker

Biopharma IPOs Had Their Best Showing In More Than A Year In Q1

Even So, Quarter Ended With No IPOs In Final Month

Evaluate and Scrip tracked six IPOs by drug developers on Western exchanges in the first quarter, a total not seen since Q1 of 2025. The $1.81bn raised was the highest since Q4 of 2021.

MANDY JACKSON, Managing Editor, ***Scrip***

There were six biopharmaceutical company initial public offerings that raised a total of $1.81bn in the US during the first quarter of 2026. The number of IPOs was the highest since Q1 of 2025, and the gross proceeds represented the highest dollar amount since Q4 of 2021, according to an Evaluate and *Scrip* analysis of offerings on Western exchanges. However, all of the Q1 IPOs occurred in the first two months of the quarter, with no first-time offerings in March.

Stock markets globally continue to feel the effects of uncertainty associated with the ongoing war in Iran, and biopharma valuations have been impacted by US Food and Drug Administration leadership and policy changes. However, drug developer stocks have outperformed other sectors, making biopharma a standout sector among other industries with significant IPO activity.

Three of the six companies that went public during the first quarter closed their first day of trading above their IPO prices, but only two of the six were trading above their offering prices as of April 10. The average return versus IPO prices as of April 10 was 35.9%, buoyed by hair loss drug developer Verademics, whose stock price has jumped 304.7% since the company's offering in February. SpyGlass Pharma, which went public two days after Verademics, is up 29.7% versus its IPO price, while the four decliners are trading 6.2% to 50% below their offering prices. (*See table at the end of this article for detailed company stock performance.*)

The six IPOs so far this year are notable for the amount of money raised, with the offerings grossing $172.5m to $400m, or an average of $302.3m. That average outpaces the 2025 IPO market, in which 12 biopharma companies raised $1.77bn in first-time offerings in the US, or an average of $147.5m.

The pace of IPOs in Q1 illustrates the periodic hesitancy – and, in early February, the momentary exuberance – of investors considering putting their money behind biopharma first-time offerings. Aktis Oncology was the first out of the gate on Jan. 8, raising $318m initially and $365.4m by the time the offering closed and bankers sold overallotments.

It took nearly a month for drug developers to grab the attention of IPO investors again, but then four offerings priced in a three-day period. Verademics grossed $294.8m from its Feb. 3 offering, while Eikon Therapeutics and AgomAb Therapeutics launched their IPOs on Feb. 4, and SpyGlass priced its offering on Feb. 5. Cancer-focused Eikon grossed $381m, while AgomAb raised $200m to initiate a Phase IIb clinical trial later this year for ontunisertib (AGMB-129) in fibrostenosing Crohn's disease. SpyGlass grossed $172.5m to fund a Phase III program in glaucoma.

The last and largest IPO in the US for Q1 was three weeks later – Generate Biomedicines' $400m offering on Feb. 27 to fund its artificial intelligence-enabled biologics discovery and development programs, including Phase III trials of long-acting anti-TSLP antibody GB-0895 in severe asthma.

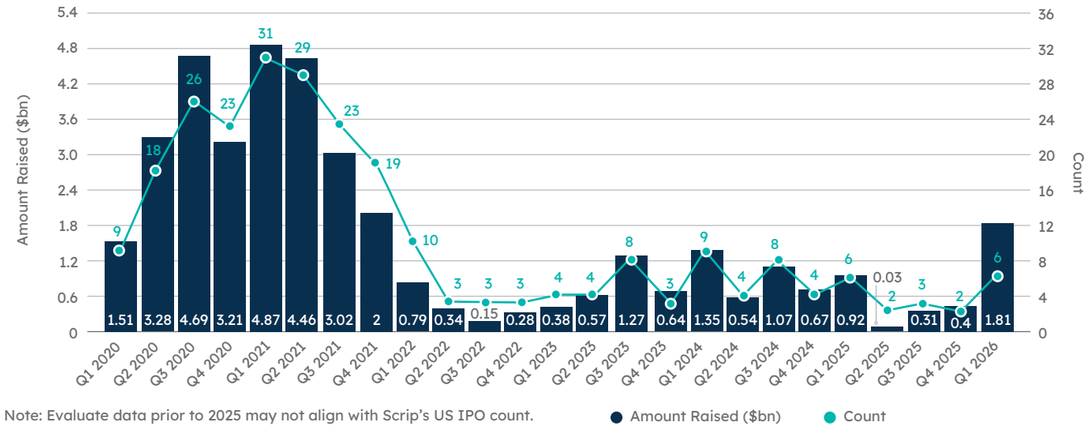
There were three IPOs on Asian exchanges in Q1. Kanaph Therapeutics and IMbiologics raised KRW40bn ($27m) and KRW52bn ($35.1m) in March offerings on South Korea's Kosdaq market. Kanaph is developing bispecific antibodies, small molecules and antibody-drug conjugates (ADCs) for cancer, autoimmune disorders and eye diseases, and will use its IPO proceeds to move its preclinical programs into the clinic. IMbiologics will build out its biologics pipeline beyond the programs it out-licensed to Navigator Medicines in 2024.

