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Where pharma are investing for the future of medicine

Biopharma deal making in 2023

Contents

Restocking pharma pipelines requires partnering with biotechs

Biotechs raised $16.9 billion through 158 follow-on offerings, while there were 381 public and other financings that raised $16.86 billion and 493 private VC rounds that raised $22.2 billion.

Historically, when the capital markets' enthusiasm for the biotech sector has gone from cool to cold, companies have turned to partnering as an alternative source of support.

As investors began turning away from biotech in late 2021, there was an expectation among commentators that this might trigger an upsurge in both mergers and acquisitions (M&A) activity and biopartnering deals. This did not happen.

During 2022, the global biotech sector saw a drop off in its ability to raise finance. After record-breaking fundraising in 2020 and 2021, investor enthusiasm waned in 2022. Indeed, the $60.8 billion collected by biopharma companies throughout 2022 was down by 48.6% from 2021 and 54.8% from 2020.[1] Global initial public offerings were thin on the ground, with only 35 completed generating $4.85bn. Biotechs raised $16.9 billion through 158 follow-on offerings, while there were 381 public and other financings that raised $16.86 billion and 493 private VC rounds that raised $22.2 billion.

According to BioWorld, M&A activity was at its lowest level since 2013, and while the reported bio partnering deal values for 2022 were the second highest recorded, the number of transactions was the lowest since 2018. With the pharma sector still struggling when it comes to R&D productivity, it continues to rely heavily upon biotechs for innovative ideas.

With interest rates still high across the globe and the world economy still facing challenges from geopolitical tensions, biotech executives have been advised to manage their capital even more tightly, make the finds they have last longer, focus on mainly the lead programs, and find alternative sources of finance. VCs, who have raised considerable sums in recent years, are likely to reserve more for existing portfolio companies. There is an expectation that corporate venture capitalists may return to the fore in financing biotechs.

Big Pharma's growing reliance on external sources of innovation was evident in Clarivate's latest Top 100 Global Innovators™ report.[2] What the analysis reveals is that the leading pharma companies are responsible for a smaller share of pharmaceutical inventiveness, while over the last decade, the number of pharmaceutical inventions is approaching double its annual production rate, which is largely due to increased innovation from Mainland China.

Biotech innovation still speaks with an American accent, but that influence is declining... in 2022, some 43% of biopartnering transactions involved at least one United States-based company.

In 2020 the number of pharmaceutical-related inventions filed by Mainland China-based entities, for the first time, exceed the total for all other countries and regions -- a continuing trend. Moreover, in the past decade there has been a doubling in pharma-related inventive activity from academia.

A geographic analysis of dealmaking activity confirms that biotech innovation still speaks with an American accent, but that influence is declining, while the influence of Asia-Pacific-based industry, most notably entities based in Mainland China, is rising. In 2022, some 43% of bio partnering transactions involved at least one United States-based company, while 15% of all transactions involved only United States-based biotechs. Moreover, 29% of deals involved at least one European partner, while one in four transactions had at least one participant from the Asia-Pacific region.

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Our data and expertise

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A muted year in M&A activity

At the start of 2022, many pharma companies were sitting on large cash piles and facing a wave of patent expiries in the coming years. Biotechs were plummeting in value, giving pharmas far more leverage in dealmaking.

Yet an expected uptick in M&A activity, especially for so-called bolt-on activities, failed to materialize. According to BioWorld data, only 99 M&A transactions, potentially worth $75.3 billion, completed during the year – the lowest number in the past decade and the second lowest total potential value for biotech mergers and acquisitions.[3]

Mergers and acquisitions are one of the most favorable exits for early investors because it gives them an opportunity to realize a return on their investment with few strings attached. With the downturn in the capital markets, biotech share prices have fallen well below their historic highs, leaving investors reluctant to sell at deeply discounted prices.

While pharma might have been expected to be attracted by lower valuations, headwinds included the higher cost of capital, uncertainty around the Inflation Reduction Act's potential impact on the sector, and greater scrutiny of deals by regulators such as the U.S. Federal Trade Commission (FTC) and the European Commission.[4] Consequently, bolt-on deals, which do not attract such scrutiny from antitrust authorities, comprised the lion's share of activity.

Amgen's intent to acquire Horizon Therapeutics for $28 billion was first announced in December 2022 but was held up by an FTC request for more information.[5] All eyes will be on Pfizer's proposed $43 billion acquisition of the ADC developer Seagen, which is not expected to complete until the end of the year or early 2024 if it clears the relevant competition authorities.[6]

Indeed, delays in getting clearance from regulators is said to have slowed down the completion of what became 2022's largest M&A deal, CSL's $12.3 billion acquisition of Vifor Pharma, the Swiss specialty pharma with leadership in iron deficiency, nephrology & cardio-renal therapies.[7] Initially announced and agreed at the end of 2021, when it would have registered as that year's most valuable pharma M&A transaction, the deal did not complete until August 2022.

By acquiring Vifor, CSL expanded its portfolio breadth, with the addition of ten commercialized products including Ferinject/Injectafer, Venofer, Veltassa, and soon Korsuva. The acquisition gave CSL leadership positions across multiple franchises, with an expanded pipeline of 37 products across all development phases, representing an increase of 37% in pipeline volume and up to four product launches expected in 2022/23.

Vifor gives CSL complementary assets across its existing therapeutic focus areas, including hematology and thrombosis, cardiovascular-metabolic, and transplant, along with access to new adjacencies across nephrology, dialysis and iron deficiency, with strong market positions and growth opportunities in each area. Recently approved drugs in the Vifor portfolio – Tavneos and Korsuva – are expected to offer significant commercial momentum across these new adjacent focus areas.

CSL acquired Vifor in an all-cash public tender offer of $179.25 per Vifor Pharma share, representing an acquisition consideration of approximately $12.3 billion, an implied premium of approximately 40% to the last closing price of Vifor Pharma shares on the Swiss SIX on December 1, 2021.

Pfizer was the most acquisitive big pharma in 2022, investing some of the cash its COVID-19 vaccine efforts generated. Pfizer's largest deal, the $11.6 billion acquisition of Biohaven Pharmaceuticals, saw Pfizer return to the neuroscience fold.[8] Pfizer paid $148.5 a piece for the Biohaven shares, representing a 33% premium to Biohaven's volume-weighted average selling price over the three months prior to the deal announcement. The acquisition provides Pfizer with a portfolio of promising calcitonin gene-related peptide (CGRP) receptor antagonists including rimegepant, an innovative migraine therapy approved for both acute treatment and prevention of episodic migraine in adults.

