

A complex path forward

Beyond Borders:
EY Biotechnology Report 2023



Building a better
working world

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To our clients and friends



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This 33rd edition of our Beyond Borders report sees the US and European biotechnology (biotech) industry seeking a new path forward. At the time of publication in mid-2023, the priorities of biotech companies will vary based on the level of their commercial maturity. Biotech commercial leaders (companies with at least US\$500 million in annual revenue), along with their big pharma counterparts, are in dire need of addressing innovation deficits and in search of new revenues to offset the massive wave of pending patent expirations. On the other end of the spectrum, emerging biotechs face a capital-constrained operating environment and are wholly focused on getting to the next value inflection point with minimal cash burn. However, the handful of fortunate emerging biotechs with de-risked, late-stage assets will likely attract lucrative multiples for partnering or outright acquisitions. These dynamics together mean a complex path forward for the biotech industry as a whole.

The biotech industry must navigate this complex path forward by driving efficient capital allocation and streamlining its core operations, from research and development to supply chain to commercial operations, while trying to maximize organic and inorganic growth through the use of M&A and alliances. Despite these challenges, biotech's deep capabilities around innovation and the importance of its product offerings mean the industry still maintains a favorable mid- to long-term outlook. Companies that focus on the fundamentals will be poised to lead the next phase of expansion once the impact of the recessionary environment and tighter monetary policies subsides.

Amid surging product demand and investor focus on the sector, biotech performed extraordinarily well during the early waves of the global chaos caused by the COVID-19 pandemic by attracting an influx of new capital. By early 2022, however, the stimulus to the biotech market was fading fast. In the previous edition of this report, we wrote: "the financial environment for biotech has significantly shifted in the opening months of 2022, with valuations plunging and the IPO window closing." This shift has since continued and intensified, with biotech now facing reduced capital availability in a landscape of higher interest rates, tightening credit conditions, and broader macroeconomic and geopolitical disruption. Moreover, the industry is bracing for a tougher regulatory environment in the wake of the US Inflation Reduction Act (IRA), as well as the action taken by the US Federal Trade Commission (FTC) to block Amgen's acquisition of Horizon Therapeutics. The IRA will have significant implications for how the industry secures reimbursement for its innovation in the future, while the FTC's activity is generating major concerns that regulation will stifle innovation by restricting therapies' ability to scale through acquisitions by larger biopharma companies. By all measures, from revenues to financing, M&A investment and beyond, biotechs experienced declining performance and increasing challenges in 2022.

However, despite these challenges, the industry's capacity to innovate as a whole remains robust. Biotech R&D continues to fuel an innovation renaissance in new biopharma products and platforms, and the pandemic emergency served to highlight the strategic importance of the sector to national and international health and security. As always, there will be winners and losers within the sector. Good science leading to differentiated products will always be the key to success in this R&D-driven industry, but as they plan ahead, biotechs must recognize the need to supplement scientific excellence with a strategic focus on achieving operational efficiency in all areas of the business.

The life sciences have changed beyond all recognition over the past century, yet the rate of change is now accelerating as the technologies to enable a data-driven intelligent health ecosystem begin to penetrate the industry. As companies seek the right model for future growth, they must also be mindful of this underlying turn toward a digitalized, data-driven, personalized care system. Companies that can best adapt to the current changing conditions, combining cutting-edge innovation with a newly tightened focus on efficiency and resilience in business fundamentals, will emerge from the downturn strengthened and in a position to drive the next wave of growth for the biotech industry as it evolves toward a smarter, more personalized future.



The year in review

The biotech industry must navigate this complex path forward by driving efficient capital allocation and streamlining its core operations, from research and development to supply chain to commercial operations, while trying to maximize organic and inorganic growth through the use of M&A and alliances.



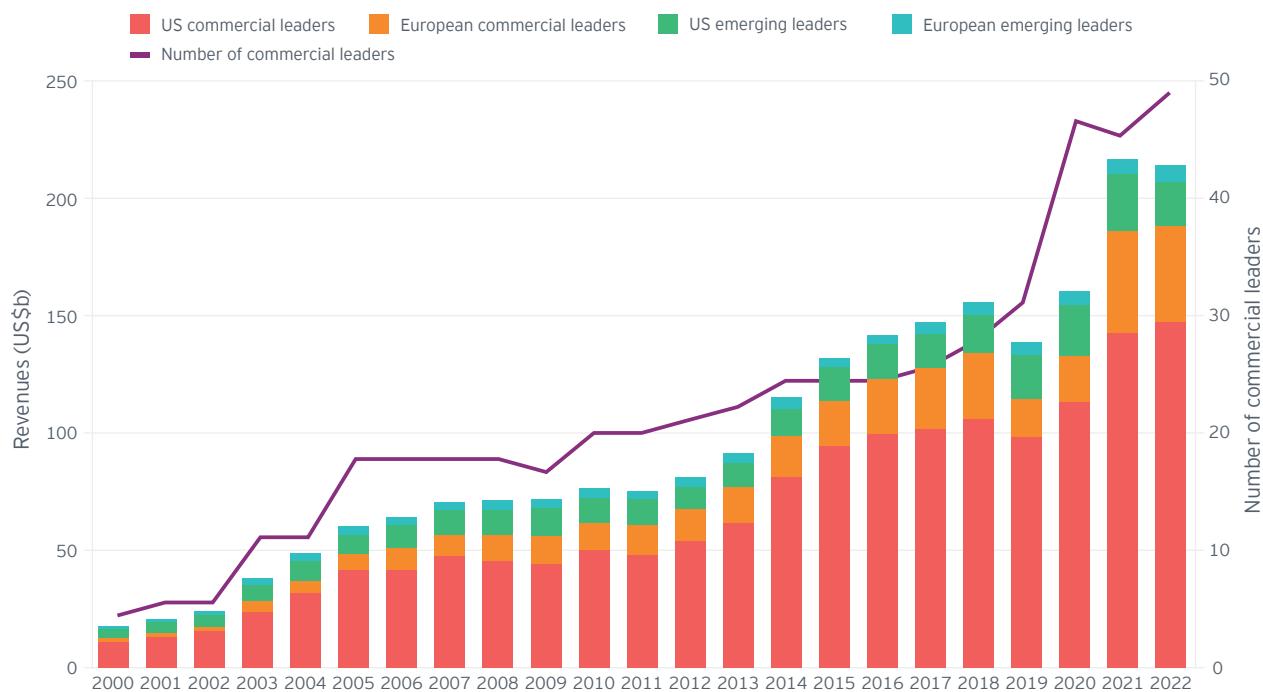
After a huge revenue surge in 2021, driven by the booming market for COVID-19 vaccines, therapies and testing, biotech's growth normalized in 2022. Public biotech companies in the US and Europe collectively amassed revenues of US\$215 billion in 2022, down 1% from the previous year (see Figure 1). Two of the largest biotechs, BioNTech and Gilead Sciences, saw revenues fall due to declining demand for their COVID-19 vaccine and antiviral treatment, respectively, while Regeneron's loss of emergency use authorization and funding from the US government resulted in a US\$5.8 billion decline in sales of its REGEN-COV treatment.