Suzhou Ribo Life Science went public on the Hong Kong Stock Exchange (HKEX) on Jan. 9, grossing HKD1.8bn ($231m) to fund its pipeline of small interfering RNA (siRNA) therapies.

2026 Biopharma US IPO Performance

Three out of six drug developers that went public in the US during the first quarter of this year ended their first day or trading in positive territory, but as of April 10 only two are in the black.

Biotech IPOs On Western Exchanges By Quarter



Note: Evaluate data prior to 2025 may not align with Scrip's US IPO count.

Source: Evaluate Pharma, Scrip.

Company	IPO Date	IPO Price	Gross Proceeds ($m)	First Day Close	Return Vs. IPO	April 10 Closing Price	Return Vs. IPO
Aktis Oncology (AKTS)	8-Jan	$18	$365.4	$22.40	24.4%	$16.88	-6.2%
Verademics (MANE)	3-Feb	$17	$294.8	$37.75	122.1%	$68.80	304.7%
Eikon Therapeutics (EIKN)	4-Feb	$18	$381	$15	-16.7%	$9	-50%
AgomAb Therapeutics (AGMB)	5-Feb	$16	$200	$14.65	-8.4%	$10.54	-34.1%
SpyGlass Pharma (SGP)	5-Feb	$16	$172.5	$26.40	65%	$20.75	29.7%
Generate Biomedicines (GENB)	27-Feb	$16	$400	$12.65	-20.9%	$11.41	-28.7%
			Total: $1.81bn		Average: 25.6%		Average: 35.9%

Source: Scrip

March Surge Lifts First Quarter M&A Totals To Recent Highs

The biopharma sector announced 41 merger-and-acquisition deals during Q1 2026, according to Evaluate, with a late March run of multibillion-dollar bids.

JOSEPH HAAS, Senior Writer, *Scrip*

The expected uptick in merger-and-acquisition activity during 2026 got off to a sporadic start in the first quarter, until March brought a spring-like bursting of volume and valuation, according to data from Evaluate. The first quarter of 2026 saw a 32% increase over the fourth quarter of 2025 in M&A transaction volume, to 41 deals, while total valuation of approximately $54.88bn represented a 19% increase over the $46.15bn seen in the previous quarter.

January yielded a good pace of deals but with fairly low values, while February saw only seven M&A transactions, although one was 2026's biggest to date, Gilead's proposed $7.8bn buyout of Arcellx on Feb. 23. Then, March both entered and exited like a lion as 22 of the quarter's 41 deals occurred during the month, including four of the year's five largest purchase prices to date. All told, March accounted for nearly 66% of the total proposed spend on acquisitions during the first quarter.

Even though 2025 saw a rise in M&A transactions and higher valuations compared to the historic lows of 2024, biopharmaceutical industry observers still predicted a continued upward trend in 2026. Anticipated drivers of increasing activity included ample spending firepower, the urgency presented by incoming patent cliffs and the booming presence of China's biopharma sector.

The Five Largest M&A Deals Of The First Quarter

Purchaser	Acquired	Upfront Value	Date
Gilead	Arcellx	$7.8bn	Feb. 23
Merck & Co.	Terns	$6.7bn	March 25
Eli Lilly	Centessa	$6.3bn	March 31
Biogen	Apellis	$5.6bn	March 31
Servier	Day One	$2.5bn	March 6

Source: Evaluate

Metrics Back Hopes For Big Year Ahead

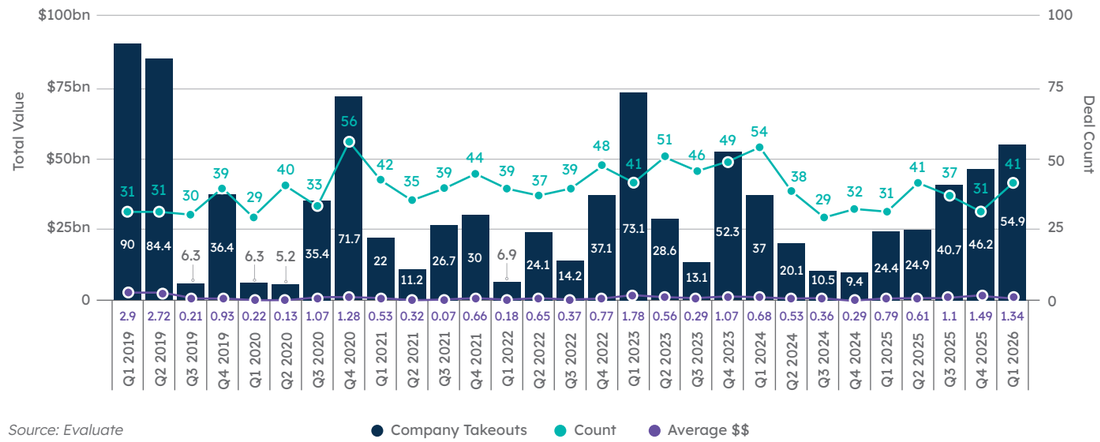
Several metrics suggest that Q1 2026 might augur a boom in biopharma M&A activity, as the 41-deal volume total tied Q2 2025 as the largest total since the 54 recorded in the busy first quarter of 2024. Meanwhile, total valuation of nearly $55bn topped every quarter since the $52.2bn recorded during the fourth quarter of 2023.