Interestingly, Biohaven's non-CGRP development stage pipeline compounds were spun off into a new company called Biohaven Ltd., which will also be entitled to royalties based on sales generated by rimegepant and zavegepant. Those assets include the Kv7 ion channel activators, glutamate modulation, and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure assets excluded from the Pfizer acquisition. Former shareholders of Biohaven will receive one share in the new company for every two original shares.

In a bid to expand its offering in the inflammation and immunology therapeutic areas, Pfizer acquired Arena Pharmaceuticals and its portfolio of diverse development-stage therapeutic candidates in gastroenterology, dermatology, and cardiology for $100 a share, valuing the deal at $6.7 billion.[9] Pfizer was particularly eager to access Arena's etrasimod, an oral, selective sphingosine 1-phosphate (S1P) receptor modulator currently in development for a range of immuno-inflammatory diseases including ulcerative colitis, Crohn's Disease, atopic dermatitis, eosinophilic esophagitis, and alopecia areata.

Building on a 30-year legacy in the rare hematology space, Pfizer reinforced its commitment to treating sickle cell disease (SCD) with the acquisition of Global Blood Therapeutics.[10] Paying $68.50 a share, representing an enterprise value of $5.4 billion, Pfizer has picked up voxelotor, a first-in-class medicine that directly targets the root cause of SCD, plus a pipeline of preclinical and clinical investigational assets focused in SCD. These include GBT021601 (GBT601) and inclaclumab, both of which have FDA orphan drug designation.

Bristol Myers Squibb also hit the acquisition trail, expanding its precision oncology portfolio through the $4.1bn acquisition of Turning Point Therapeutics.[11] The transaction gives BMS a pipeline of investigational medicines designed to target the most common mutations associated with oncogenesis, including repotrectinib, a next-generation, potential best-in-class tyrosine kinase inhibitor targeting the ROS1 and NTRK oncogenic drivers of non-small cell lung cancer (NSCLC) and other advanced solid tumors.

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Seeking to maintain its leadership position in inflammation and nephrology, Amgen splashed out $3.7 billion to acquire Chemocentryx and its portfolio of orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer.[12] Notably, the acquisition gives Amgen Tavneos, a transformative, first-in-class, orally administered selective complement component 5a receptor inhibitor treatment for patients with anti-neutrophil cytoplasmic autoantibody-associated vasculitis.

Biocon Biologics cemented its position as a global leader in biosimilars by building on a decade-long partnership with Viatris and acquiring its biosimilars business in a $3.34 billion transaction.[13] Through the deal, Biocon takes full ownership of seven biosimilars that were part of a collaboration between the two companies, as well as Viatris' rights for in-licensed adalimumab and etanercept biosimilars and Viatris' rights for an aflibercept biosimilar. Post-acquisition, Biocon boasts 20 biosimilar assets, including insulins and monoclonal antibodies, spanning therapy areas such as diabetes, oncology, immunology and ophthalmology.

Similarly, to accelerate its biosimilar development capabilities and future performance in novel drug development, Samsung Biologics bought out Biogen's near-50% stake in the Samsung Bioepis joint venture.[14] Samsung expects the deal to equip Bioepis with improved autonomy and agility in business operations. For Biogen, which was struggling with the launch of its controversial Alzheimer's treatment Aduhelm (aducanumab), the deal is seen as a tactical withdrawal that will generate short-term cash.

The sale of the stake does not signal a retreat from the biosimilars sector. Biogen retains the right to sell Samsung Bioepis' biosimilars to three blockbuster TNF inhibitors in Europe, with an option to handle the Mainland China market, as well as global rights to two anti-VEGF eye treatments. Samsung Biologics paid Biogen up to $2.3 billion for its stake in the joint venture, with $1 billion in cash and $1.25 billion in two installments to be deferred over two years.

In a bid to bolster its specialty pharma and vaccines franchises, GlaxoSmithKline acquired Affinivax in a deal worth potentially $3.3 billion and Sierra Oncology for up to $1.9 billion.[15] GSK's Affinivax acquisition includes a next-generation 24-valent pneumococcal vaccine candidate (AFX3772), currently in phase II development, based on the highly innovative Multiple Antigen Presenting System (MAPS™) platform technology. The distinctive plug-and-play nature of MAPS™ enables the targeting of a broad range of infectious diseases.

The initial use of the technology has been directed primarily toward preventing pneumococcal disease. Applicability of the technology has also been demonstrated for additional infectious disease pathogens, including those that cause hospital-acquired infections.

Under the terms of the deal, GSK acquired 100% of the outstanding shares of Affinivax for an upfront payment of $2.1 billion paid upon closing and committed to two potential milestone payments of $0.6 billion to be paid upon the achievement of certain pediatric clinical development milestones.

With an eye on expanding its oncology franchise, GSK acquired Sierra Oncology, a California-based biopharma focused on targeted therapies for the treatment of rare forms of cancer.[16] Most notably, GSK picked up momelotinib, a late-stage potential new medicine with a unique dual mechanism of action that may address the critical unmet medical needs of myelofibrosis patients with anemia. The compound complements GSK's *Blenrep* (belantamab mafodotin), building on the company's expertise in hematology.

GSK acquired Sierra Oncology for $55 per share in cash, valuing the business at approximately $1.9 billion. This sum represents a premium of approximately 39% to Sierra Oncology's closing stock price on April 12, 2022, the day before the plan to buy was announced, and approximately 63% per cent to Sierra's volume-weighted average price over the previous 30 trading days to that.

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UCB acquired Zogenix in a deal underpinning its commitment to addressing unmet needs of people living with epilepsy, and with an increasing focus on those living with specific or rare forms of epilepsy.[17] The deal provides the Belgian pharma assets that complement its existing medicines and expand its clinical development pipeline of epilepsy and rare disease therapies.