However, aside from the headwinds caused by the reduction in short-term demand for these pandemic-related products, the underlying industry maintained a stable growth trajectory. While the 1% revenue dip seen in 2022 is a stark contrast to the 35% growth registered in 2021, this dramatic change is almost entirely driven by fluctuations in demand for COVID-19 vaccines, antivirals and other products. Without the revenue impact of COVID-19 products in the portfolios of five leading biotechs alone, the industry's revenues inched forward 3.7% in 2022, compared with 5.2% growth in 2021. As such, biotech's fundamentals are expected to weather the current storm, and the industry's continued growth should provide some much-needed reassurance as the broader biopharma industry braces itself to confront another major challenge in the form of a steep patent cliff rapidly approaching in 2023.

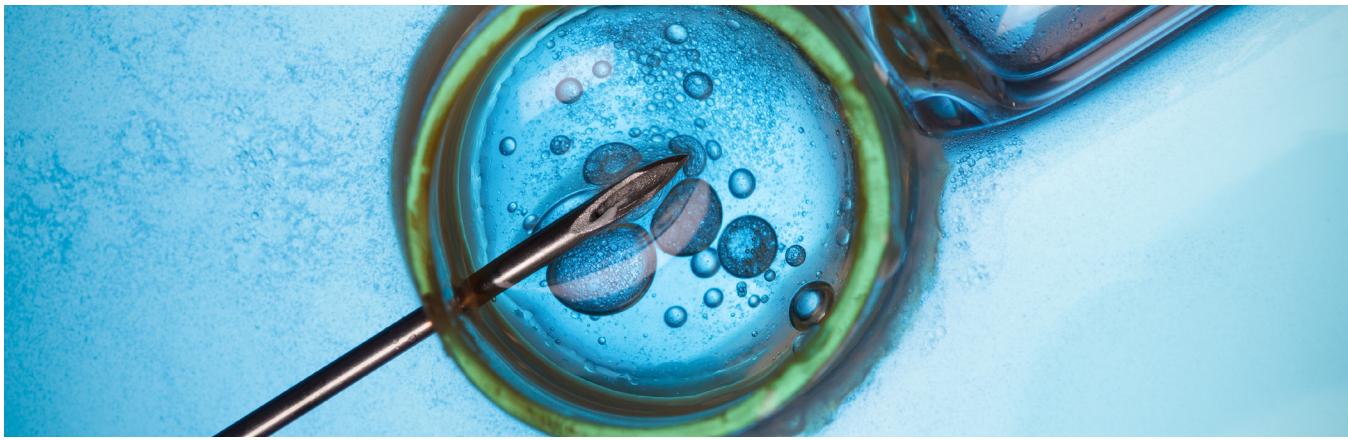
US\$215b

2022 revenue for US and European public biotech companies

Figure 1. US and European public company revenues, 2000-22



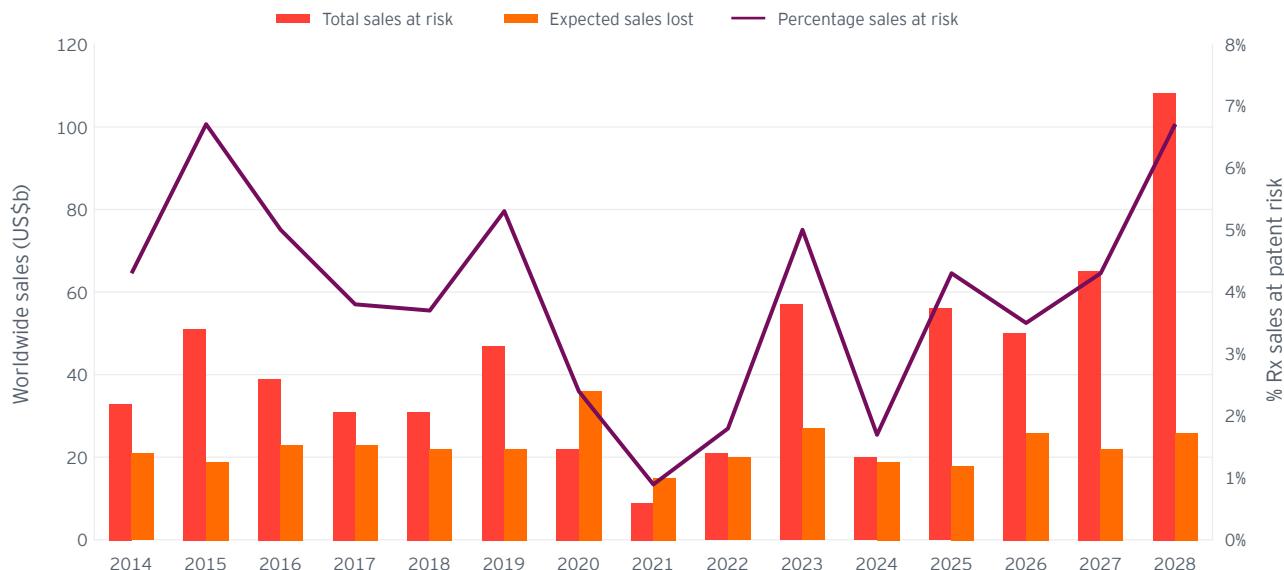
Sources: EY analysis, company reports
Commercial leaders are companies with revenues >=US\$500m



... the next 5 years will see another 17 products, currently representing over US\$145 billion in annual revenues, lose their patent protection ...

