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Scrip Asks...What Does 2024 Hold For Biopharma? Part 2: The Funding Environment, M&A And Partnering

Creativity And Rigor Needed To Weather Lean Times

by Eleanor Malone

Biotech entrepreneurs tend to be an optimistic group, and there were many pockets of hope for 2024. However, the consensus remains that depressed valuations and paucity of fresh funds will continue to pose a challenge for the sector, and companies will need to prioritize carefully and work even harder to demonstrate and create value.

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Since biotech valuations on public markets peaked in September 2021, the sector has had to contend with reduced financing availability and harsher conditions for deal-making. In December 2023, *Scrip* surveyed a wide range of executives and experts across the biopharma universe to understand their sentiment around financing, M&A and partnering going into 2024. While most observers anticipate the situation will continue to be difficult in 2024, there was also a fair amount of optimism, albeit sometimes only partial.

"The funding environment for biopharma start-ups in 2024 is anticipated to be generally challenging," noted Koji Tamada, CEO of Japanese start-up *Noile-Immune Biotech*, which is developing CAR-T cell therapy for solid tumors and which completed an initial public offering (IPO) on the Tokyo Exchange in June 2023 after delaying the listing because of market turbulence earlier in the year. "However, certain companies are expected to succeed in attracting investor support. Moreover, the ongoing and proactive exploration of mergers and acquisitions, as well as partnerships, is a common approach among companies, and we may see some results of these efforts materialize in 2024."



Michael Salako, investment director at UK life science venture capital company Start Codon, also thought partnering would be a key activity in a financially challenging 2024.

"Signs are that the funding environment for 2024 is generally going to be a difficult one. If the US Federal Reserve starts to reduce interest rates (which could happen as soon as Q2 2024), this would enable capital to be moved out of risk-free money market funds and into potentially higher yielding, riskier asset classes such as venture capital (other countries would likely follow suit on reducing rates). However, this kind of change takes time to trickle down to those seeking funding. I'd expect any benefit from a change like this to only be felt by companies towards the end of 2024 or early in 2025," he warned.

"Other factors making the funding environment challenging are uncertainty around when the IPO window will open again. When this does open up, it should alleviate the need for VCs [venture capital investors] to continue sustaining companies on the cusp of going public," Salako went on. "The appetite for mergers and acquisitions is also still unclear, with many in big pharma continuing to restructure off the back of declines in drug sales around COVID-19 products. All of this backs up the likelihood of 2024 being a difficult year for the industry.

"As a result, I'd predict we will see an increase in partnering activity, as private companies seek partner relationships to signal market demand to investors. This would help extend runways and enable a big pharma/biotech ramp-up in engagement on smaller, less-committed, transactional deals around novel and differentiated products."

Salako's overall view was that, "taken together, companies that can weather the storm through 2024, could emerge in a strong position as we head into 2025."

Tom Goodman, London-based partner at law firm Cooley, was another predicting ongoing troubles. "Global macro conditions will continue to provide challenging conditions for European fundraising into 2024 and so some of the trends that emerged in 2022 and 2023 are likely to remain with dilutive and non-dilutive deals taking longer to build and execute and private and public investors continuing to be selective and favour clinical-stage companies," he said.

On the other hand, Asit Parikh, CEO of precision medicine discovery firm <u>MOMA Therapeutics</u>, <u>Inc.</u>, expressed cautious optimism: "November was a good month, with XBI [the Nasdaq Biotechnology Index] climbing about 15% through the first week of December, driven by increasing investor confidence that rate cuts will start to happen in the first half of 2024. There have been a number of private financings and reverse merger announcements over the past few weeks, which is a positive sign that the uptick in XBI is real. Several big M&A deals (<u>Carmot Therapeutics</u>, <u>ImmunoGen</u>, <u>Cerevel Therapeutics</u>) suggest that pharma also expects a more biotech-friendly financing environment next year. So yes, it's definitely looking up," he said – although he also warned that there would be "no magical full recovery expected."



Cody Powers, principal, leader of the portfolio and business development practice at life sciences consulting firm ZS, highlighted some trends to watch for: "Specialty financing such as royalty financing will continue to expand as biotechs look to alternatives in the absence of traditional sources. One trend to look out for would be any obvious reaction and reallocation of M&A, licensing, and fundraising capital as IRA negotiations proceed, and companies decide how/when to react – including both large and mid-caps, as well as venture capital." [The US Inflation Reduction Act (IRA) is introducing drug price negotiation for Medicare.]

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Optimism

"I'm convinced that 2024 is the turning point for the biotech sector. Despite a challenging stretch with two years of relative underperformance, the horizon is getting brighter," said Cary Claiborne, CEO of *Adial Pharmaceuticals, Inc.*, which develops medicines for addictions. "Low valuations may initiate a flurry of acquisition activity, becoming an opportunity during the harsh conditions."

Claiborne's optimism was targeted towards the latter part of the year: "The high interest rates will continue to be a hurdle for funding and growth potential because higher yields on investments such as treasury debt reduce the current discounted value of future cash flow. But mid-2024 is when the tide could turn. If





interest rates ease, mergers and acquisitions, commercial success and clinical/regulatory triumphs will take precedence over monetary concerns. This change could transform the funding landscape and kickstart a better path forward for the second half of 2024," he said.

For Gil Bashe, managing partner, chair global health and purpose at FINN Partners and a member of the Galien Foundation's executive committee, "too many hyperfocus on the year-to-year drop in venture funding and are wringing their hands on the future of health innovation. That's ill-advised!"

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Cary Claiborne, Adial Pharmaceuticals

Referring to research by Galen Growth,

he saw light at the end of the tunnel following first-half 2023 performance: "Venture funding in North America is returning to pre-pandemic levels. Funding is up 13% from the second half of 2022 and values remained nearly constant from Q1 to Q2. While Asia Pacific and the Middle East have not yet stabilized post-pandemic, North America's value share of global funding rose to 77% for the half-year. Despite funding tumult, the first half of 2023 reported a 1.2x growth in partnerships compared to the same period in 2022."