Under the terms of the agreement, UCB paid Zogenix $26 a share in cash, plus a contingent value right for a potential cash payment of $2 should EU authorities grant approval of Fintepla as an orphan medicine for treatment of Lennox-Gastaut syndrome (LGS) by December 31, 2023. The drug is already approved in the U.S. and E.U. as a treatment of seizures associated with Dravet syndrome in patients two years of age and older. The upfront consideration represented a 72% premium to Zogenix shares based on the 30-day volume weighted average closing stock price of Zogenix prior to signing.

Major biopharma M&A deals completed in 2022

Target	Acquirer	Focus	Date	Potential value ($ millions)
Vifor Pharma	CSL	Rare disease	08/09/2022	$12,300
Biohaven Pharmaceuticals	Pfizer	Migraine	10/03/2022	$11,600
Arena Pharmaceuticals	Pfizer	Immuno-inflammation	03/11/2022	$6,700
Global Blood Therapeutics	Pfizer	Sickle cell disease	10/05/2022	$5,400
Turning Point Therapeutics	Bristol Myers Squibb	Oncology	08/17/2022	$4,100
Chemocentryx	Amgen	Autoimmune	10/20/2022	$3,700
Viatris' biosimilars business	Biocon Biologics	Biosimilars	11/29/2022	$3,340
Affinivax	GSK	Vaccines	08/16/2022	$3,300
BIIB stake in Samsung Bioepis	Samsung Biologics	Biosimilars	01/27/2022	$2,300
Zogenix	UCB	Neurology	03/07/2022	$1,900
Sierra Oncology	GSK	Rare disease	07/01/2022	$1,900

Source: BioWorld

Merck & Co. leads biopartnering drive

Big Pharma was the biggest driver of biopartnering activity, having a role in almost half the deals for which financial terms were shared.

The most active large pharma company was Merck & Co. (also known as Merck Sharp & Dohme or MSD), participating in 15 such partnering deals in 2020. Merck signed what may have been the year's most valuable deal and committed up to $22.7 billion, should all deals achieve their milestones. With 12 deals, Sanofi was the second most active dealmaker, with two deals in the year's top ten and all deals potentially worth $22.3 billion. Bristol Myers Squibb, also with two deals in the year's top ten, committed the third-largest amount to biopartnering deals in 2022, at $18.1 billion across eight transactions. Takeda was the number one dealmaker in the Asia-Pacific region by spend, committing a total of $8.3 billion across four deals--although the company's deal with Nimbus Therapeutics to acquire 034858, a potential best-in-class, oral allosteric TYK2 Inhibitor, for $6 billion, accounted for the lion's share.

With late-stage assets scarce, and pharma companies on the hunt for genuinely game-changing innovative science, this trend for earlier stage assets is likely to be sustained.

Interestingly, while big pharma faces a major patent cliff starting in 2025, most of the high value partnering deals focused on preclinical assets, accounting for 49 of the 65 partnering deals with a potential worth of more than $1 billion. Not only was the number of preclinical deals signed higher than in previous years, so was the size of the upfront payments on offer. With late-stage assets scarce, and pharma companies on the hunt for genuinely game-changing innovative science, this trend for earlier stage assets is likely to be sustained. In contrast, 2022 saw year-on-year declines in both the number and upfront payment value of clinical-stage partnering deals.

There were three deals involving clinical-stage assets among the top 10 transactions announced in 2022. These included:

- Takeda's deal with Nimbus Therapeutics, which included a $4 billion upfront payment for a psoriasis treatment candidate scheduled to go into Phase III studies in 2023[18]
- Summit Therapeutics' deal with Australian biotech Akeso, in which Summit Therapeutics licensed exclusive rights to develop and commercialize ivonescimab (PD-1/VEGF) bispecific in the United States, Canada, Europe, and Japan for an up-front fee of $500 million, with Akeso Inc. retaining development and commercialization rights for the rest of the world, including Mainland China [19]
- Gilead's Kite Pharma's global strategic collaboration with Arcellx to co-develop and co-commercialize Arcellx's lead late-stage product candidate, CART-ddBCMA, for the treatment of patients with relapsed or refractory multiple myeloma. Arcellx received an upfront cash payment of $225 million and $100 million equity investment from Kite[20]
- Much of the biopartnering activity focused on the acquisition of the key platform technologies that are expected to underpin the development of medicines in the coming decades.

Top 10 biopharma transactions in 2022 by total potential value

Principal	Partner	Therapy area	Technology	Potential value ($ millions)	Date
Sichuan Kelun-Biotech Biopharmaceutical Co.	Merck & Co.	Cancer	Antibody-drug conjugate	$9,475	12/22/2022
Poseida Therapeutics	Roche	Cancer	Cell therapy	$6,220	08/03/2022
IGM Biosciences	Sanofi	Oncology/ Immunology	Antibody technology	$6,165	03/28/2022
Nimbus Therapeutics	Takeda Pharmaceutical	Inflammation	Small molecule	$6,000	12/13/2022
Exscientia	Sanofi	Oncology/ Immunology	AI/Machine learning	$5,300	01/07/2022
Evotec	Bristol Myers Squibb	Cancer	Small molecule	$5,000	05/11/2022
Akeso Biopharma	Summit Therapeutics	Cancer	Bispecific antibodies	$5,000	12/06/2022
Arcturus Therapeutics Holdings	CSL Sequirus	Infectious diseases	RNA technology	$4,500	11/01/2022
Immatics	Bristol Myers Squibb	Cancer	Cell therapy	$4,260	06/02/2022
Arcellx	Kite Pharma	Various	Cell therapy	$4,225	12/09/2022

Source: BioWorld

Pharmas stepping up efforts to access ADCs

Antibody–drug conjugates (ADCs) were the focus for more than one in five of the billion dollar plus partnering deals in 2022.

This emerging class of therapeutics has so far seen regulatory approvals mainly as single agents targeting solid and hematological malignancies. Next generation ADCs will be enhanced by combinatorial approaches underpinned by the identification of targets with tumor-specific expression, improved conjugation technologies, and novel linkers and payloads offering superior therapeutic effects. Co-administration with anti-angiogenic compounds, HER2-targeting drugs, DNA-damage response agents and immune checkpoint inhibitors represent potential combination targets.

In a bid to augment its oncology pipeline, Merck signed the year's potentially largest deal when it agreed to an exclusive license and collaboration agreement with Mainland China-based Kelun-Biotech, a subsidiary of Sichuan Kelun-Biotech Biopharmaceutical Co.., to develop seven investigational preclinical antibody-drug conjugates (ADCs) for the treatment of cancer, along with exclusive options to obtain additional licenses to ADC candidates.[21] Kelun-Biotech retains the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Mainland China, Hong Kong and Macau.