Early 2023 saw a landmark loss-of-exclusivity (LOE) event, with the US launch of Amgen's first biosimilar version of AbbVie's Humira (adalimumab), among the best-selling drugs¹ of all time. This event is just the beginning, as four other blockbuster monoclonal antibodies (mAbs) that commanded over US\$14 billion in total 2022 revenues are also facing LOE and biosimilar market challenges by the end of 2023. Further, the next 5 years will see another 17 products, currently representing over US\$145 billion in annual revenues, lose their patent protection and surrender market share to lower-priced competitors (see Figure 2). Since 2019, biosimilar uptake has reportedly soared in the US market, with biosimilar replacements of key oncology-branded mAbs such as Herceptin (trastuzumab) and Avastin (bevacizumab) crossing the 80% mark in the first half of 2022.

Figure 2. Historic and projected revenue erosion through loss of exclusivity, 2014-28



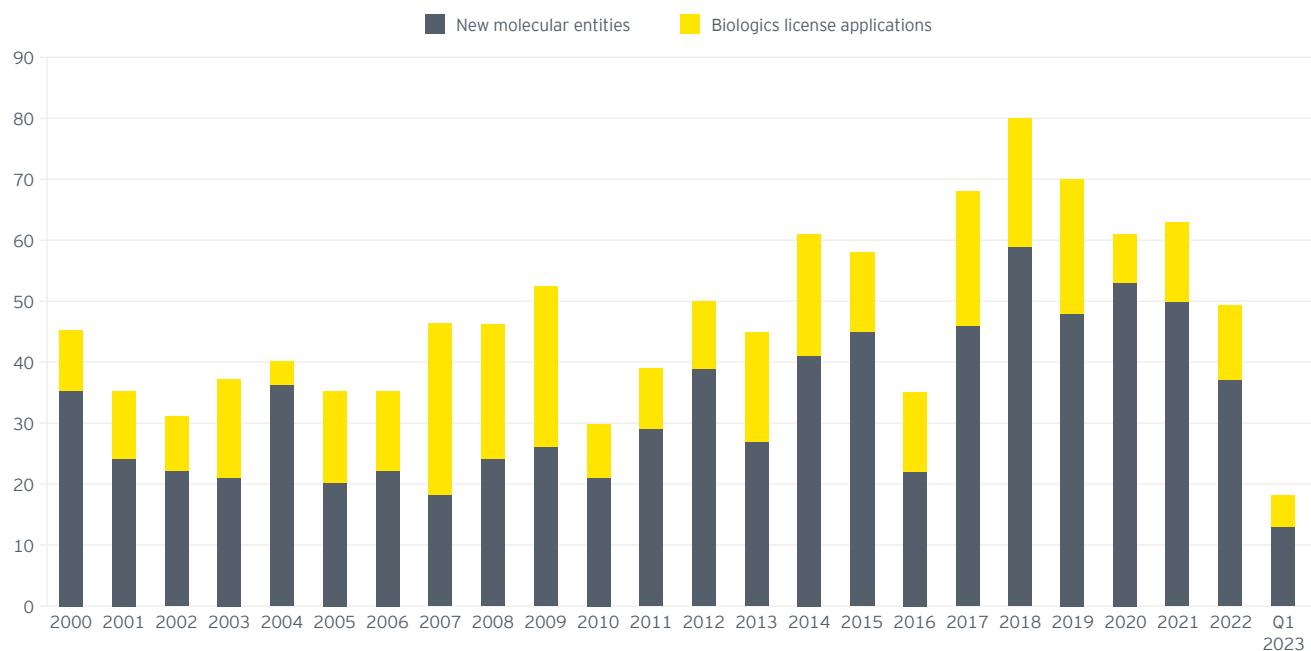
Sources: EY analysis, Evaluate Pharma (August 2022).

Total sales at risk refers to a product's annual revenue in the year before loss of exclusivity. Expected loss is the difference between that sales-at-risk number and the first full year of sales post expiry, as reported by companies for historic expiries or computed by Evaluate Pharma's consensus for those still to happen.

1. <https://www.statista.com/statistics/318206/revenue-of-humira>

Faced with the loss of these products' established income, the industry is confronting an innovation deficit and will be dependent on biotech's capacity to innovate and replenish lost revenues to sustain growth. The industry has enjoyed notable success in developing and launching new products in recent years, with an annual average of 69 US FDA approvals for new molecular entities (NMEs) and biologics license applications (BLAs) over the five-year period from 2017 to 2021. In 2022, the number of FDA approvals dropped to 49 (37 NMEs and 12 BLAs; see Figure 3).

Figure 3. US FDA product approvals, 2000-Q1 2023

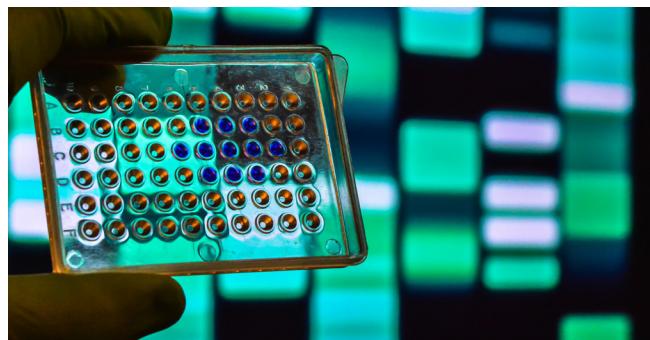


Sources: EY analysis, FDA website.

*Data for biologic license applications from 2000 through 2022; new molecular entities from 2011 through 2022

Note: For 2000 to 2011, NMEs include new biologics but exclude new indications, new formulations and generic drugs

Reportedly, the dip in approvals was primarily driven by staffing shortages at the FDA, which was seeking to fill over 400 jobs in 2021. By the third quarter of 2022, the number of advertised roles had dropped to nearly 50, encouraging hopes that the agency's approval and other regulatory processes will regain the momentum they lost during the pandemic crisis. The first quarter of 2023 did see a resurgence in approvals as 18 total products (13 NMEs and 5 BLAs) were authorized.