Astellas Pharma, Inc.'s Issei Tsukamoto, senior vice president, head of business development, also highlighted the uptick in transactions. "While many faced a challenging year in dealmaking, there is good cause for optimism in 2024. M&A and financing activities in biotech sector are returning, and we can hope for a more 'normal' if not quite a 'boom' in activity in 2023," he predicted.

"Biotechs will continue to face non-trivial fundraising headwinds at the beginning of the year (in both public and private markets), but there is some reason to believe that it could improve as the year progresses on the back of significantly reduced inflation and broader ongoing equity market run at the end of 2023 across sectors," said ZS's Cody Powers.

Brian Finrow, co-founder and CEO, <u>Lumen Bioscience</u>, <u>Inc.</u> (which has developed a platform that uses the algae spirulina to develop and manufacture oral biologic drugs), expected 2024 "to be a turning point for biopharma in two big ways. First, as the ugly biotech returns of late 2021 through early 2023 drop off 12-month trailing fund performance returns, our sector will start looking more appealing to generalist investors, hopefully inducing fresh fund flows. If rates



remain flat (or better: decline) this should help as well. This is assuming no new wars, of course — an unreliable assumption the past couple years, sadly.

"Second, VC and big pharma herds will complete the rotation they began in 2021: stampeding away from vaccines and COVID-19 and fully into obesity and cardiometabolic disease, perhaps with continued AI overtones." But he warned of the limits of clairvoyance. "Which trend they chase next is anyone's guess, of course. That herd behavior will prevail is easy to predict, but Anna Wintour was the only one to ever make fashion trend-picking look easy and she has no equivalent in biopharma."

Sara Bonstein, chief financial officer at *Insmed Incorporated*, thought interest rate trends would aid a recovery. "2024 will be an exciting and pivotal year across the industry. Macro-wise, based on historical trends, the end to rate-tightening, and potentially even rate cuts, could result in a boom for biotech," she said. "I expect M&A to continue to accelerate, as we see companies in the sector having very attractive (low) current valuations with limited funding options."

Jim Polson, senior managing director – financial communications, FTI Consulting, agreed. "Coming out of a difficult few years for fundraising and deal-making, the health care and life sciences industry is poised for an uptick in activity in 2024," he said.

Niels Riedemann, CEO and co-founder of *InflaRx N.V.*, also highlighted the positives. "The past year has taught us that, even in difficult times, good things can happen, and we did see some successful catalyst-triggered financings in 2023, including our own. We expect this to hold true for the year ahead. In addition, the pace of deal-making appears to be accelerating, with a steady stream of billion-dollar-plus collaborations and acquisitions making headlines."





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Sara Bonstein, Insmed

For Bonstein, the sector's intrinsic value to society will play its part, too. "Importantly, as an industry, we have made tremendous progress medically in 2023 and are on track for a record year of drug launches. Overall, I am optimistic about the year ahead in our sector. Although I expect it will continue to be bumpy along the way, at the end of the day, late-stage, stand-out data will continue to prevail even in the toughest of markets."

Another driver will be big pharma's need to replenish its commercial portfolios. "With many big pharma

drugs coming off patent in the near future, we expect this trend [accelerated deal-making] to continue," said Riedemann. "Biotechs are taking new approaches to addressing unmet medical needs, and, especially in hot areas like immunology, this is creating win-win opportunities for biotechs and big pharma. We look forward to seeing more breakthrough developments in 2024."

"The majority of recently commercialized therapies have come from innovative biotechnology companies, which have been traditionally financed by venture capital, the capital markets and eventually big pharma," pointed out Amit Kumar, CEO of oncology-focused *Anixa Biosciences*, *Inc.* "Unfortunately, two years of difficult times have resulted in numerous company bankruptcies, consolidations and contractions. 2024 may be the year when the macro trends combined with survival of the fittest biotech companies will enable a resurgence of this very important industry. While bloodletting will continue for many companies that have poorly characterized technologies or high-cost business models, the cream will rise to the top. Investor interest in these Darwinian survivors will resume, and pharma, with very deep pockets, will take advantage of the market conditions to earnestly begin refilling their pipelines through partnering and acquisitions. I expect forward-looking CEOs to properly capitalize their companies and prioritize investment in their highest-value assets."

"On funding, I see weakness continuing through 2024 but I do think the nadir has passed and there is room for more optimism and an increase in momentum," said Eliot Forster, CEO of pain drug developer *Levicept Ltd*.

"Companies in need of capital should be prepared to act quickly when the broader market rebounds – whether they're looking to IPO or raise funds via a private or public round," Polson counselled. "For those companies that are well-funded longer-term, driving home their balance



sheet strength to investors who are still somewhat hesitant in a shaky market will be a value-driver and differentiator."

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Creative Financing

Necessity is the mother of invention. Several of our commentators focused on the need for inventiveness around financing during these lean times.

"With a challenging year behind us in terms of capital and stock markets, I believe that creative financing strategies will become even more important in 2024," said Daniel Vitt, CEO of *Immunic Inc*, which is developing oral small molecules for inflammatory and autoimmune conditions. "For companies with a robust pipeline and meaningful advanced-stage assets, there are various options for access to capital, including the stock markets, venture capital, project financing, debt financing or partnering/business development. In particular, non-dilutive funding options through partnerships and collaborations will become more important and I think also more frequent in 2024 as a means to extend the cash runway."

"It will continue to be a tough environment to access capital, so creative business models certainly look more appealing," said Daphne Zohar, founder and CEO of *PureTech Health plc*, which combines progressing wholly owned development programs with establishing new companies that it supports to advance drug candidates and which can raise their own funds externally. "One of the advantages of the hub-and-spoke model we pioneered is that it reduces our reliance on capital markets. At PureTech, we have generated around \$800m from the sales of equity in our founded entities, royalties and partnership revenues and have been able to fully fund our pipeline for the last six years without raising more capital. This is very rare for a clinical-stage biotech company."

"The macroeconomic environment means financing for biopharma is likely to continue below the levels seen during the peak of the pandemic – but promising projects will continue to be funded," said Catherine Pickering, CEO of cancer treatment developer <code>iOnctura SA</code>. "Investors are looking for projects with sound scientific rationale, with convincing preclinical and clinical data a necessity in a funding environment that has become much more risk averse. With IPOs so hard to get off the ground, many biotechs will stay private for longer, instead favoring other strategies to raise capital alongside equity financing, including venture debt, non-dilutive funding such as grants, partnerships and mergers."