Average deal value of roughly $1.34bn provided a more complicated picture, posting a decline of 10% from the $1.49bn average posted during the final quarter of 2025. Still, Q1 2026 was the second highest average since Q1 2023. Of the 41 M&A deals in the first quarter of 2026, 13 had no reported value. One way, therefore, to consider the quarter's total valuation of $54.88bn, is that it averaged to $1.96bn per deal for the 28 deals with reported value.

Fifteen of the first quarter's M&A deals had total potential value greater than $1bn, nearly half of the 32 recorded during all of 2025 and nearly three-quarters of 2024's tally of 21 such deals. Meanwhile, for highest deal value, 2026 has not yet seen a transaction to top last year's $14.6bn takeout by Johnson & Johnson of Intra-Cellular, but Q1 2026 yielded four M&A deals that would have been the most expensive of 2024.

While Gilead's in-progress $7.8bn bid to acquire cancer immunotherapy firm Arcellx on Feb. 23 is the deal with the highest upfront value so far for 2026, a flurry of multibillion-dollar deals late in March greatly altered the quarter's valuation numbers. Three of the year's five highest upfront

Quarterly Biopharma M&A



Source: Evaluate

bids were reported between March 25 and March 31, while the fifth-largest upfront of 2026 arrived on March 6.

Gilead has offered $115 per share at closing along with a contingent value right of $5 per share to boost the prospects of its cancer affiliate Kite Pharma by acquiring its northern California neighbor Arcellx. On April 1, Gilead announced the tender offer had been extended from April 2 to April 24; the transaction requires a majority of outstanding Arcellx shares, along with shares already owned by Gilead, be tendered, but as of March 31 that figure had only reached 7.5% of the outstanding shares.

If it closes, the deal would bring Arcellx's D-Domain chimeric antigen receptor (CAR) technology platform that could potentially produce next-generation CAR T-cell and bispecific therapies with improved specificity and enhanced binding affinity.

Gilead/Kite and Arcellx have been partnered on CAR-T candidate anitocabtagene autoleucel (anito-cel) for relapsed or refractory multiple myeloma, which has a Dec. 23 action date at the US Food and Drug Administration. Acquiring full ownership of that asset likely drove Gilead's acquisition interest.

The first quarter's other acquisition deals with the highest upfront value were:

- Eli Lilly's March 31 offer to buy sleep therapy specialist Centessa Pharmaceuticals for $38 per share, a 35% premium with an estimated upfront value of $6.3bn, while a CVR could increase the deal's total value to $7.8bn. The UK-headquartered biotech's lead candidate cleminorexton (ORX750), an orexin receptor 2 agonist, has demonstrated a potential best-in-class profile in Phase IIa clinical studies across narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia.
- Merck & Co.'s $6.7bn bid announced March 25 to acquire Terns Pharmaceuticals and its Phase I/II chronic myeloid leukemia therapy TERN-70. Merck is offering $53 per share for the California biotech in an ongoing effort to bolster its cancer portfolio, led by anti-PD-1 agent Keytruda (pembrolizumab), the sector's top-selling drug, but one slated to lose exclusivity in 2028.
- Biogen's $5.6bn proposal on March 31 to acquire Apellis Pharmaceuticals and add that company's complement inhibitor franchise of kidney and rare disease products to its portfolio and pipeline. Analysts have questioned the deal's price tag, but completing the transaction would bolster Biogen's near-term revenue as it deals with loss of exclusivity erosion to its multiple sclerosis franchise, while also providing a "path into nephrology," according to CEO Christopher Viehbacher.
- Servier's March 6 bid of $2.5bn up front to acquire oncology firm Day One Pharmaceuticals would add pediatric glioma drug Ojemda (tovorafenib), approved by the FDA in 2024, to the French firm's portfolio. The proposed purchase price equates to $21.50 per share, an 89% premium to Day One's 10-day pre-announcement average share price.

Pharma's Pipeline Size Dipped In 2025

There has been a fall in the number of drugs in development, latest annual data from Citeline show, but the figure is thought to point to a flattening, rather than contracting, of the pipeline.

ALEXANDRA SHIMMINGS,
Executive Editor,
Scrip

There has been a small drop in the number of drugs in the biopharma development pipeline, Citeline's just-released Pharma R&D Annual Review has found – the first decline since the mid-1990s. The total number of pipeline drugs in active development now sits at 22,940, nearly 4% lower than at the same time last year.