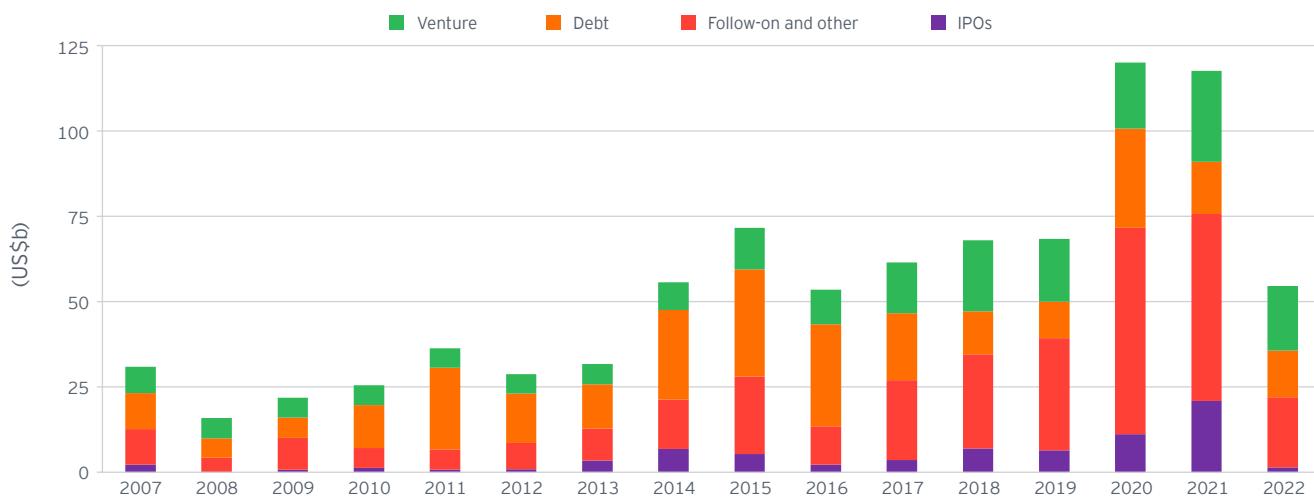




Despite the drop in approvals in 2022, biopharma innovation remains healthy. The clinical pipeline contains over 20,000 active drug candidates around the globe, according to one estimate.² Moreover, multiple new therapeutic modalities with high clinical and commercial potential are rapidly reaching maturity, with the list of new approvals for 2022 including, for example, new gene therapies developed by bluebird bio and CSL Behring. Cell and gene therapies are among the most prominent of the novel modalities, alongside new products developed through the mRNA platforms, new radiopharmaceuticals and the antibody-drug conjugates (ADCs), which made headlines in early 2023 when Pfizer agreed to acquire ADC specialist Seagen for US\$43 billion.

These genuinely innovative new platforms are widely seen as critical to the industry's strategies around negotiating the patent cliff and sustaining growth into the future. However, industry leaders will need to be mindful of the underlying health of the biotech sector, which largely fuels the sector's R&D engines. After highly productive financing for the industry in 2020 and 2021 (with the industry raising nearly US\$240 billion in two years), 2022 saw a 54% annual decline in the levels of capital available to the biotech sector in the US and Europe. The US\$54.6 billion raised in 2022 represented the lowest annual investment in the industry since 2016 (see Figure 4), but this figure is broadly in line with pre-pandemic expectations (indeed, if 2020 and 2021 are omitted, total financing for 2022 is similar to the industry's annual financing average over the previous decade). However, the two years of exceptionally high financing during the pandemic have created unusual conditions within the biotech sector, and companies must now adjust to the removal of those conditions.

Figure 4. Capital raised in the US and Europe, 2008-22 (US\$b)



Sources: EY analysis, Capital IQ and Dow Jones VentureSource.

2. "Pharma R&D Annual Review 2023," Pharma Intelligence website, pages.pharmaintelligence.informa.com/LDG_R-D_Review_2023.

The reduced levels of debt financing (down 10%) are a predictable response to rising interest rates. More concerning for smaller companies in the sector is the 63% drop in follow-on public offering capital raised, as well as the effective near disappearance of the biotech IPO market, which fell by 93% in 2022. By contrast, biotechs raised nearly US\$21 billion in IPO financing in 2021. With the subsequent major correction in biotech valuations that had soared during the initial phases of the COVID-19 pandemic, these newly public companies have seen significant challenges.

Of the 223 companies taken public in 2020 and 2021, and still publicly traded at the end of 2022, 91% of them saw their market value at IPO drop, with an average decline of more than 50%. Alongside the sharp reduction in follow-on funding, this sounds an ominous note for the long-term prospects for many of these newly launched companies.

Concerns over long-term viability extend beyond this group of newly public biotechs to the wider sector. Analysis suggests that as of 2022, 55% of emerging biotechs (companies with less than US\$500 million in annual revenue) held insufficient cash to sustain them for the next two years, with 29% having less than one year's cash remaining. This figure is an increase from 2021, when only 18% of biotechs had less than a year's cash in reserve, and it emphasizes the need for companies to keep a close eye on cash reserves.

Venture funding for the sector fell 29% in 2022, but the venture funding total of US\$18.9 billion remains well above the previous 10-year average. Further, a potential commitment of US\$3 billion went to the high-profile, longevity-focused startup Altos Labs – a huge outlier in terms of historic venture capital (VC) investment in the sector. While the ongoing injection of VC and private equity funding will help to sustain biotech's innovation ecosystem, investors are likely to pursue de-risking strategies such as targeting products that can deliver clinical or commercial validation sooner.