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"There are limited signs that the biopharma sector is poised for a rebound despite more than two years of financing challenges. In essence, we still have a long way to go before we get closer to what used to be considered 'normal'," cautioned Bruce Leuchter, Neurvati Neurosciences' CEO. "Many companies will likely continue to face challenges in raising capital in 2024. Efforts to support the industry's financial health may be enabled by new and more flexible financing and clinical development solutions capable of mitigating risk and enhancing drug development efficiency. Some investors sensing opportunity in the chaos are embracing innovative models including a differentiated partnership approach now used by some investment firms. These models identify clinical-stage assets and then formulate

clinical-stage assets and then formulate and implement plans to advance them through late-stage development and regulatory approval under mutually beneficial terms. This creative approach represents a compelling alternative to the conventional options employed across the spectrum of biopharma companies," he said.

"Finding collaboration, funding and the right support have long been hurdles for researchers to overcome in bringing innovations from the lab to the clinic, and these hurdles have only become higher in today's tough fundraising environment. Too often, research is getting stuck between the lab and the



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Catherine Pickering, iOnctura

next phase of development, particularly for less common diseases or the more challenging areas of science that can carry more risk for commercial companies," observed Stéphane Maikovsky, interim CEO of UK medical research charity *LifeArc*. "Alternative funding mechanisms that don't follow the traditional VC route, such as partnering between charities, academia and the industry, will provide the path we need to unlock innovation for patients – funding the tricky, early-stage work that helps to reduce risk and makes it easier and more appealing for the significant investment that is ultimately required in the later stages of drug development." Another benefit to this approach is that "charities also have enormous power to coalesce the network of



researchers, the patient community and industry partners that are required to drive the innovation capable of addressing the biggest challenges faced by patients, across a range of diseases," he noted.

Meanwhile, Cody Powers of ZS expected that "specialty financing such as royalty financing will continue to expand as biotechs look to alternatives in the absence of traditional sources."

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Partnerships

"2023 has been a year of haves and have nots in partnering as in other areas. The top of the market remained robust, with billion-dollar deals for hot therapeutic areas and for late-stage assets, as did the market for early-stage collaborations and licenses. The middle of the market has been slower. Deal values have largely been holding but volumes have been down, with term sheets harder to come by, slower to be agreed and negotiation processes more drawn out," said Frances Stocks Allen, a London-based partner at law firm Cooley. "We anticipate much of the same in 2024."

Partnerships are a necessity both for big pharma looking to feed innovation into its hungry pipelines, and for biotech looking to fund and commercialize its discoveries. "A potentially elevated interest-rate environment in 2024 highlights the importance of partnerships to progress biopharmaceutical pipelines," said Ann-Hunter van Kirk, senior equity research analyst, biopharmaceuticals at Bloomberg Intelligence.





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Kathy Bergsteinsson, Affini-T Therapeutics

"Given the stasis in the public and private markets for biotech, strategic capital and partnerships have a renewed opportunity to impact how smaller biotechs and large caps think about growth," said Kathy Bergsteinsson, chief financial officer, Affini-T Therapeutics, Inc.

"While the financing environment will continue to thaw for well-positioned companies, in the new year, biotech companies will maintain their emphasis on deal-making to advance programs, burnish the balance sheet and extend

runway," said Peter DiLaura, chief business and strategy officer at regulatory T-cell therapy developer *Sonoma Biotherapeutics*. "In 2024, we'll see both asset-centric deals and compelling discovery partnerships, which require a strong fit between parties across multiple dimensions."

"It appears likely that a challenging funding environment will persist for the biotechnology industry. Faced with continued macroeconomic uncertainty, companies will do well to look to non-dilutive funding avenues to sustain their research endeavors," advised Arthur Sands, CEO of targeted protein degradation specialist *Nurix Therapeutics, Inc.* "Biotech innovators with drug discovery platforms will be well served by leveraging their cutting-edge technologies to collaborate with like-minded biopharma companies looking for breakthrough drugs to build robust future pipelines. Our own experience at Nurix demonstrates that our collaborative partnerships have not only enhanced the efficiency of our discovery engine but also have served as an important capital source, helping to mitigate the financial risks of drug development and allow for expansion of research and development into different therapeutic areas. By fostering synergies and sharing the burden of the high costs of drug development, these partnerships not only ensure the progress of scientific breakthroughs but also fortify the resilience of the entire biotech ecosystem."

"More and more, companies are trying to find the right partners to apply the technology to disease biology in a way that accelerates the path to the patient. We don't have time, especially in these types of markets, for anything else," said Amanda Kay, senior partner and chief business development officer at *Flagship Pioneering*. "Brush away the noise from the volume of companies and data sharing; what's needed is partnered teams that both believe in the vision. While that has always been the basis of great partnerships and big leaps forward, it is even more pronounced now."



"There is a lot of cutting-edge science being done by biotechs in both Europe and North America. We are seeing that big pharma is increasingly willing to make a bet on earlier-stage innovation, rather than just partner for late-stage assets," commented Stefan Fischer, managing partner (finance) at investment firm TVM Life Science Management GmbH. "We saw this pay off with *Eli Lilly*'s bets on obesity and Alzheimer's disease. We see this trend continuing, as pharma must look beyond short-term revenue generation towards longer-term growth strategies. Areas of particular interest for pharma include: cardiovascular disease; immunological conditions; neurology; metabolic disease; and oncology."

"In 2023, Merck & Co., Inc. USA's business development and licensing organization secured more than 70 significant transactions spanning multiple disease areas and phases of development," pointed out

Sunil Patel, senior vice president, head of corporate development and business development & licensing (BD&L) at <u>Merck & Co., Inc.</u> "In the year ahead, we will continue to pursue the best external science to augment and complement our pipeline and act decisively to secure opportunities where we see science and value align. New and emerging

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Sunil Patel, Merck & Co., Inc.

technologies are driving important progress in drug development with compelling new evidence from several new mechanisms and modalities, and I expect to see this continue in 2024."