Merck paid Kelun-Biotech a $175 million upfront payment, and Kelun-Biotech is also eligible to receive future development, regulatory and sales milestone payments totaling up to $9.3 billion on the conditions that the company does not retain Mainland China, Hong Kong and Macau marketing rights for the option ADCs and all candidates achieve regulatory approval, plus tiered royalties on net sales for any commercialized ADC product. Merck said it intends to make an equity investment in Kelun-Biotech.

Merck's deal with Kelun-Biotech was an expansion of an existing relationship. Earlier in the year, Merck agreed to pay $47 million in upfront payments to license rights to SKB-264 outside Mainland China, Hong Kong, Macao, and Taiwan, although $17 million had already been paid as part of an existing collaboration, with another $1.36 billion in potential milestone payments plus royalties on sales in the balance. Kelun-Biotech and Merck will collaborate on certain early clinical development plans, including evaluating the potential of SKB-264 as a monotherapy and in combination with Keytruda (pembrolizumab) for advanced solid tumors.

Currently, SKB-264 monotherapy is rapidly advancing in a phase 3 registrational study for the treatment of locally advanced or metastatic triple negative breast cancer (TNBC), as a combination therapy with the anti-PD-L1 monoclonal antibody KL-A167 for metastatic TNBC in the first-line setting, and in combination KL-A167 with or without platinum-based chemotherapy in patients with advanced or metastatic non-small cell lung cancer.

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Leading antibody drug conjugate biopartnerships in 2022 by total potential value				
Principal	**Partner**	**Therapy Area**	**Potential value ($ millions)**	**Date**
Kelun-Biotech	Merck & Co.	Cancer	$9,475	12/22/2022
ImmunoGen	Eli Lilly & Co.	Cancer	$1,745	02/15/2022
Mersana Therapeutics	GlaxoSmithKline	Cancer	$1,460	08/08/2022
Kelun-Biotech	Merck & Co.	Cancer	$1,410	05/17/2022
Sutro Biopharma	Astellas Pharma	Cancer	$1,357	06/27/2022

Source: BioWorld

Having previously walked away from ADCs, recent developments in the field prompted Eli Lilly to return and explore their potential by teaming up with ImmunoGen once more. In a global, multi-year definitive licensing agreement, Immunogen granted Lilly exclusive rights to research, develop, and commercialize ADCs directed to targets selected by Lilly based on ImmunoGen's novel camptothecin technology, with ImmunoGen retaining full rights to the camptothecin platform for all targets not covered by the Lilly license.[22]

Lilly paid ImmunoGen an upfront payment of $13 million, reflecting initial targets selected by Lilly, and may select a pre-specified number of additional targets, with ImmunoGen eligible to receive an additional $32.5 million in exercise fees if Lilly licenses the full number of targets. ImmunoGen is also eligible to receive up to $1.7 billion in potential target program exercise fees and milestone payments based on the achievement of pre-specified development, regulatory, and commercial milestones. ImmunoGen is also eligible for tiered royalties as a percentage of worldwide commercial sales by Lilly. Lilly will be responsible for all costs associated with research and development.

In 2011, ImmunoGen granted Lilly three exclusive development and commercialization licenses to use ImmunoGen's maytansinoid Targeted Antibody Payload (TAP) technology with Lilly monoclonal antibodies to develop anticancer ADC therapeutics. Lilly paid an upfront fee of $20 million and was potentially on the hook for a further $200 million in milestone payments. While the three programs did progress, in 2018, Lilly terminated the deal.

Mersana Therapeutics was one of the most active ADC-focused biotechs in 2022, inking two $1 billion-plus partnerships with pharma companies. The largest deal, and potentially the third-most valuable ADC deal in 2022, saw GlaxoSmithKline paying $100 million upfront in an option deal for Mersana's preclinical-stage XMT-2056, which could bring up to $1.36 billion more in option exercise payment, development, regulatory and commercial milestones.[23] XMT-2056 is an Immunosynthen ADC that targets a novel epitope of HER2, designed to activate the innate immune system through STING signaling in both tumor-resident immune cells and in tumor cells.

Earlier in the year, Mersana signed an agreement worth up to $1 billion with Johnson & Johnson's Janssen Biotech to research and develop antibody-drug conjugates (ADCs) for three cancer targets. Janssen paid $40 million up front and may have to pay an additional $1 billion in potential milestone payments. Janssen will provide proprietary antibodies for three targets and Mersana will use its Dolasynthen technology.

Bay Area biotech Sutro BioPharma is developing immunostimulatory ADCs (iADCs), a next generation modality with the potential for effective and efficient approaches for treatment of cold tumors so as to bring new drug therapies to patients who do not respond to existing therapies. Sutro signed an exclusive global licensing deal with Astellas to develop iADCs for three biological targets selected by the Japanese pharma company.[24] Sutro received an up-front payment of $90 million for the three targets and is eligible for up to $422.5 million in milestone payments for each potential candidate, as well as tiered royalties ranging from the low double-digits to mid-teens.

Earlier in the year, Mersana signed an agreement worth up to $1 billion with Johnson & Johnson's Janssen Biotech to research and develop antibody-drug conjugates (ADCs) for three cancer targets.

Harnessing the power of data

Among pharma there is significant debate about the potential impact artificial intelligence and machine learning (AI/ML) may have in improving the economics of research and development. Through partnering, pharma companies can gain access to AI technology, data and data scientists and engineers.

One of the most active pharma companies in 2022 partnering with AI/ML companies was the French pharma giant Sanofi, which inked three of the four most valued deals in 2022. In addition to building an internal data science capability, Sanofi has also established some marquee relationships with AI/ML companies.

In the largest partnering deal involving AI/ML assets, one building on an existing six years of working together, Sanofi and U.K.-based Exscientia unveiled a ground-breaking research collaboration and license agreement to develop up to 15 novel small molecule candidates across oncology and immunology that leverages Exscientia's end-to-end AI-driven platform using actual patient samples.[25] Exscientia was paid $100 million upfront and has the potential of earning up to $5.2 billion in total milestones, plus tiered royalties from the deal. The partners will collaborate using Exscientia's AI platform for target identification and design of drugs, through to patient selection for trials.