The 3.92% fall from 2025's figure pretty much reversed the 4.60% increase seen from 2024 to 2025 (which was itself the second-lowest rate of expansion seen in a decade). Also, the number of new products entering the Pharmaprojects database during 2025 was 4,488, slightly down from the 4,546 arrivals during 2024.

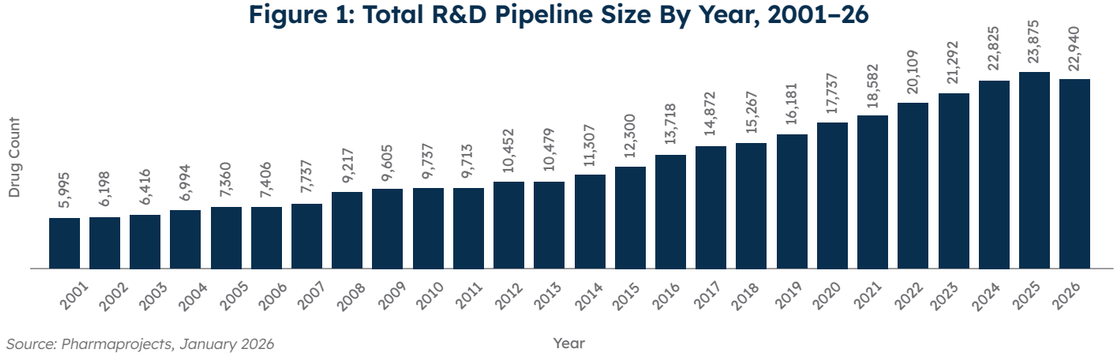
But the report's author Ian Lloyd, Citeline's senior director of content strategy, believes there is no need for undue concern. Although changes in internal editorial practices in the Pharmaprojects database, from which the data are culled, have muddied the waters somewhat, he says the real picture is more stable. "This year's figure is probably consistent with earlier years and it is the 2025 figure which is anomalous. In reality, the overall pipeline size has probably been fairly flat over the past few years."

The oncology field still provided 38.6% of all newly identified drug candidates, a negligible decline from the previous year's percentage. But a clear growing trend is emerging for neurologicals, which once again came in second place, providing 14.4% of new candidates, up from 13.8% in 2024 and 12.7% the previous year. The percentage of new candidates being targeted against rare diseases slipped back from 20.0% to 19.4%.

The Pharma R&D Annual Review

The *Pharma R&D Annual Review* is based on a snapshot of the Pharmaprojects database taken in the first week of January. It counts all drugs disclosed as being in development by pharmaceutical companies, from those at the preclinical stage, through the various stages of clinical testing and regulatory approval, and up to and including launch. Launched drugs are still counted, but only if they are still in development for additional indications or markets. A similar report has been published annually since 1993, allowing for meaningful comparisons to be made across the decades.

Figure 1: Total R&D Pipeline Size By Year, 2001–26



Source: Pharmaprojects, January 2026

AstraZeneca contributed the most new candidates with 46, easily eclipsing 2024's chart-topping 37 from Novartis. The US continued to be the country where most new drug development starts, with its 1,809 new drugs increasing the gap on China, which posted 1,373, in a possible sign that the Chinese R&D boom is beginning to slow.

Breaking down the pipeline by development phase shows that the editorial changes put in place at Pharmaprojects had their greatest impact on the preclinical stage – each of the clinical phases all posted increases. The number of drugs in Phase I is up by 2.7% (6.8% in 2025), in Phase II by 9.1% (6.3%), and those in Phase III by 8.8% (same as last year).

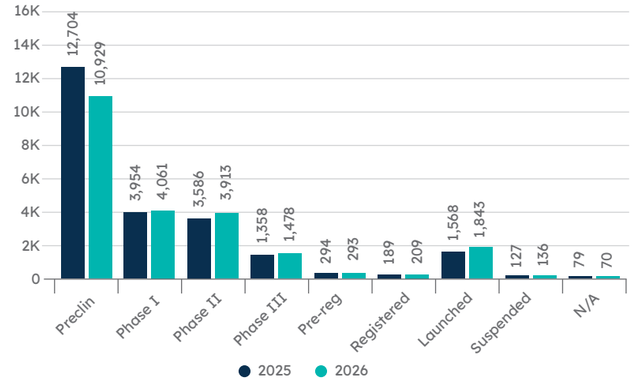
In Figure 3, a look at more long-term trends shows that while the numbers at Phase I and Phase II have consistently risen over the past two decades, this has not always been the case for Phase III, which plateaued during 2017–2021, but its upward trajectory is now back.

Table 1 lists the 25 firms with the largest pipelines. This year, Roche returns to the top spot, having briefly surrendered its crown to Pfizer last year. AstraZeneca shoots up to number 2, growing its pipeline (by 8.3%) as indeed do over half of the companies in the top 25. The top 10 companies are largely the same characters as last year, with AbbVie the only newcomer, edging out GSK.