"I expect we will continue to see more partnerships bringing together different capabilities, helping to accelerate scientific breakthroughs," said Uli Stilz, vice president and head of <u>Novo Nordisk</u> Bio Innovation Hub. "I anticipate this because of the critical role partnerships can play in nurturing early ideas and addressing unmet need. The process of a research concept becoming a drug is a long journey – one that requires significant research, preclinical and development understanding. Partnerships enable opportunities to help lift innovation and ensure ideas that have the potential to make an impact have the resourcing and expertise needed. Most importantly, by bringing together capabilities via a partnership, organizations can complement the work they are pursuing internally, and find additional opportunities to drive innovation to support the patient populations they serve. Partnerships can help open doors to new frontiers of science, new approaches and more. Looking ahead, I'm excited to see how partnership models continue to evolve within our industry, and what potential opportunities they will unlock."



So what should biotech companies be considering when positioning themselves for a partnership? "Comps [deal valuation metrics] for early discovery collaborations have normalized versus those that occurred 2020-early 2022. Still, I do expect more platform deals will happen in 2024 versus what we saw in 2023. A must for these deals is credibility of the biotech in the eyes of the pharma: what experience does the leadership team have, what is the evidence their platform can deliver, what is their track record for execution?" said MOMA's CEO Asit Parikh.

"With asset deals, willingness of biotechs to share meaningful rights to advanced/lead assets will be a catalyst for pharma deals; the flip side of that is acceptance by pharma that they will have to share some US value to incentivize biotechs to do these deals, especially if the cost of capital comes down a bit," he went on.

"Partnering preferences will continue to favor biotechs with strong proof-of-concept data or anything AI-related," thought Abid Ansari, chief financial officer of OncoC4, Inc., a cancer medicine developer based in Maryland. "Additionally, I think small biotech boards with next-generation programs are now increasingly receptive to partnering lead assets in the hopes of receiving enough near-term cash to generate proof-of-concept data."

Helen Chen, Greater China managing partner and Asia Healthcare sector head at L.E.K. Consulting, highlighted the trend for US and European companies to partner in China. "Globalization, or 'crossing the ocean,' is a key theme amongst Chinese pharmas. For the most part, the Chinese are seeking

partnerships, as navigating the complexities of international markets solo are considered too risky," she said, while acknowledging "there are

exceptions, of course."

Chen continued: "Chinese innovation is finally an acknowledged theme by big pharmas and innovative biotechs in the West. **BioNTech**, for example, picked up a bi-specific PD-L1 and VEGF-A from Biotheus, a HER3 ADC [antibody-drug

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conjugate] from MediLink Therapeutics and two compounds (both HER2 and TOP1 ADCs) from



<u>DualityBio</u></u>. Established Chinese pharma <u>Hengrui</u>, for example, has partnered the ex-China rights for its PARP-1 inhibitor and claudin 18.2 ADC to the German <u>Merck</u>, camrelizumab and roviceranib to <u>Elevar Therapeutics</u>, and EZH2 to <u>Treeline Biosciences</u>. The number of licensing deals from Chinese biopharmas is now consistently averaging 40 per year."

Abid Ansari, OncoC4

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Deal Structures

"Given the recent challenging capital markets environment, more biopharma companies are expected to consider strategic and non-dilutive transactions to continue developing their assets," according to Neel Patel, executive managing director at Syneos Health Consulting. Along with the increased preference for deal-making over straight fundraising, some predicted increased creativity in how deals are structured.





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Dave Moore, Novo Nordisk

"Biopharma deal-making will continue its recent upward trend into 2024, and we can expect a greater variety of deals," commented Dave Moore, executive vice president of corporate development at *Novo* Nordisk A/S. "We will see more creative deal structures and bespoke integration models that go beyond classic acquisitions, helping to leverage the individual strengths that each partner brings to a collaboration - ultimately leading to better outcomes for patients. At the same time, deals will continue to spread beyond the established biotech hubs. Promising innovation is happening in many parts of the world today, and

this will eventually be reflected in the biopharma deal landscape."

"More than ever, with the continued uncertain macroeconomic environment, creative, dynamic partnerships are needed to unlock the potential of innovative science and address critical industry challenges," said, Astellas Pharma Inc.'s Tsukamoto. "Having an open mind as to how deals are structured, whether an M&A, in- or out-licensing, R&D collaboration or investment, will be key. The success stories will be the partnerships that started with a long-term vision, seamlessly combined complementary capabilities, and made room for the collaboration to evolve as the innovation progresses. Through tailored, flexible approaches, we can transform our collective potential to deliver greater value to patients, sooner."

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M&A

"The slowdown in the capital markets activity didn't produce the expected M&A boom in 2023 and as the public markets are likely to struggle to have meaningful activity in the first half of 2024 we believe we will see more M&A activity," said Stephen Rosen, partner and head of the London corporate practice at law firm Cooley.

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"Companies that have been contemplating a crossover round in early 2024 ahead of an IPO are likely to find themselves targets of well-capitalized companies looking to benefit from the continued lag in valuations. We are starting to see more sponsors focus on public-to-private transactions in the sector and believe this will be a trend that will continue in 2024," he continued. "Governments are still grappling with aligning the desire for a strong and vibrant life sciences market with the need to ensure that the regulatory framework is robust and one that can support growing companies and this should lead to bold CEOs seeing opportunities for targeted M&A and an ability to pick up smaller players who don't have the luxury of cash longevity as the system plays catch up.



"There has been plenty of strategic alignment of priorities by boards and investors and during 2023 this resulted in a number of asset disposals. We see this as a prelude to a period of meaningful M&A activity in 2024 as these companies look to add scale and pipeline in a more focused way. Given the increasing flexing of muscles by regulators across the globe we see the likely trend in 2024 being for slightly smaller M&A deals as buyers look to hopefully avoid unwanted regulatory attention which will inevitably cause delays and increase deal costs and execution risk."

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Stephen Rosen, Cooley

OncoC4 CFO Abid Ansari also foresaw targeted deals in 2024: "I expect we will see a number of additional bolt-on acquisitions. With several pharma companies spinning out non-core businesses and trying to navigate patent cliffs, more capital will be free to support potential growth areas. We are in a situation where mature small biotechs are trading at attractive valuations."

"With inflation coming down, we should see interest rates fall and cash move back into equities."