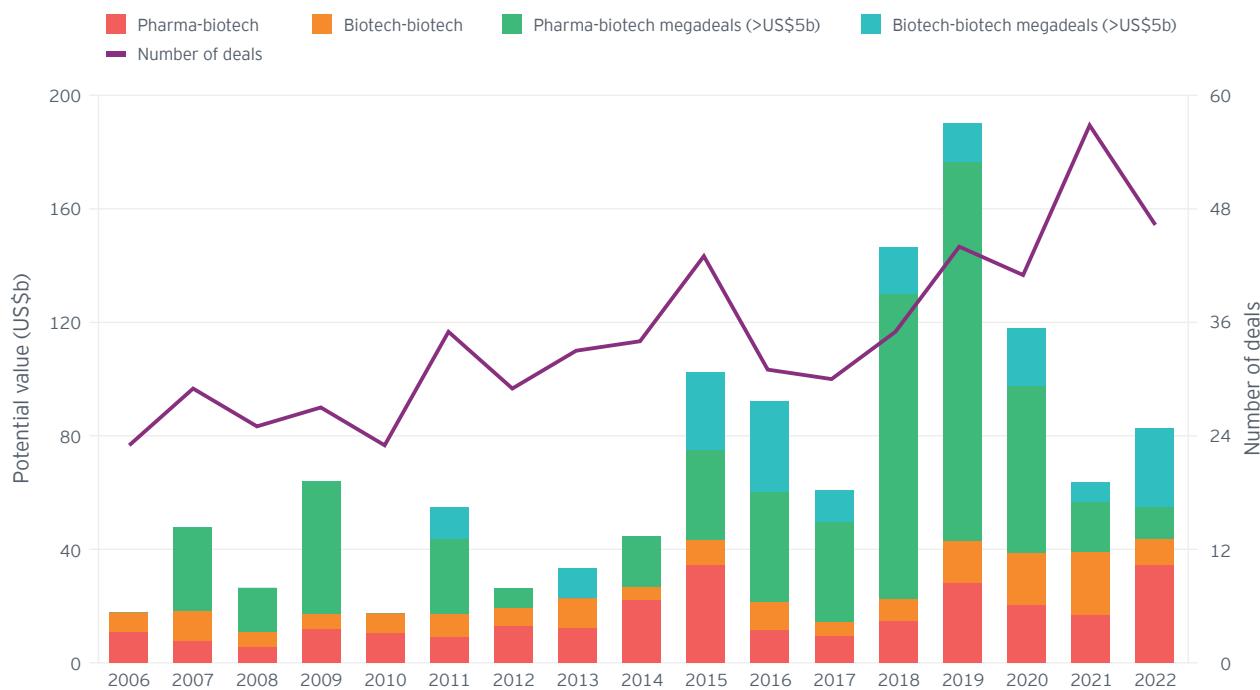
This shift in investment priorities may present challenges for new modalities, which are still seeking commercial validation since these platforms are likely to require novel infrastructure and manufacturing processes. As Lorence Kim, cofounder and managing partner at Ascenta Capital, notes, “with the emergence of new modalities, there are important questions around how you handle the scaling up of processes, capacity and availability.”

Biotechs and their investors continue to be impacted by a string of bank failures, most notably by Silicon Valley Bank (SVB), the bank of choice for many in biotech. While a catastrophe was largely avoided, early-stage biotechs need to revisit their liquidity policies and diversify their banking strategies. SVB's collapse has taught biotechs to spread their money across multiple startup-friendly banks rather than relying on only one. The bank's demise also leaves smaller biotechs without an alternative lender since many other banks have raised their funding thresholds to points that make investment difficult for smaller entities. SVB's absence may mean that fewer companies receive financing, and some biotechs may need to pare back pipelines of medicines in development. However, those companies with sound management and strong pipelines will continue to be funded.

The ongoing uncertainties in the geopolitical and global macroeconomic environment are likely to limit appetite for dealmaking in the near term ...

The constrained financing environment for small biotechs, particularly those focused on new modality platforms, highlights the importance of M&A for biotech. With lower capital availability, the obvious exit route for biotechs is to seek acquisition. However, the industry's larger players had little appetite for major dealmaking in 2022, with M&A investment increasing slightly compared with 2021 but still well below the levels witnessed between 2018 and 2020. Moreover, the total number of deals fell in 2022, with investment value heavily dependent on a few large-scale deals, most notably Amgen's US\$27.8 billion proposed takeout of Horizon Therapeutics. In all, around 56% of the deals in 2022 saw larger pharma companies acquiring biotechs, with the remainder consisting of consolidation within the biotech sector itself. The generally subdued M&A environment continued into the first quarter of 2023, when Pfizer's acquisition of Seagen masked very low levels of deal value across the sector.

Figure 5. US and European mergers and acquisitions, 2006–22



Sources: EY analysis, Capital IQ, MedTRACK and company news.

Chart excludes transactions where deal terms were not publicly disclosed.

Chart excludes Thermo-Fisher/Life Technologies transaction (US\$13.6 billion) because the acquirer is neither a pharma nor a biotech.