Outside of the top 10, the list has a strong Asian flavor, with three Chinese (Jiangsu Hengrui, Sino and CSPC) and four Japanese companies (Takeda, Otsuka, Astellas and Daiichi Sankyo). There is also a rise for Novo Nordisk, as it tries to counter huge competition in the obesity market, while Germany's BioNTech enters the top 25 for the first time on the back of completing its acquisition of CureVac.

But big pharma makes up just part of the whole. At the other end of the scale, the report shows that there are now 1,075 companies with just two drugs in their portfolios (up from 997 last year), and 2,976 firms with just a single drug (up from 2,638), with the loss of some small firms being counterbalanced by 496 new companies entering the database throughout the year. This has led to

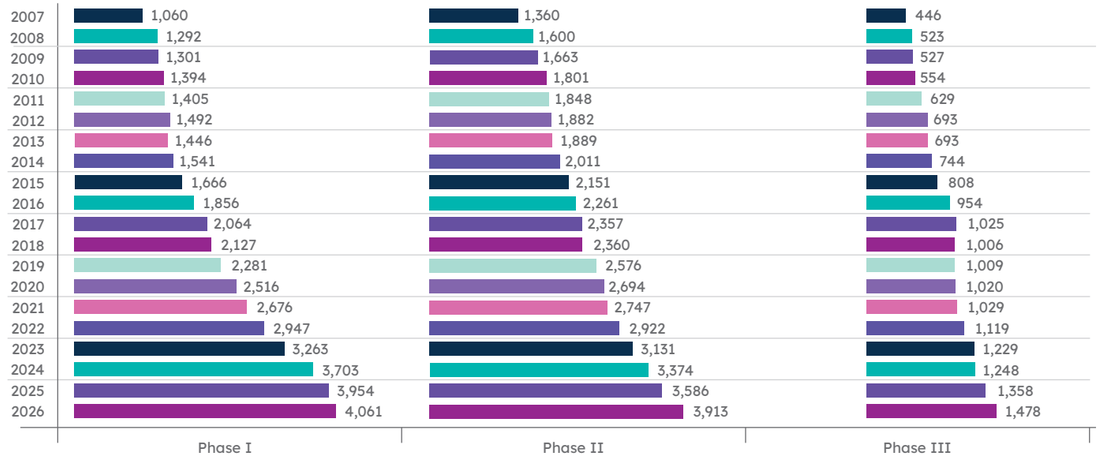
Figure 2: Pipeline By Development Phase, 2026 Vs. 2025



N/A = not applicable and is applied to companion diagnostics prelaunch

Source: Pharmaprojects, January 2026

Figure 3: Clinical Phase Trends, 2007–26



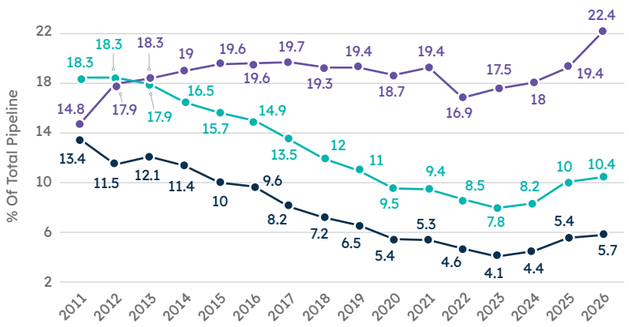
Source: Pharmaprojects, January 2026

Table 1: Top 25 Pharma Companies By Size Of Pipeline

Position 2026 (2025)	Company	No of Drugs in Pipeline 2026 (2025)	No of Originated Drugs 2026	Trend
1 (2)	Roche	262 (261)	147	↔
2 (4)	AstraZeneca	261 (241)	166	↑
3 (1)	Pfizer	257 (271)	163	↓
4 (5)	Sanofi	251 (233)	135	↑
5 (3)	Novartis	244 (254)	137	↓
6 (7)	Eli Lilly	233 (224)	138	↑
7 (6)	Bristol Myers Squibb	214 (227)	124	↓
8 (8)	Merck & Co.	207 (216)	103	↔
9 (11)	AbbVie	200 (190)	76	↑
10 (9)	Johnson & Johnson	198 (200)	111	↔
11 (10)	GSK	185 (194)	88	↔
12 (13)	Jiangsu Hengrui Pharmaceuticals	178 (173)	163	↔
13 (12)	Takeda	167 (187)	61	↓
14 (14)	Boehringer Ingelheim	143 (133)	90	↔
15 (15)	Sino Biopharmaceutical	119 (125)	93	↔
16 (19)	CSPC Pharmaceutical	117 (102)	96	↑
17 (22)	Novo Nordisk	109 (97)	70	↑
18 (17)	Gilead Sciences	107 (106)	67	↔
19 (16)	Otsuka Holdings	107 (114)	57	↔
20 (18)	Bayer	100 (104)	65	↔
21 (21)	Astellas Pharma	98 (100)	49	↔
22 (23)	Daiichi Sankyo	91 (88)	47	↔
23 (20)	Amgen	90 (100)	53	↓
24 (-)	BioNTech	80 (50)	59	↑↑
25 (-)	Teva Pharmaceutical Industries	78 (74)	27	↔