Pharma needs to bolster its pipeline to compensate for patent expiries, which will fuel M&A and licensing, and get deals done before prices rise," said Tim Dyer, CEO of <u>Addex Therapeutics Ltd</u>.

"Pharma consolidation has been ongoing for some time as a function of patent cliffs. I don't expect this to be different in 2024. As the cost of capital declines, biotech will have more options which may result in more private and public financing and also increase biotech-pharma deal flow particularly on the platform side," said MOMA's Asit Parikh.

Cancer therapy company *Inspirna, Inc.*'s CEO Usman Azam took a similar view. "I predict that the M&A scene will be highly active, with large pharma needing to urgently enrich their pipelines inorganically to offset declining revenues in the next 3-5 years," he said.

"There is a cautious optimism for biopharma deal-making in 2024, driven by forward-looking Fed [Federal Reserve] guidance on the stability of interest rates and large pharmaceutical companies' desire to fill revenue and pipeline gaps," said Syneos Health's Patel. "Buyers may continue to pursue alternative funding pathways to finance acquisition of companies trading below book value. Large pharma companies will attempt to fill revenue gaps due to impending patent cliffs via acquisitions of late-stage de-risked assets. Larger transactions may face headwinds, considering recent FTC challenges."

Michael Shah, pharmaceutical industry analyst at Bloomberg Intelligence, agreed. "The biotech funding environment remains tough, raising concerns around the cash horizons for pre-revenue companies, yet the pace of US interest rate hikes has slowed to a halt for now. Consensus suggests rate cuts starting in Q1, which could help reinvigorate M&A and sector interest. Several large drugmakers are well positioned to do deals, which may be needed to offset longer-term patent expirations. Most are well capitalized, and while many are agnostic to size and can flex their balance sheets should larger opportunities arise, bolt-on and in-licensing will likely remain favored. That's especially given increased antitrust scrutiny, which could ease if the next US president is a Republican," he commented. "We expect an opportunistic and disciplined approach to prevail with the availability of clinical data a key determinant in the pace of activity, especially as cost-synergy-driven deals take a back seat to science-led ones. Most continue to evaluate deals within their core strengths and across all stages of the pipeline, though early-stage assets are likely preferred."



As for areas likely to be favored in M&A, "Datacentric organizations will be rewarded, as we have already seen in the latter half of 2023," thought Inspirna's Azam. For Syneos's Patel, "there is likely a stronger appetite for novel Phase I oncology programs, followed by marketed products for pain."

"In our sector, neuroscience, there has been amazing progress in the understanding of the brain and its function. Positive data in schizophrenia and Alzheimer's are fuelling interest in the sector and the buyout of Cerevel shows that pharma is taking note," commented Addex Pharma's Dyer.

"I anticipate we'll see a push and pull in M&A

activity, particularly in oncology where big pharma companies are looking to expand their pipelines with innovative science, products and platforms driven by biotech companies leading the charge in advancing new tools and techniques. We've seen this a number of times with ADCs and immunotherapy, and we will continue to see this trend in 2024," said Affini-T's Bergsteinsson.

"Data-centric organizations will be rewarded, as we have already seen in the latter half of 2023."

Usman Azam, Inspirna, Inc.

ZS's Cody Powers picked oncology and metabolic disease as areas of interest: "In 2024, I expect to see continued momentum on M&A from large cap biopharma – both in areas that became predominant themes in 2023 (ADC, GLP-1) but other areas as well."

"M&A will be driven by the ongoing fundamental demand for late-stage

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"M&A will be driven by the ongoing fundamental demand for late-stage development and commercial assets as big pharma and big biotech look to bolster portfolios in the face of looming patent expiries," said Levicept's Eliot Forster. "For early-stage M&A, I think it will be much more selective with some particularly hot areas being metabolism and obesity and synthetic lethality in cancer."

"Global transactions are down in volume and value, however, there are pockets of high activity. PE [private equity] exits have slowed dramatically in 2023, but mid-market transactions from private sellers and corporate carve-outs have picked up, and there is a notable emphasis in some subsectors, such as cell and gene therapy services, integrated drug discovery and strategic market access. Expect 2024 to build over

"2024 will be challenging for the biotech industry, especially when it comes to early research and development (R&D), a key indicator for the sector. A rocky economy and turbulent stock market has caused IPOs to dwindle and VC firms to hoard cash instead of investing in new

the first couple of quarters, with a strong

investment bank Lincoln International.

finish," said James West, MD at

development and commercial assets as big pharma and big biotech look to bolster portfolios in the face of looming patent expiries."

Eliot Forster, Levicept



companies," said Carl Foster, chief business officer at Standigm, an AI drug discovery company. "As a result, many pharma companies are looking for down and dirty merger and acquisition deals. There is likely to be an increase in deals and acquisitions in the late-stage technology arena as these are more appealing to companies that are worried about revenue, compared to new early-stage projects."

Hakim Yadi, co-founder and CEO of techbio firm Closed Loop Medicine, which develops prescription products combining drugs and software, thinks M&A will be just one effect of a wider need for major change. "This year has proven to be a real test for businesses across the board. It's evident that a significant number of distressed assets are struggling to secure funding and meet their objectives and I believe we're on the brink of witnessing a wave of mergers and acquisitions. Many of these companies have been attempting to solve siloed individual problems,



but what our health care system truly needs are comprehensive, system-wide solutions," he said. "Considering the inherent global market instability, the ever-evolving landscape of medical technologies, and the surging market demands, sticking to the status quo is a surefire way to fall behind. To not only survive but thrive in 2024, businesses must embrace agility, strategy, and assertiveness. This necessitates a fundamental overhaul of outdated business models and a willingness to seek external investments that can modernize global health care to align with the shifting global needs, interests, and capabilities."

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Accountability

During the boom times of 2020-2021, a great many companies in the biotech sector were able to attract large sums of money. Now money is scarcer, investors' due diligence is tightening and those seeking funding need to make sure their business plans – and their scientific propositions – are watertight.