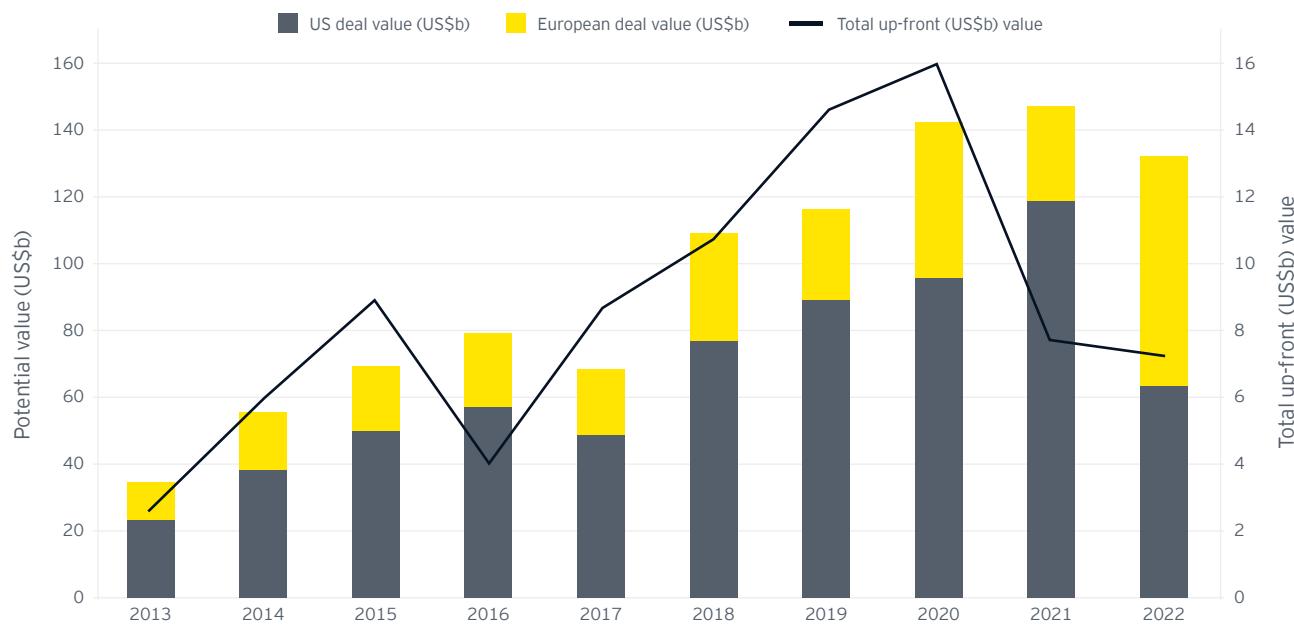
The ongoing uncertainties in the geopolitical and global macroeconomic environment are likely to limit appetite for dealmaking in the near term, with low levels of M&A investment mirrored in other sectors worldwide. However, the US regulatory environment is also a factor. For example, the US Federal Trade Commission's greater scrutiny around antitrust may have implications for large-scale mergers. Most recently, the agency announced it would attempt to block the Amgen acquisition of Horizon Therapeutics, potentially upending the rare disease business model that has dominated the industry for the last 40 years. The advent of the IRA has also increased uncertainty around drug pricing, making it more difficult for acquirers to evaluate potential targets and their portfolio assets into the future.

Moreover, the industry has shown a strong preference in recent years to access innovation through alliances and partnerships rather than outright acquisition. Life sciences companies signed alliance deals with a potential value of US\$132.1 billion – the third-highest total in the past decade – over the course of 2022.

US\$132.1b

Potential value of alliance deals signed with life sciences

Figure 6. US and European biotech alliance deals, 2013-22



Sources: EY analysis, Biomedtracker.



For biotechs, the downside of this alliance activity is that only 6% of the total potential value of these 2022 deals came in the form of guaranteed up-front payments, with subsequent payments dependent on future milestones. With reduced options for accessing capital, biotechs are generally not negotiating these partnership arrangements from a position of strength, and the terms of these deals offer little immediate additional capital for small companies.

The industry may ultimately emerge strengthened from these challenges. Andrew Hack, a partner with Bain Capital Life Sciences, anticipates that the current operating environment “will ultimately lead to a more efficient ecosystem of companies advancing truly innovative products. ... as an industry, we will come out of this as better stewards of capital, as well as disciplined organizations that will deliver more with less.”

Creating a more efficient biotech ecosystem that focuses on the fundamentals and takes a new path forward will involve addressing many challenges and transformations, some of which are explored in this report. These include:

- Building better financial and operational resilience across the sector
- Focusing on capital allocation strategies to secure future growth in both the short and long term
- Optimizing tax management in an increasingly complex and data-driven operating environment
- Making use of digital technologies to refine manufacturing and supply chain processes
- Leveraging the potential of artificial intelligence (AI) and other tech tools to streamline commercial engagement models
- Navigating the shifting regulatory environment and its impact on product pricing

Ultimately, while biotechs must evolve their operating models due to the current changing landscape, innovation will remain the core strength of the industry and the heart of the biotech business model. The challenge of the patent cliff could be an inflection point for the industry, as biotech's innovation renaissance becomes the critical revenue driver for the wider biopharmaceutical industry. As biotechs adjust their strategies and operations to focus on their fundamentals, they must fuse their innovative energies with a greater focus on discipline and efficiency. If they do, the industry has an opportunity to become an even more essential – and resilient – component of the biopharma ecosystem.





Good science leading to differentiated products will always be the key to success in this R&D-driven industry, but as they plan ahead, biotechs must recognize the need to supplement scientific excellence with a strategic focus on achieving operational efficiency in all areas of the business.



Why lean and efficient biotechs will thrive despite tough times

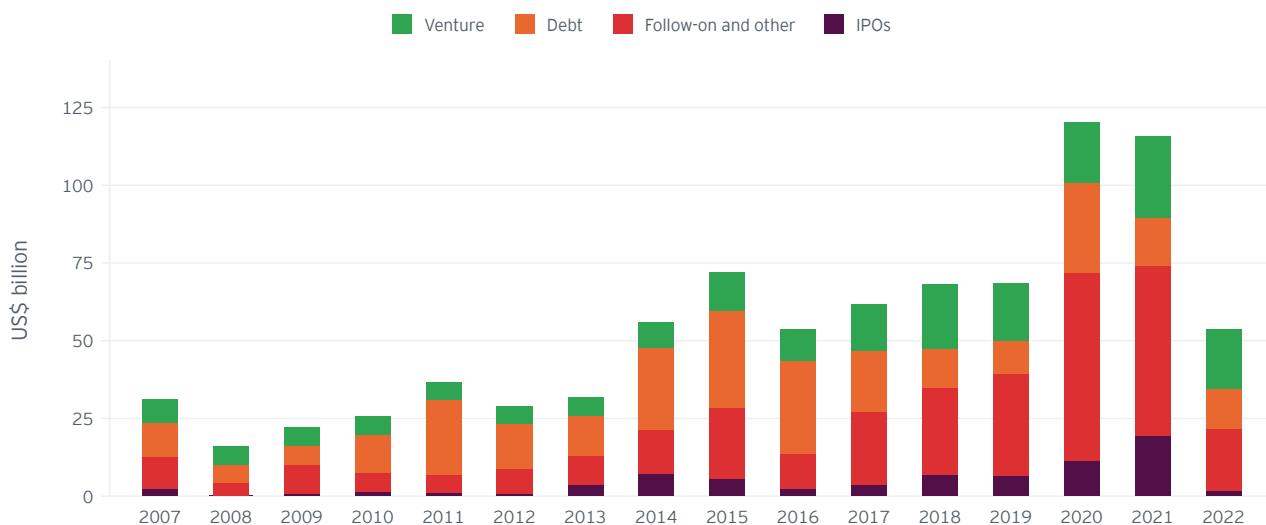
As disruption continues for the sector, more than 30 biotechs have filed for bankruptcy since 2020, and 55% of the publicly held emerging biotechs we track biotechs we track have less than two years of cash on hand. While tough financial times have thinned out the herd, companies that can shift to leaner operations and focus on financial resilience are likely to thrive.