Source: Pharmaprojects, January 2026

Figure 4: Share Of The Pipeline Contributed By Top 10 Companies, Top 25 Companies, And Companies With Just One Or Two Drugs, 2011–26



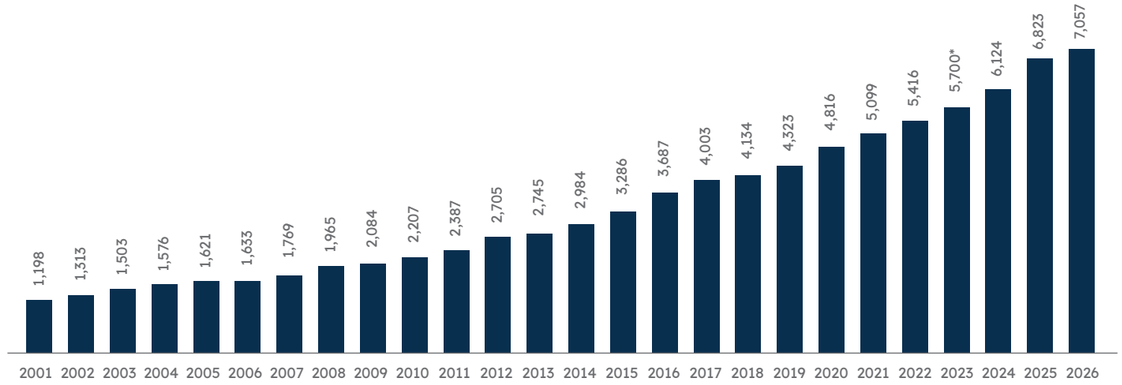
Source: Pharmaprojects, January 2026

some rebalancing of the pipeline, with these small firms now accounting for 22.35% of drugs, up from 19.4% (*see Fig. 4*). "As both the top 10 and the top 25 companies increased their relative contributions too, this suggests a squeeze in medium-sized firms," Lloyd said.

Despite the drop in drug numbers, the total number of companies involved in R&D posted another increase this year, albeit rising at a slower rate. Figure 5 shows that 7,057 companies had an active pipeline at the start of January 2026, an increase of 3.4%, but well below 2025's 11.4% rise.

The rise of the Chinese industry has been a predominant theme in recent years, and more evidence of its importance can be seen by looking at where the companies are headquartered. 19% of all pharma R&D firms are now based in the country, up from 17% a year ago. But the US is fighting back, also increasing its share, from 39% to 41%. "It looks like these advances have come at the

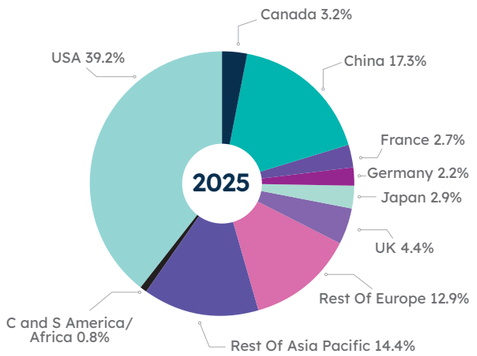
Figure 5: Total Number Of Companies With Active Pipelines, 2001–26



*Estimated figure

Source: Pharmaprojects, January 2026

Figure 6: Total Number Of Companies With Active Pipelines, 2025–26



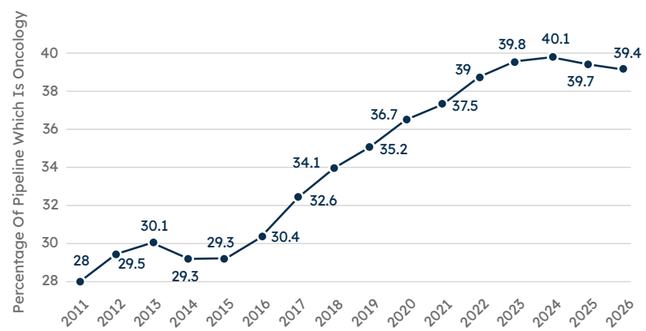
Source: Pharmaprojects, January 2026

expense of Europe – while France, Germany and the UK shares hold firm, the rest of Europe looks to be in retreat," said Lloyd.

As with the pipeline as a whole, of the 14 broad therapeutic areas, most saw a small drop in numbers. Cancer continued to be the main focus for pharma, but its pipeline shrank by 4.6% this year, slightly above the overall rate of 3.9%. Second-placed neurologicals, by contrast, only declined by 1.5%. Meanwhile, some therapeutic areas, such as immunologicals, cardiovascular and blood & clotting, bucked the trend by actually growing their portfolios, with immunologicals posting a 20.6% increase in drug candidates (note that drugs can be counted in more than one therapeutic area).