"In the biotech market there remain headwinds with a circa 30% decline in funding from the 2021-22 highs, which brings the environment to pre-COVID levels on a dollar-for-dollar basis. As you look deeper, the picture is mixed with some notable increases and decreases. Overall volumes and values are lower compared with the past three years," noted Lincoln International's James West. "High-quality biotech assets with significant data are finding their way to successful venture financing," he said, although he added that "investors are becoming more critical and demanding of clinical data for these rounds to reduce their risk as much as possible, due in part to the flatlined IPO exit route, forcing investors to reconsider their options."

"Last year, there was a clear cleansing process which will continue, although I expect this to lessen as companies learn they must offer a complete package: strong management teams, clear



"Going into 2024, the sector will continue to see a challenging VC environment and lack of public market access, certainly in the first half," predicted Alexander Gebauer, cofounder and executive chairman of *Galimedix Therapeutics, Inc.* "Last year, there was a clear cleansing process which will continue, although I expect this to lessen as companies learn they must offer a complete package: strong management teams, clear data and

data and convincing technology – plus commercial concepts – are the minimum requirements."

Alexander Gebauer, Galimedix

convincing technology – plus commercial concepts – are the minimum requirements. This cleansing is a good thing: investors are more stringent than before, only supporting the strongest companies." This stringency also comes from strategic partners, he noted: "Pharma partners take a longer view with greater scrutiny and rigor." He nevertheless expected "deal valuations will increase again" but via more cautious structures: "more back loading, lower up-front with greater milestone payments."

"The past two years have tested life sciences management teams and boards to the fullest, in all aspects of their businesses. Looking ahead to 2024, the lessons learnt during the preceding year in terms of the value of having lean and highly data-centric organizations, coupled with capital-efficient cultures, will be key to differentiating successful small and mid-size private and public life sciences companies," declared Inspirna's Azam.

"It is highly likely that the paucity of capital across the life science and biopharma sectors will continue well past 2024, given the backlog of companies seeking to go public and the plethora of public companies needing to raise follow-on-capital," warned Ali Pashazadeh, CEO of financial and strategic advisory firm Treehill Partners. "As a result, Treehill expects an even greater degree of scrutiny by boards and investors on the merits of deploying capital from the dwindling cash reserves to conducting clinical studies. We also anticipate a greater degree of accountability and ownership being asked not only of management but also service providers to ensure optimal trial design and trial execution." Indeed, the current financial cloud could have a silver lining: "This will hopefully lead to an improved probability of success and greater return on investment," said Pashazadeh. "If our predictions are right, embracing the challenging financing environment will allow us all to revise the ingrained expectation that a significant percentage of Phase III studies will undoubtably fail – [at the moment] service providers are almost given a free pass on clinical trial delays and ballooning change order charges."

"One of the most telling statistics I've heard in my career is that once a drug goes to patients in a Phase I clinical trial, about 7% of these drugs make it all the way to commercialization, while 93% fail," Jon Isaacsohn, CEO of *CinRx Pharma*, pointed out in a similar vein. "I think innovators



in our industry are aware of this disconnect, and always looking to improve our processes. In the new year, I think we'll see more companies exploring new structures for funding and operating to help alleviate some of these drug development roadblocks."

Søren Møller, managing partner at Novo Seeds Investments took a similar view to Pashazadeh, adding the need for flexibility into the mix: "In 2024, the biopharma industry may still face a challenging fundraising landscape marked by tightened capital availability. Companies must navigate this environment with a heightened focus on capital preservation and value creation. It's advised that firms adopt strategic and prudent strategic and financial planning, emphasizing longer cash runways to ensure sustainability," he said. "Adaptability and strategic foresight are key for companies to thrive amidst potential challenges whilst continuing to pursue innovative scientific approaches for the benefit of patients and society."

TVM's Stefan Fischer also expected the 2024 funding environment to "continue to be challenging, especially for smaller, development-stage companies with no revenues." He emphasized the need to keep focused on a key goal: "It is critical that companies spend wisely and drive programs forward in a focused way. At TVM, we take a capital-efficient approach for our early-stage, project-focused companies – providing sufficient funding to get to a key value inflection point – technical clinical proof of concept."





"The key for earlier stage companies is to carefully manage cash and focus on advancing assets to clinical or near clinical stage; as ultimately, good science will always prevail."

Antonin de Fougerolles, Evox Therapeutics

Evox Therapeutics Limited's CEO

Antonin de Fougerolles also urged biotechs to focus on key pipeline advances. "The funding, M&A, and partnering environment has been extremely challenging over the past 12 months. There has been an increased emphasis on clinical-stage assets and companies with platform technologies have fallen out of favour. There are of course exceptions to this, with certain fields continuing to attract a lot of interest, including genome editors, drug conjugates, and anything in the obesity space. This highlights that

there are opportunities to be had but at the moment the interest is still very narrowly focused. For 2024, I expect to see more of the same, with concentrated efforts in a few specific fields. The key for earlier stage companies is to carefully manage cash and focus on advancing assets to clinical or near clinical stage; as ultimately, good science will always prevail," he said. "I am expecting these trends to continue at least until the US elections in November 2024."

For Nancy Whiting, CEO of *Recludix Pharma*, the balancing act continues: "Even as access to capital begins to open, small biotechs are still going to be evaluating ways to most strategically advance their pipeline. Leaders will continue to operate prudently and look to prioritize indications, as well as execute on select partnerships that bring in additional expertise and funding to ensure that promising product candidates are still advanced, while retaining the required substantial value to attract investors. It will remain a balancing act, as the need for innovation for patients with challenging diseases remains urgent, but companies are expected to execute with tightened resources."

It should not all be about cash preservation, thought MOMA's Asit Parikh. "How does an emerging/early-stage, private biotech stay viable and well-funded today?" he wondered. "The classical answer is by operating frugally and extending runway for as long as possible... laser focus on getting to the next data readout and parking/slowing secondary programs and activities. But that's not the whole story. Like many things there is a U-shaped curve: you have to keep an eye out for opportunistic possibilities and shouldn't stand in the way of value generation. Having a committed workforce that is stimulated and empowered to generate fresh ideas that bring great ROI at low cost is a huge value add."