After multiple years of capital flowing into the biotech market – allowing even biotechs that had little clinical evidence available to tap into large amounts of funding and secure often wild valuations, the tides have turned for the sector. Biotech funding has declined steeply since general investors pulled out of the market in early 2022, and the window for initial public offerings has largely closed.

Compounding these difficult financial circumstances for the sector are macroeconomic factors that are making it harder for biopharmas to operate. For example, geopolitical tensions and escalating deglobalization have increased uncertainty and cost in the supply chain, shifts in demographics and access to skilled workers have put constraints on talent, and inflation-driven interest rate increases have been increasingly tough on profitability.

These largely uncontrollable circumstances make it even more important for biotech companies to focus on the fundamentals of preserving cash and producing strong data and evidence to showcase their overall resilience to potential investors.

Figure 7. Capital raised in the US and Europe, 2007-22 (US\$b)



Sources: EY analysis, Capital IQ and Dow Jones VentureSource.



Doing more with less

Even though large pharmaceutical companies are sitting on an unprecedented amount of firepower (i.e., approximately \$1.4 trillion in cash that could be used for M&A as of the end of 2022), the industry has largely been cautious with dealmaking over the last two years.

This puts biotechs in a tough spot; traditionally, IPOs or acquisitions are the most likely exits for biotech investors. But with opportunities for additional funding looking increasingly scarce, biotechs – particularly those in the early stages of maturity – need to manage their cash burn to reach their next value-inflection point.

Biotechs that want to attract capital or be acquired by a large pharma in this environment must demonstrate solid clinical trial results and have a strong management team. Companies can take several actions to operate more efficiently during the current market correction and demonstrate their overall resilience until investment in the sector cycles back to more prosperous times:

- ▶ **Show data-driven value:** Biotechs need to be able to articulate a clear, data-driven value proposition that shows how current cash will get them to the next milestone and how that next milestone will continue advancing that value proposition. Being able to validate a product or technology in the clinic or through partnership with a larger player will help attract further investment. Many large pharmas are opting to forgo traditional acquisitions and create alliances that let them de-risk an asset or explore a platform. These types of alliances have many benefits for biotechs, allowing the smaller company to access some of the expertise, knowledge and resources of its larger pharma partner.
- ▶ **Manage the cash burn:** Preserving cash to deploy to core R&D activities is essential, and it requires companies to deploy variable cost structures for non-core activities. Key actions include using resources such as contract research organizations as well as contract development and manufacturing

organizations to further reduce infrastructure and talent costs. Smaller companies, in particular, have a lot of opportunities to pool their resources with other smaller biotechs at incubators or places that offer labs as a service. Utilizing the biotech ecosystem can help these enterprises capitalize on the efficiencies of scale by sharing office space, lab space, expensive lab equipment and support staff, thus cutting much of their back-office expenses.

▶ **Rely on technology:** Advances in technology give biotechs the freedom and power to connect with patients in any geography and allow operations to run more efficiently, enabling staff to focus on more value-added tasks. Biotechs also can tap into data from wearable technology or use virtual clinical trial models to help them move their product or platform to the next stage more quickly.

▶ **Grow responsibly:** One of the most expensive costs for a small company is talent. Smaller companies should consider operating leaner and not rushing into creating the executive team. Instead, they can expand the team slowly and rely more heavily on the operational knowledge of their VC investors. Typically, VC investors have access to highly skilled talent pools, including professionals who sit on company boards, and often participate in company management. Further, they typically bring a wealth of expertise gleaned from their participation in a variety of startups. As such, VC firms don't just provide capital investment; they also frequently invest time and know-how.

Biotechs need to find new ways to extract efficiencies from their organizations and need to revisit traditional business models to see what makes sense in an evolving marketplace. There are still opportunities for biotechs with strong fundamentals and solid clinical trial results to garner the attention of their big pharma counterparts, accessing their billions in dry powder.