For more in-depth information, download the Citeline Pharma R&D Annual Review 2026 at www.citeline.com/RD26.

Figure 7: Proportion Of The Pipeline In Development For cancer, 2011-26



EU Pharma Reform: The Changes Ahead

By **Eliza Slawther** and **Anabel Costa-Ferreira**

A final draft version of the pharma reform package was published on March 6, 2026, marking a significant step forward for the new legislation which has been under political negotiation for several years.

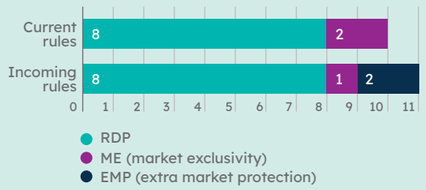
The package, which comprises a new directive and regulation for governing pharmaceutical products in the EU, will overhaul and replace the over 20-year-old existing general pharmaceutical legislation, and two other regulations on pediatric medicines and orphan drugs.

Formal adoption of the draft package is anticipated later this year. The infographic below highlights the key differences between the existing rules and the new legislation.

Regulatory Data Protection

The new pharma package will maintain the existing baseline regulatory data protection (RDP) period of eight years. However, rather than automatically receiving two years of market protection (MP), companies will receive one additional year of market protection.

Some products could benefit from an extra two years of market protection, up to a maximum of 11 years total protection (8 years RDP + 1 year baseline MP + up to two extra years of MP) but they must fulfil certain criteria.



Conditions For Extra Market Protection

Drugs that satisfy special conditions as per the table below will be granted an additional year of market protection, **up to a maximum of 11 years total protection**. Requirements below:

1. If the particular product addresses an unmet medical need (+12 months).
2. The product contains a new active substance (NAS), and the marketing authorization (MA) applicant demonstrates one of the following criteria (+12 months):

   i. Clinical trials supporting the initial marketing authorization application (MAA) use a relevant and evidence-based comparator in accordance with the scientific advice provided by the relevant agency; and the MAA has been first submitted to the competent authority in the EU, or has been submitted no later than 90 days after the submission of the application for the first marketing authorization outside the EU, or was conducted in multiple member states.

   ii. if the MA applicant justifies that a comparative clinical trial was not possible, but clinical trials were conducted in more than one member state and the MA was submitted first in the EU or within 90 days of the first submission outside the EU.
3. If the company obtains an authorization for one or more new therapeutic indications that bring a significant clinical benefit in comparison with existing therapies (+12 months).

Source: European Parliament, Council of the EU.

Orphan Drug Market Exclusivity

Orphan drugs currently benefit from a fixed 10 year period of baseline market exclusivity. The new rules will see this reduced to nine years, but products that address a disease with no currently available medicinal treatment and which bring a clinically relevant reduction in morbidity or mortality will be known as "breakthrough orphan medicinal products". These will receive the greatest amount of market exclusivity, up to 11 years.

EU Orphan Exclusivity: New Rules Vs Existing Rules

	Orphan Drug Regulation No 141/2000	Draft pharma package
Standard orphan medicine exclusivity	10 years	9 years
Breakthrough orphan medicinal products	10 years	11 years
Well established use orphan medicinal products	10 years	4 years
Extensions of exclusivity: New indication for a different orphan condition (for a maximum of two additional indications)	10 years	+1 year

Source: Orphan Drug Regulation No 141/2000 and Council of the EU

Antimicrobial Research Incentives

The pharma package aims to introduce two new incentives for the development of antimicrobial products – transferable exclusivity vouchers (TEVs) and a subscription model that delinks the volume of antimicrobial sales from the reward received.

Companies would likely want to use a TEV for a product with high sales, rather than the antimicrobial for which it was granted, the *Pink Sheet* notes. This is why the voucher is transferable. It can be sold either to another company altogether or used for a different product within the original company's pipeline, although there are strict rules around the use of TEVs set out in the draft regulation.

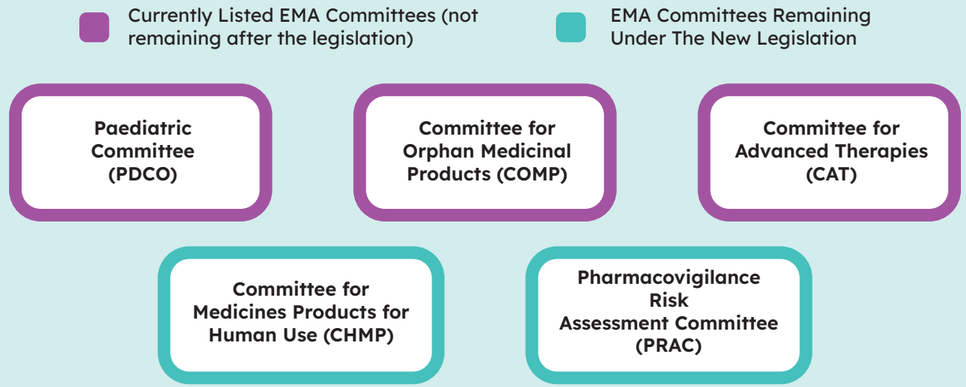
TEVs are known as a "pull" incentive. They offer an extra year of market protection for a product, which means that companies can benefit from another year of sales before generic or biosimilar versions of their branded drug enter the market.