Abivax SA's CEO Marc de Garidel noted that big pharma still needed biotech to replenish its own



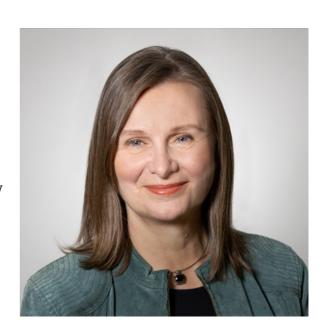
pipelines. "2024 will largely be characterized by a continued unstable geoeconomic environment and see similar difficulties in raising capital or concluding partnerships as in 2023. However, in my experience, a tough geopolitical and economic context does not mean that capital is not accessible at all or no deals will be made, as big pharma is looking to buy largely derisked and big potential drugs to feed their growth," he said. "It rather means that very targeted and thoughtful investment decisions are made and only the most promising and advanced development projects get financed."

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Collateral Damage

The straitened funding environment is leading to company failures. While some commentators argue that survival of the fittest is no bad thing, the extinction of companies that cannot secure sufficient funding may lead to collateral damage. One victim may be innovation itself, worries Christelle Huguet, head of R&D at *Ipsen SA*. "Strong science remains the trigger for partnering and deal-structures, yet in many cases the deal itself can be just as important as the scientific breakthrough to accelerate innovation. In 2024, I am concerned that we may see a shift to deals in areas of 'safe innovation', resulting from environmental factors such as the Inflation Reduction Act in the US and revision of the Orphan Medicinal Products Regulation in Europe. At Ipsen, we talk about mindful risk-taking: harnessing

scientific expertise, commercial experience (combined with a little bit of gut instinct), to accelerate innovation," she said. "But if the environment ceases to reward bold innovation, I foresee future trends in deal-making will be to build on established pathways and treatments, and not to take the greatest risks to make scientific discoveries and create new treatments that revolutionize



"If the environment ceases to reward bold innovation, I foresee future trends in deal-making will be to build on established pathways



care for people around the world."

Also at risk are the patients themselves, argues Lisa Sellers, CEO of Vector Laboratories. "In 2024, I hope we foster an ecosystem that benefits patients. Biotech companies will struggle to use novel technology to treat rare diseases. Many companies haven't paced themselves to meet investor expectations. As a result, patients are lost when clinical trials end due to insufficient funds. For those with efficacious clinical data, there is a lack of patient fallback and patients are not

and treatments, and not to take the greatest risks to make scientific discoveries and create new treatments that revolutionize care for people around the world."

Christelle Huguet, Ipsen

heard. In 2024, biopharma must support the heart of innovation within smaller biotech companies to bring therapies to patients. Big pharma partnerships fed innovation in 2023. In 2024, pharma and venture capital will partner with biotechnology to ensure patients are top of mind among shifting investment strategies. Venture capital will favor unique business models to ensure sound science solves unmet needs. As others seek to catch up to the US's position as health care innovators, pharma must invest in biotechnology innovation to benefit patients and a thriving economy," she urged.

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Valuations

"Although we have a strong belief in the fundamentals of our industry and the long-term value it can create, 2023 has undoubtedly been a challenging year for biotech, with companies facing limited access to capital. This is likely to continue well into the new year," predicted Roel Bulthuis, managing partner and head of investments, Syncona Investment Management Limited. "However, we are seeing reasons for optimism in the market. Value recognition is shifting further towards later-stage clinical assets and pharma will continue to replenish its portfolio with the late-stage innovation that continues to bubble away in biotech. Generally, we expect a strengthening of this feeder dynamic between biotech and pharma and alongside this a continued recovery in valuations for later-stage assets."

However, Bulthuis warned that "the challenge of access to and cost of capital remains for earlier-



stage companies. Young biotech needs to be more careful than ever with its cash and pipeline prioritization. Prudence and patience will be paramount in enabling companies to survive and grow, before ultimately unlocking substantial value later in their lifecycles."

"Valuation step-ups will be few and far between," thought OncoC4's Ansari. "On the public side, companies trading at or below cash will continue to have reverse merger interest from private companies looking for their next funding source. The key is finding those reverse mergers where an obvious synergistic benefit is realized from the combination. Such strategic alignments have consistently demonstrated robust trading performance in the after-market and will continue to do so."



"Venture and private

capital will continue to be the lifeblood for new and emerging start-ups. However, with lower valuations the industry needs to completely reset expectations on what exit outcomes will be for the foreseeable future," said Hillary Frank, chief platform officer at Vive Collective, a new investment platform for digital health and healthtech companies. "As a result, the amount and the way digital health companies will be capitalized needs to change fundamentally."

Bloomberg Intelligence's van Kirk spotlighted the pushes and pulls on valuations for gene editing

companies. "Late-stage gene editors could soar following a troubled 2023, though

excitement around CRISPR

"With lower valuations the industry needs to completely reset expectations on what exit outcomes will be for the foreseeable future."

Hillary Frank, Vive Collective

Therapeutics/Vertex Pharmaceuticals' Casgevy (exagamglogene autotemcel) achieving the first ex vivo approval in the UK may be dampened by conditioning concerns and intensified focus on the potentially superior safety profile of off-target edits in newer-generation technologies such as prime and base editing," she said.

"Additionally, we watch editors'

reimbursement and pricing in Europe as gene-therapy precedents suggest

stalemate negotiations could pressure EU sales. Our discussions with EU regulators find hard



resistance to multi-million-dollar therapy prices."

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Public Markets

Look hard at all your options and seriously consider alternatives is probably the general message for companies looking to go public this year.

"I think the IPO window will be slow to open and lag Series A-XO market thawing," MOMA Therapeutics' CEO Parikh said. "There remain almost 200 public biotechs trading at negative enterprise values. So, series B and later private companies must also consider round extensions and reverse mergers as alternative financing vehicles if they have less than 12-18 months of cash at the end of 2023. Partnership and M&A are a great option, you need to look hard to create the opportunities but so much of it is also based on timing... what is the partner looking for and can you help solve their need?"

"Many companies will be waiting for the right time to launch their IPO and that's not easy to predict in this market," said Iraj Ali, CEO of *Achilles Therapeutics*, who also had some practical advice for those brave enough to proceed. "Preparing for an IPO is a significant investment – when we did ours, we limited the number of people from the operating team involved so everyone else could remain focused on running the business. That could be even more important in 2024 given the uncertainties involved."