Sanofi and U.K.-based Exscientia unveiled a ground-breaking research collaboration and license agreement to develop up to 15 novel small molecule candidates.

Exscientia will lead small molecule drug design and lead optimization activities all the way up to development candidate nomination. Sanofi will then take responsibility for preclinical and clinical development, manufacturing and commercialization. The companies have been working together since 2016. In 2019, Sanofi in-licensed Exscientia's novel bispecific small molecule candidate capable of targeting two distinct targets in inflammation and immunology.

Sanofi also secured the drug discovery capabilities of Hong Kong-based clinical-stage AI-driven drug discovery company Insilico Medicine.[26] The multi-year, multi-target strategic research collaboration will leverage Insilico Medicine's Pharma.AI platform to advance drug development candidates for up to six new targets. The collaboration with Insilico is also expected to boost the discovery efforts of the Sanofi Institute for Biomedical Research, the company's R&D center in Mainland China.

Under the terms of the agreement, Sanofi will pay Insilico Medicine up to $21.5 million, covering upfront and target nomination fees, to access Insilico's Pharma.AI and gain access to a team of interdisciplinary drug discovery scientists, with the aim of identifying, synthesizing, and advancing high-quality lead therapeutic compounds up to the development candidate stage. Additional payments of up to $1.2 billion will be made if key research, development and sales milestones are met. The collaboration also establishes mid-single to low double-digit tiered royalties for resulting products.

In a third strategic and exclusive research collaboration, Sanofi agreed to pay San Francisco-based Atomwise a $20 million upfront to leverage its AtomNet platform for computational discovery in order to identify, synthesize, and advance lead compounds for up to five targets.[27] Subsequent payments pegged to key research, development, and sales milestones could total more than $1 billion. In addition, tiered royalties have been established for products developed through the collaboration.

Amgen agreed to combine its expertise in engineering protein-based therapies with Generative Biomedicine's machine learning-enabled drug generation platform to discover and create protein therapeutics for five clinical targets across several therapeutic areas and multiple modalities.[28] As part of the research collaboration, Amgen will pay $50 million in upfront funding for the initial five programs, with a potential transaction value of $1.9 billion plus future royalties, as well as the option to nominate up to five additional programs at additional cost. For each program, Amgen will pay up to $370 million in future milestones and royalties up to the low double digits.

In a bid to build, expand and refine its biologics capabilities, Merck & Co. signed a deal to access Absci's Bionic Protein platform to design new biologic candidates and explore the expression of complex proteins.[29] Under the terms of the collaboration, Absci will deploy its Bionic Protein™ non-standard amino acid technology to produce enzymes tailored to Merck's biomanufacturing applications and will receive an upfront and certain other milestone payments. In addition, Merck has the option to nominate up to three targets and enter into a drug discovery collaboration agreement. Absci is eligible to receive up to $610 million in upfront fees and milestone payments for all three targets, as well as research funding and tiered royalties on sales.

The challenge for big pharma is to identify those AI/ML businesses that can genuinely have an impact on drug discovery and development. The size of the upfront fees and potential size of the milestone payouts is testament to the dearth of pharma-ready businesses and the appetite for AI/ML companies and their data management capabilities. While pharma companies will continue to pursue marquee partnerships and self-contained capability builds, it is essential that the big pharma companies learn how to embed AI/ML approaches into all parts of their businesses for these collaborations to bear fruit.

Leading AI/ML biopartnerships in 2022 by total potential value

Principal	Partner	Therapy Area	Potential value ($ millions)	Date
Exscientia	Sanofi	Oncology/ immunology	$5,300	01/07/2022
Generate Biomedicines	Amgen	Various	$1,900	01/06/2022
InSilico Medicine	Sanofi	Various	$1,220	11/08/2022
Atomwise	Sanofi	Various	$1,020	08/18/2022
Absci Corporation	Merck & Co.	Not disclosed	$0.610	01/07/2022

Source: BioWorld

Cell therapy platforms maintain their allure for pharma

Aiming to access next generation cell therapy opportunities, Roche inked a research collaboration with Poseida Therapeutics to develop off-the-shelf, or allogeneic, CAR-T cell therapies to address medical needs for patients with certain blood cancers.[30]

The global pact covers multiple existing and novel off-the-shelf cell therapies against targets in multiple myeloma, B-cell lymphomas and other indications.

Under the agreement, Poseida will receive $110 million upfront and could receive up to $110 million in near-term milestones and other payments in the next several years. In addition, Poseida is eligible to receive research, development, launch, and net sales milestones and other payments worth up to $6 billion, as well as tiered net sales royalties into the low double digits, across multiple programs.

Roche gets from Poseida either exclusive rights or options to develop and commercialize a number of allogeneic CAR T programs in Poseida's portfolio, including P-BCMS-ALLO1, an allogeneic CAR T for multiple myeloma under phase I investigation, and P-CD19CD20-ALLO1, an allogeneic dual CAR T for B-cell malignancies. Terms of the contract also include tiered net sales royalties in the low double digits.

Bristol Myers Squibb confirmed its commitment to developing next generation cell therapies across a number of deals during 2022. The largest in potential value is a deal that expanded its relationship with Immatics, initiated by Celgene before its acquisition by BMS.[31] Utilizing Immatics' gamma delta T cell-derived, allogeneic Adoptive Cell Therapy platform, ACTallo, and a suite of next-generation technologies developed by Bristol Myers Squibb, the companies will develop two programs owned by BMS, with both companies having an option to develop up to four additional programs each.

Under the terms of this agreement, Immatics received an upfront payment of $60 million and the promise of up to $700 million per Bristol Myers Squibb program through development, regulatory and commercial milestone payments, as well as tiered royalty payments of up to low double-digit percentages on net product sales. Immatics will be responsible for preclinical development of the initial two Bristol Myers Squibb-owned programs and will receive additional payment for certain activities that Immatics could perform at BMS's request. Bristol Myers Squibb will assume responsibility for clinical development and commercialization activities of all BMS-owned programs thereafter.

In addition, Bristol Myers Squibb and Immatics will expand their 2019 collaboration agreement focused on autologous T-cell receptor-based therapy (TCR-T), with the inclusion of one additional TCR target discovered by Immatics. As part of this expansion, Immatics will receive an upfront payment of $20 million and be eligible for milestone payments and royalties.