TEVs would be subject to several rules, however...

1. A TEV can only be transferred once.
2. If a TEV is being used for a medicinal product other than the priority antimicrobial concerned, the use of the voucher should only take place in the fifth or sixth year of the RDP period.
3. TEVs would not be eligible for use on products with annual gross sales of more than €490m ($566m) in the preceding four years. MA holders must demonstrate that this information has been audited by an independent, external auditor.
4. A voucher may only be used if the MA of the priority antimicrobial for which the right was initially granted has not been withdrawn.

The draft regulation does not set out a clear pathway for the proposed subscription model. Instead, it states that it is "necessary to consider further union level action to support the development of antimicrobials and address existing market failures. Accordingly, a voluntary subscription model for the joint procurement of antimicrobials should be developed to ensure that a market exists for developers that delinks volumes sold from payment received."

Changes To The European Medicines Agency



The EMA should, "where necessary", establish the appropriate working parties to ensure the adequate expertise for the evaluation of medicines, including an Environmental Risk Assessment working party, the forthcoming legislation says.

That working party should have the scientific expertise necessary to characterize and assess the environmental risks, and the mitigation measures for such risks, related to the use and disposal of medicinal products.

Another major change is that the scientific evaluation period, ie the time it takes for the EMA to assess MAAs for medicines, will reduce from 210 days to 180 days.

Will US FDA Staffing Issues Endanger Regulatory Flexibility Despite Steps Forward?

MICHAEL MCCAUGHAN,
Contributor,
Pink Sheet

The approval of Denali's Hunter syndrome treatment Avlayah showed the FDA still has regulatory flexibility in rare disease reviews, but also illustrates why that flexibility may be at risk.

The US Food and Drug Administration's approval of Denali's Avlayah (tividenofusp alfa-eknm) suggests regulatory flexibility is alive and well at the agency.

Sighs of relief were understandable. The FDA accepted a novel biomarker, reduction of cerebrospinal fluid heparan sulfate, as an endpoint to support accelerated approval after backing away from the pathway in several recent cases involving other rare disease therapies.

But the broader lessons from the Avlayah approval may not be so encouraging for the long term. Regulatory flexibility does not happen organically in the decision to approve or reject an application, but is built on an extensive foundation of FDA engagement with sponsors and the broader community.

The foundational work still is in jeopardy as the FDA continues to lose experienced review staff.

A Long Process Before The Filing

The decision by the FDA to accept heparan sulfate as a biomarker came after a long process that included a 2024 Reagan-Udall Foundation meeting on biomarkers, which included HS as a case study for a potentially novel surrogate endpoint in neuronopathic mucopolysaccharidoses (MPS) disorders. Several sponsors with active MPS programs, including Denali, presented.

The meeting featured then-Center for Biologics Evaluation and Research director Peter Marks in his emerging role as the agency's de facto rare disease lead. At the meeting, advocates described CBER as more receptive to accepting HS as an endpoint for accelerated approval than the Center for Drug Evaluation and Research.

The Denali approval suggests the positions flipped. With Marks gone, CBER rejected two of the therapies discussed at the meeting, Ultragenyx' UX111 and Regenxbio's clemidsogene lanparvovec. The Regenxbio complete response letter specifically cited CBER's uncertainty about the "novel biomarker" as a key factor.

But the bigger message is the acceptance of HS as a surrogate took sustained engagement by FDA officials in CBER and CDER over several years, as well as a strong push by Marks, to move forward. The work may be increasingly challenging for the agency given the loss of experienced staff and leadership during the Trump administration.

Still Political Overtones, Sensitivity To Using Accelerated Approval

The FDA's approval also reinforced some reasons for concern. In addition to sending a press release, then-Acting CDER Director Tracy Beth Høeg posted a video on X announcing the action.

The video is noteworthy as another new and unusual communication tool for the FDA in the second Trump administration and because of the implication that using accelerated approval triggers sensitivities that merit some extra explanation.

Høeg said the approval included a postmarketing requirement for a randomized clinical trial.

"Importantly this trial is already over 95% enrolled, and we will be getting an answer about clinical benefit promptly," she said. "In the meantime, families and their children will have access to this treatment in a critical window of time where there is the greatest potential for benefit."

The acting CDER director discussing the approval publicly furthers the impression that center directors are the main deciders on new drug reviews.

Høeg's video does not indicate she was directly involved in the approval decision. She credited and thanked the review staff for its work, but the communication approach implies a direct responsibility at the center director level that has not been the FDA's practice in the past.

Høeg was removed as acting CDER director on May 15 after Makary resigned on May 12.

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