"In 2024, quality science will continue to find highly motivated investors and strategic partners, with a few factors to consider. From the public markets standpoint, the new year promises to be tricky with the positive influence of what appears to be cooling inflation and a pause in interest rate hikes potentially offset by the uncertainty that comes with a contentious presidential election," said Stu Mackey, global head of business development at <u>Daiichi Sankyo Co., Ltd.</u> "This could mean more challenging months ahead for innovation-based start-ups." However, he highlighted the availability of alternative options: "It seems there is still plenty of investment capital at venture firms, and significant appetite within big pharma for deals to supplement pipelines. Within the





ADC space, we are seeing both of these factors, with strong strategic interest in acquisitions and alliances, and continued funding of innovators interested in bringing forward next-gen solutions."

L.E.K. Consulting's Helen Chen took a global view. "Biotech stocks are down all around the world. While it looks like the US is beginning to recover, the jury is still out for China's capital markets. The S&P biotech index is down at about 40% of its 2021 peak, whereas the Heng Sang biotech index is still only about one third of its 2021 peak. Meanwhile, most Western investment funds have pulled out of China, leaving the market to Asian investors who are less knowledgeable about the industry and

"From the public markets standpoint, the new year promises to be tricky with the positive influence of what appears to be cooling inflation and a pause in interest rate hikes potentially offset by the uncertainty that comes with a contentious presidential election."

Stu Mackey, Daiichi Sankyo

living through its first downturn." She also noted that "a similar story is playing out on the private equity and venture capital side. Deal volumes are now just above 2019 levels. The difference is that we were on the upward trajectory in 2019, now we don't know when the recovery is likely to be."

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Venture Capital

Cooley's Tom Goodman had a positive outlook on venture capital funding for biopharma.

"The volume of European VC deals increased quarter on quarter in the second half of 2023 and, if as expected, interest rates hold or even fall in 2024 we could see greater deployment of capital by investors that continue to hold large volumes of dry powder." He

"Europe remains a key centre for innovation and the favorable



noted that "Europe remains a key center for innovation and the favorable valuations and cost of capital relative to the US will encourage inbound private investment from US funds, many of whom now have boots on the ground in London and other European hubs."

OncoC4's Ansari took a "curate's egg" view of the VC market: good in parts. "Capital will continue to be selectively allocated to private companies with novel assets having at least proof-of-concept data," he predicted.

Jan Van den Bossche brought a VC investor perspective to the discussion, as a partner in the life science team at Andera Partners. "Our

current priority when looking at new funding options is to be prepared to fund companies for longer. The reality is that a lot of M&A attention is going to public and/or late-stage companies right now. This is because pharma is focused on short-term needs as they near patent cliffs in the next five years and need to look for assets to refill their pipelines. For us, this means managing our portfolio carefully, and concentrating our bets before pharma moves again towards mid-sized, private companies.



valuations and cost of capital relative to the US will encourage inbound private investment from US funds."

Tom Goodman, Cooley

"When choosing a financing strategy, it is important to keep in mind that the current market volatility – driven by volatile expectations regarding the interest rate evolution – will most likely continue into 2024," Van den Bossche went on. "Nevertheless, the IPO market will remain selectively open for high-quality companies. This unpredictable environment needs to be taken into consideration when developing a financing strategy."

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Advanced Therapies

Various commentators shared their views on the attractiveness of companies developing advanced therapies in the difficult funding environment. "Deal-makers are seeing ADCs, protein degraders, bi-specifics, and machine-learning-enabled products as being 'hot' acquisition targets in 2024, with sustained interest in cancer vaccines and gene therapies," said Syneos Health Consulting's Patel.



Matt Lang, CFO at

TrakCel, which provides cell and gene therapy software solutions, recognized that "the funding environment for companies within the advanced therapy sector has been challenging for most of 2023 due to global economic uncertainty having a significant negative effect on investment levels. Unfortunately, this does not look set to change immediately in 2024 with company valuations likely to be suppressed for some time. However, those companies better positioned will likely explore opportunities for partnerships or acquisitions as they scale. Others will remain focused on consolidating costs and stretching cash runways until valuations

"As the CGT [cell and gene therapy] industry continues to rapidly expand, it suggests a very positive outlook for the sector and I predict significant inward investment into the sector during the second half of the year."

Matt Lang, TrakCel

improve. Longer term, we do see a brighter future. As the CGT [cell and gene therapy] industry continues to rapidly expand, it suggests a very positive outlook for the sector and I predict significant inward investment into the sector during the second half of the year."

"Making predictions is a perilous exercise, especially in light of the many political, geopolitical, and interest rate uncertainties," admitted Stéphane Boissel, CEO of *SparingVision*. His view, however, is that big pharma will invest in advanced therapies. "In our field of

genomic medicines, I foresee continuing strategic interest from pharma following the approval of the first CRISPR-based gene-editing therapy developed jointly by Vertex Pharmaceuticals and



CRISPR Therapeutics. This landmark approval highlights the industry's move towards precision in treatment – a trend that is set to deliver meaningful clinical and commercial advancements. By focusing on precisely aligning technologies with specific disease profiles, companies can significantly expand their ability to offer groundbreaking treatments to more patients. I anticipate a surge in pharma players new to genomics, investing in these breakthrough technologies as future therapeutic modalities."

"The rapid evolution of technologies across sectors, rise in modular genetic medicines and subsequent challenges in manufacturing next generation therapeutics are major factors impacting contemporary drug development," said David Fontana, chief operating officer at *Umoja Biopharma, Inc.*, who also sees widening interest in deal-making in the field. "The complex and dynamic nature driving innovation necessitates diverse expertise, making partnerships invaluable for tapping into a broader knowledge base. More than just capital exchanges, sharing of technologies, techniques and strategies in emerging fields is becoming increasingly common, especially among companies with platform technologies who are looking to create a robust therapeutic pipeline.

"As these trends continue, partnerships will become increasingly more necessary to accelerate innovation, and facilitate the development of groundbreaking solutions beyond what one can do alone. We've already seen a rise in partnerships in 2023 and this trend will continue in 2024 to propel the industry forward," Fontana predicted.

Additional reporting by Joseph Haas.