Bristol Myers Squibb also signed a deal to bring together Century Therapeutics iPSC-based gamma delta T and NK cell platforms with the U.S. pharma's expertise in cell therapy and oncology drug development, with the aim of developing potentially best-in-class allogeneic cell therapies to help patients with hematologic and solid tumor malignancies.[32] As part of the deal, described by Bristol Myers Squibb as an important part of its investment strategy in next-generation cell therapies for hematologic and solid tumors, Century Therapeutics received both a $100M upfront payment and $50M equity investment from Bristol Myers Squibb, with potential for additional $3 billion in payments plus royalties on global net product sales across multiple programs.

While most cell therapy deals focus on various cancers, Bristol Myers Squibb also showed its ambition to develop cell therapies for other indications. Bristol Myers Squibb and GentiBio agreed to develop new engineered regulatory T-cell (Treg) therapies to re-establish immune tolerance and repair tissue in patients living with inflammatory bowel diseases (IBD).[33] The partnership applies GentiBio's modular engineered Treg platform and scalable manufacturing process to produce stable and disease-specific engineered Tregs against multiple targets. Bristol Myers Squibb has the right to develop and advance up to three of the resulting programs into clinical trials. GentiBio received an undisclosed upfront cash payment and could be eligible for up to $1.9 billion in potential future development and commercial milestones and royalties.

In a deal highlighting how biotechs can gain more than hard cash through bio partnerships, Arcellx and Kite Pharma agreed a global strategic collaboration to co-develop and co-commercialize Arcellx's lead late-stage product candidate, CART-ddBCMA, for the treatment of patients with relapsed or refractory multiple myeloma.[34] While the deal enables Gilead Sciences' Kite to expand into a new area of high unmet need, Arcellx will advance its commercialization ambitions by tapping into Kite's highly coordinated, vertically integrated organization from R&D to commercialization to manufacturing to deliver cell therapy globally and at scale.

Under the terms of the deal, Arcellx received an upfront cash payment of $225 million and a $100 million equity investment from Kite, as well as other potential contingent payments. The companies will share development, clinical trial, and commercialization costs for CART-ddBCMA and will jointly commercialize the product and split U.S. profits 50/50. Outside the U.S., Kite will commercialize the product and Arcellx will receive royalties on sales. Kite will be responsible for the development and commercialization costs for any product under the collaboration that is not co-commercialized. After completion of the technical transfer, Kite will be responsible for manufacturing.

While pharma is ramping up its investment in cell therapy, the technology is still in its infancy. Pharma companies still need to explore ways of developing allogeneic cell therapies at scale, as well as devising more cost-efficient manufacturing processes. Companies that are able to find solutions to these challenges and/or create next generation cell therapies will be attractive partnering targets for the foreseeable future.

Leading cell therapy biopartnerships in 2022 by total potential value

Principal	Partner	Therapy Area	Potential value ($ millions)	Date
Poseida Therapeutics	Roche	Cancer	$6,220	08/032022
Immatics	Bristol Myers Squibb	Cancer	$4260.00	06/02/2022
Arcellx	Kite Pharma	Various	$4225.00	12/09/2022
Century Therapeutics Inc.	Bristol Myers Squibb Co	Cancer	$3090.00	01/07/2022
Gentibio Inc.	Bristol Myers Squibb Co	Inflammation	$1900.00	08/10/2022

Source: BioWorld

Scratching the surface of bispecific antibody potential

Advances in antibody engineering have enabled bispecific antibodies, once thought too complex to have therapeutic potential, to become a critical field of biopharma innovation.

This class of therapeutics made its market debut in 2014, when the FDA approved Amgen's blinatumomab — a CD19- and CD3-targeting bispecific antibody for acute B-cell lymphoblastic leukemia. In 2022, the FDA approved four bispecific antibodies – Genentech's faricimab and mosunetuzumab, Immuocore's tebentafusp and Janssen's teclistamab.

With such regulatory and clinical validation, it is not surprising that bispecific antibody technology companies are, and will remain, an attractive target for specialty pharma companies looking to expand their offerings. For the biotechs developing bispecific antibodies, these deals provide a clearer route to market as they tap into their partners' development and commercialization expertise.

The largest bispecific antibody deal in 2022 was transacted by Summit Therapeutics, which in-licensed Akeso BioPharma's breakthrough bispecific antibody, ivonescimab.[35] Known as AK112 in China and Australia and as SMT112 in the United States, Canada, Europe, and Japan, ivonescimab is a novel, potential first-in-class bispecific antibody combining the effects of immunotherapy via a blockade of PD-1 with the anti-angiogenesis effects associated with blocking VEGF into a single molecule. It is also a follow-up to Akeso's PD-1/CTLA-4 bispecific Kaitanni for metastatic cervical cancer, which has been approved for use in Mainland China.

In return for a $500 million upfront cash payment, and the promise of an extra $4.5 billion in regulatory and commercial milestones, Summit has secured the rights to develop and commercialize ivonescimab in the United States, Canada, Europe, and Japan, with a view to first testing the bispecific antibody in non-small cell lung cancer (NSCLC) indications. Australian biotech Akeso will be eligible for low double-digit royalties on net sales in the Summit Therapeutics markets, while retaining development and commercialization rights for the rest of the world, including Mainland China.

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Sanofi was also highly active in building out it's bispecific antibody activities through partnerships. The company signed up Adagene to develop masked versions of Sanofi candidate antibodies, using Adagene's SAFEbody technology.[36] While Adagene will be responsible for the early-stage activity, Sanofi will be solely responsible for later stage research and all clinical, product development and commercialization activities.

While Sanofi only made an upfront payment of $17.5 million to Adagene and will have the ability to advance two initial Sanofi antibody candidates in the collaboration, followed by an option for two additional candidates, Adagene will be eligible to receive total potential development, regulatory and commercial milestone payments of up to $2.5 billion for advancement of the candidates, which will be exclusively

developed and commercialized by Sanofi. Adagene will also be eligible to receive tiered royalties on global net sales of approved collaboration products.

Other bispecific deals signed by Sanofi in 2022 included an expansion of an earlier 2016 deal with Innate Pharma exploring the potential of NK cells for cancer immunotherapy,[37] a key pillar for its oncology strategy, and a collaboration with ABL Bio to develop a potential first-in-class bispecific antibody targeting alpha-synuclein and containing a proprietary brain shuttle, for alpha-synucleinopathies, including Parkinson's disease.[38]

Sanofi licensed a natural killer (NK) cell engager program targeting B7H3 from Innate's ANKET™ (Antibody-based NK Cell Engager Therapeutics) platform. Sanofi will also have the option to add up to two additional ANKET™ targets. Upon candidate selection, Sanofi will be responsible for all development, manufacturing and commercialization. Under the terms of the new license agreement, Innate received €25 million upfront payment and up to €1.35 billion total in preclinical, clinical, regulatory and commercial milestones plus royalties on potential net sales.

Sanofi signed an exclusive collaboration and worldwide license agreement with South Korea's ABL Bio to develop and commercialize ABL301, a pre-clinical stage bispecific antibody targeting alpha-synuclein and IGF1R, to treat Parkinson's disease and other potential indications with enhanced blood-brain barrier (BBB) penetration. Sanofi paid $75 million up front, with ABL Bio eligible for an additional $985 million based on the achievement of predefined development, regulatory and commercialization milestones, as well as royalties on net sales of any resulting commercialized products.

Fulfilling its desire to expand its oncology portfolio with novel late-stage asset with compelling anti-tumor activity, Jazz Pharmaceuticals secured exclusive development and commercialization rights to Zymeworks' zanidatamab across all indications in key markets including the U.S., Europe and Japan.[39] Zanidatamab is a novel HER2-targeted bispecific antibody with biparatopic binding and the potential to transform the current standard of care in multiple HER2 expressing cancers. For Canada's Zymeworks, apart from the funding, the deal brings a wealth of development and commercial experience in oncology. Zymeworks received $50 million upfront payment, with the possibility of receiving further regulatory and commercial milestones for total potential payments of up to $1.76 billion, plus royalties on net sales.

Abpro, a Massachusetts-based clinical stage biotech, sought the help of South Korea's Celltrion to further develop and commercialize ABP 102, a bispecific antibody therapy for patients suffering from HER2+ cancer, including breast, gastric, and pancreatic cancer.[40] Through this global partnership, Abpro will receive payments from Celltrion of up to $1.75 billion, including an equity investment, development and commercial milestone payments and worldwide profit sharing. Celltrion will be in charge of the development of ABP 102 following the completion of in vitro studies by Abpro and will have world-wide commercialization rights.

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In what would have been welcome news for cash-strapped MacroGenics, Gilead Sciences, which is using partnering as a means to grow its cancer pipeline in pursuit of a goal to accrue more than 20 indication approvals by 2030, secured an exclusive option to license MGD024, as well as opening the door for the companies to collaborate on two additional future research programs.[41] MGD024 is a Phase 1 CD123xCD3 DART bispecific antibody with the potential to treat various hematologic malignancies. The molecule incorporates a CD3 component that is designed to minimize cytokine-release syndrome, a potentially life-threatening toxicity, while increasing the magnitude of antitumor activity with a longer half-life to permit intermittent dosing.

Under the terms of the deal, MacroGenics, which a few months earlier had announced a 15% reduction in staffing levels and other cost-saving measures to focus on key clinical programs and extend its cash runway, received an upfront payment of $60 million from Gilead and will be eligible for up to $1.7 billion in target nomination, option fees, and development, regulatory and commercial milestones, plus tiered, double-digit royalties on worldwide net sales of MGD024 and a flat royalty on worldwide net sales of products under the two research programs.

Leading bispecific antibody bio partnerships in 2022 by total potential value

Principal	Partner	Therapy Area	Potential value ($ millions)	Date
Akeso Biopharma	Summit Therapeutics	Cancer	$5,000	12/06/2022
Adagene Suzhou	Sanofi	Cancer	$2,517	03/02/2022
Zymeworks	Jazz Pharmaceuticals	Cancer	$1,762	10/19/2022
Abpro Corp.	Celltrion	Cancer	$1,760	09/21/2022
MacroGenics	Gilead Sciences	Cancer	$1,760	10/17/2022

Source: BioWorld

In search of next generation RNA technologies

With the mRNA COVID-19 vaccines demonstrating proof of concept for the technology, it will be of no surprise that pharma is keen to access next generation RNA platforms that can overcome some of mRNA's limitations, including getting the therapeutic to the desired tissue, at the right concentrations, while limiting toxic effects.

One of the most promising platforms is the use of self-amplifying RNAs derived from the genomes of positive-strand RNA viruses. This was the focus of the most valuable deal of 2021, when AstraZeneca inked an option potentially worth more than $5 billion, with U.K. start-up VaxEquity, to collaborate on up to 26 drug targets and further develop the saRNA platform.[42] In 2022, the most valuable RNA platform partnership saw CSL-Sequirus pay Arcturus $200 million up front and offer more than $4 billion in potential development and commercial milestones for influenza, pandemic preparedness and three additional respiratory infectious disease vaccines.[43]

The pact seeks to combine Arcturus' saRNA vaccine technologies with CSL's capabilities as a commercial scale manufacturer and global distributor of influenza and pandemic vaccines. The deal also provides Arcturus with a 40% profit share for COVID-19 vaccines, up to double digit royalties for influenza, pandemic preparedness and three additional respiratory infectious disease vaccines.

In a bid to beef up its oligonucleotide-based pipeline, GlaxoSmithKline announced a strategic collaboration with Wave Life Sciences to advance oligonucleotide therapeutics including Wave's preclinical RNA editing program targeting alpha-1 antitrypsin deficiency (AATD), WVE-006.[44] The discovery collaboration, with an initial four-year research term, seeks to combine GlaxoSmithKline's insights from human genetics as well as its global development and commercial capabilities with Wave's proprietary discovery and drug development platform PRISM to advance eight GSK programs and three from Wave.

Under the terms of the agreement, Wave received an upfront payment of $120 million plus a $50 million equity investment. For WVE-006, Wave is eligible to receive up to $225 million in development and launch milestone payments and up to $300 million in sales-related milestone payments, as well as tiered sales royalties. Development and commercialization responsibilities will transfer to GlaxoSmithKline after Wave completes the first-in-patient study.

For each of GlaxoSmithKline's eight collaboration programs, Wave will be eligible to receive up to $130-$175 million in development and launch milestones and $200 million in sales-related milestones, along with tiered sales royalties. Wave will lead all preclinical research for GlaxoSmithKline and Wave programs up to investigational new drug (IND)-enabling studies. GlaxoSmithKline collaboration programs will transfer to GSK for IND-enabling studies, clinical development, and commercialization. The collaboration includes an option to extend the research term for up to three additional years, expanding the number of programs available to both parties.

Another RNA technology that is getting traction is so-called circular RNA, which has the potential for being more stable than regular RNA because cellular nucleases that attack linear RNA from the ends are unable to do so. Merck & Co. inked a deal with Orna Therapeutics, a developer of engineered circular RNA (oRNA) therapies, to discover, develop, and commercialize multiple programs, including vaccines and therapeutics, in the areas of infectious disease and oncology.[45]

Under the terms of the deal, Orna received a $150 million upfront from Merck, and is eligible to receive up to $3.5 billion in development, regulatory, and sales milestones associated with the progress of the multiple vaccine and therapeutic programs, as well as royalties on any approved products derived from the collaboration. Orna will retain rights to its oRNA-LNP technology platform and will continue to advance other wholly-owned programs in areas such as oncology and genetic disease. Merck also invested $100 million in Orna's recent Series B financing.

Having invested $700 million to build a state-of-the-art facility at Boston Seaport as part of plans to advance its RNA-based research and development activities, Eli Lilly & Co. signed a number of RNA platform deals, including an expanded agreement with ProQR NV.[46] The deal gives Lilly access to additional targets in the central nervous system and peripheral nervous system using ProQR's next-generation RNA base editing technology Axiomer platform.

Based on its original September 2021 agreement and the expanded agreement announced today with Lilly, in total, ProQR is eligible to receive up to approximately $3.75 billion in research, development and commercialization milestones, as well as tiered royalties of up to mid-single digit percentage on product sales.

With a number of big ticket initiatives around the RNA space already in play, including the 2021 $3.2 billion acquisition of Translate Bio and a commitment to invest some $2.2 billion in RNA capabilities, including $1 billion earmarked for a global center of excellence in France, Sanofi continues to be on the hunt for platforms that complement its own efforts. In a transaction worth potentially just over $2 billion, Sanofi is looking to leverage Skyhawk Therapeutics' proprietary SkySTAR platform, integrating proprietary computational biology tools, kinetic models, and conformational structural models of RNA, in order to discover and develop novel small molecules that modulate RNA splicing to address challenging oncology and immunology targets.[47]

RNA-based drugs are known to possess many advantageous traits that make them ideal candidates as novel therapeutics. They can home in on previously undruggable targets; they are easier to design and make than other molecules, at potentially lower cost; modifications can make them more stable; and unlike DNA-based therapeutics delivered by viral vectors, there are no significant risks of genotoxic effects. Consequently, the search for next generation RNA technology platforms can be anticipated to remain high on the partnering wish list of pharma companies for quite some time.

Leading RNA technology biopartnerships in 2022 by total potential value

Principal	Partner	Therapy Area	Potential value ($ millions)	Date
Arcturus Therapeutics Holdings	CSL Sequirus	Infectious diseases	$4,500	11/01/2022
Wave Life Sciences	GlaxoSmithKline	Various	$3,695	12/13/2022
Orna Therapeutics	Merck & Co.	Various	$3,650	10/16/2022
ProQR Therapeutics	Eli Lilly & Co.	CNS	$2,625	12/22/2022
Skyhawk Therapeutics	Sanofi	Oncology/ Immunology	$2,054	07/05/2022

Source: BioWorld

Learnings for an uncertain time

The rapid devaluation of biotechs, compounded by the collapse of Silicon Valley Bank, has brought about a role reversal in which biotechs, recently flush with capital, are looking at some lean years while pharmas hold all the leverage in the relationship. However, the fundamental dynamic underpinning these companies remains: they need each other in order to keep pipelines producing innovative medicines. Here are our key takeaways:

For biotechs:

- **Plan for three-to-four years of scarcity**, based on past market corrections. A multiyear capital drought means biotechs will have to be more strategic in terms of portfolio management and dealmaking. Capital efficiency becomes an existential challenge, forcing companies to prioritize opportunities carefully and opt for areas of greatest unmet medical need over low-hanging commercial and regulatory fruit.
- **Identify large pharmas on the hunt for partnerships in your area of focus.** Pharmas will be more conservative in their investments going forward, but they will be opening their purses for access to technologies and platforms that offer the promise of differentiated solutions.
- **Hold on to the value of your assets** by aligning your products and services to burden of disease and ensuring a clear course to market approval and reimbursement. Understand the competitive landscape and pursue niche offerings that will provide clear patient benefits and prove attractive to pharmas, regulators and payers.

Biotechs are the engine of innovation in the pharmaceutical industry and if they aren’t supported through this drought in funding, large pharma pipelines will dry up as surely as did venture capital for startups as the pandemic wound down.

For pharmas:

- **Don't sit on the sidelines holding your cash.** Biotechs are the engine of innovation in the pharmaceutical industry and if they aren't supported through this drought in funding, large pharma pipelines will dry up as surely as did venture capital for startups as the pandemic wound down. Accessing technologies like antibody drug conjugates, cell and gene therapies and AI/machine learning is no less essential to pharma's future than it was when the tiller was open and the mood among financial types was frothy.
- **Keep an eye on the cutting edge of medicine.** With payers under enormous pressure to cut costs and U.S. regulators opening the door to direct price negotiations for some Federal benefit programs, me-too products just won't cut it anymore. Understanding where the market is likely to be five or ten years out is mission critical, and that means staying abreast of which research is attracting the most citations, which areas are attracting the most new patent applications, which establishments or organizations are centers of excellence and what metrics regulators and HTA councils are weighting the most. Don't hold out for fire sale prices if you see an opportunity – competitors might get there first.
- **East-West geopolitical dynamics are bleeding over into the life sciences.** Recent months have seen a string of Mainland China-based biotechs establishing outposts in Europe at a time of tensions between the governments of China and the United States. Companies in this fast-expanding market are increasingly pacing their Western counterparts when it comes to innovation and are seeking partners as they look to market their products globally.

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