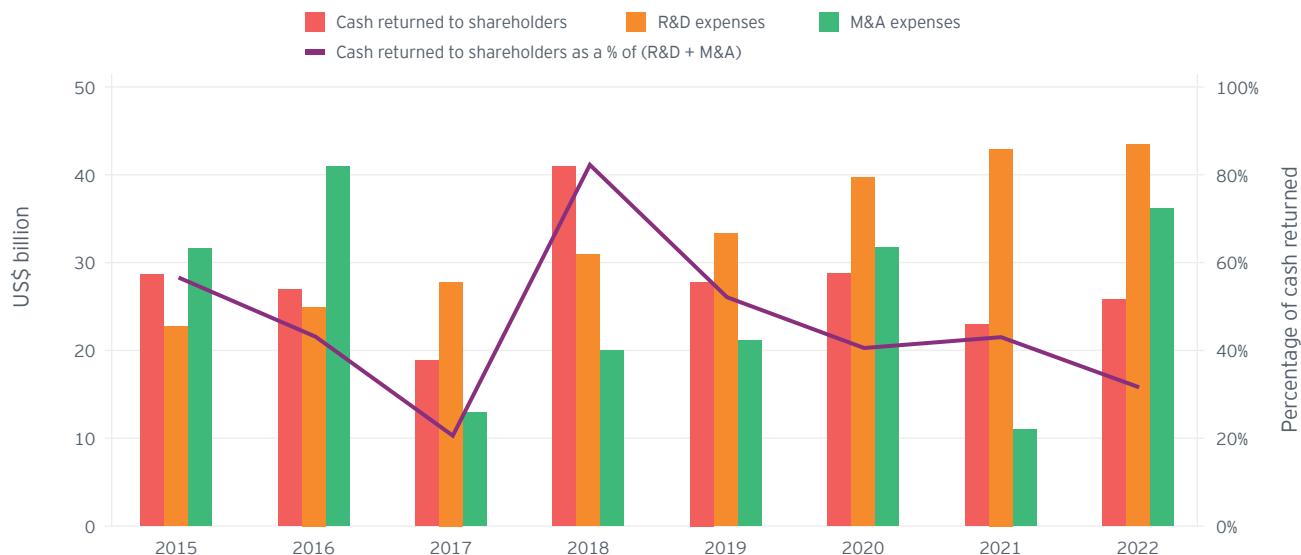


Why dealmaking will be key to nurturing the biotech innovation ecosystem

M&A plays a critical role within the biotech ecosystem. With small biotechs increasingly unable to access capital via IPO or special purpose acquisition company (SPAC) pathways (or unable to win follow-on funding to sustain themselves as public companies post-IPO), these companies are ever more likely to seek an exit via acquisition. However, leading biopharmas showed limited appetite for M&A deals in 2022. A relatively large number of deals are still being signed – the 2022 total of 47 deals was down compared with 2021 but higher than any other year in the past decade – but the US\$83.6 billion spent on these deals fell well below the five-year average total of US\$107.2 billion.

A relatively large number of these deals saw biotechs acquired by other biotechs, rather than by big biopharma players; in all, biotech-biotech deals accounted for 43.7% of all M&A spending in the sector, compared with a five-year average of 28.4%. Biotech's commercial leaders focused two-thirds of their capital allocation in 2022 on growth investment, with US\$43 billion going toward R&D spending in addition to US\$36 billion spent on M&A – the sector's highest spend on dealmaking since 2016 (see Figure 8). Biotech's commercial leaders only returned 32% of capital to shareholders (in the form of dividends and buybacks, compared with a five-year average of 47%), with these larger biotechs clearly aiming to actively build out their portfolios to sustain future growth.

Figure 8. US and European commercial leaders spending trend, 2015-22



Sources: EY analysis, Capital IQ and Dow Jones VentureSource.



However, while biotech's commercial leaders have been relatively active in making acquisitions and consolidating the sector, the leading global biopharmas largely stayed away from M&A in 2022. In all, major biopharma companies spent US\$47.1 billion on biotech acquisitions in 2022, compared with a five-year average of US\$79.6 billion. Some of the reasons for this low M&A investment are discussed elsewhere in this report: the ongoing macroeconomic uncertainty is a deterrent to dealmaking and regulatory developments such as the IRA and the increased Federal Trade Commission focus on antitrust are also unlikely to encourage acquirers. Moreover, the biggest pharma companies have placed their focus on alliances and strategic partnerships rather than outright acquisitions in recent years, with lower up-front investment in biotechs.

Nevertheless, there are strong underlying reasons to anticipate biopharma leaders returning to large-scale dealmaking by the end of 2023. One of the main reasons to expect this resurgence is simply the amount of capital now available to the wider industry. At the beginning of 2023, the biopharma sector overall held over US\$1.4 trillion in firepower (the measure of a company's capacity to carry out M&A, based on the strength of its balance sheet).

Moreover, sector leaders have every reason to deploy this capital, with the patent cliff (i.e., reduction in revenue after a patent expires) beckoning. The two biggest biotech acquirers of 2022 were Amgen and Pfizer, which jointly accounted for four of the top six deals of 2022 (and US\$48.5 billion of the overall value) – both are facing significant exposure to patent expiries. Amgen faces loss of exclusivity on several of its key products by 2030, including Enbrel, Prolia/Xgeva and Otezla, collectively worth over US\$10 billion in 2022. Meanwhile, Pfizer is set to lose market exclusivity on 11 products by 2030, including Eliquis and Ibrance, the company's two biggest revenue generators in 2022 outside its COVID-19 franchise. However, with sales of its COVID-19 vaccine and antiviral Comirnaty and Paxlovid pushing Pfizer's 2022 revenues over US\$100 billion, the company has been the exception among big biopharmas in its willingness to allocate capital to M&A. Pfizer spent US\$17 billion to acquire Biohaven and Global Blood Therapeutics in 2022 and has continued this approach into 2023, with plans to spend US\$43 billion to acquire Seagen in March.



While Pfizer and Amgen have set the pace for M&A, most leading companies have some exposure to the approaching patent cliff, with US\$200 billion in revenues at risk by 2030 across the industry.³ The good news for the industry's leaders is that biotech is still generating the innovations needed to replace those threatened revenues. The heralded innovation renaissance in biotech has seen multiple new product modalities developed, including cell therapies, gene therapies and the ADCs that formed the basis of the Seagen portfolio acquired by Pfizer. Above all, the mRNA platforms developed by BioNTech and Moderna have demonstrated the scale of the commercial opportunities new modality platforms can offer the sector as it seeks to close the growth gaps caused by patent expiry. If the major biopharma players begin returning to the dealmaking table in the near future, the increased injections of capital can strengthen biotech's innovation ecosystem and enable the continued development of products and platforms that will help secure the biopharma industry's future growth.

3. "Evaluate Pharma World Preview 2022 - Outlook to 2028," Evaluate website, www.evaluate.com/thought-leadership/pharma/world-preview-2022-report, 8 October 2022.



Pulling levers to execute a successful capital allocation strategy



Duane Van Arsdale

Treasurer
Johnson & Johnson

We recently sat down with Duane Van Arsdale, Treasurer of Johnson & Johnson (J&J), to discuss the company's capital allocation strategy and how it's reacting to the current market environment.

Ernst & Young LLP (EY): How does the current market environment shift the thinking about dealmaking? Is there more focus on alliances than straight M&A?

Duane Van Arsdale: At Johnson & Johnson, we are very balanced in our approach to business development activities. We continue to pursue early-stage investments, both through our JJDC venture capital investment arm and Johnson & Johnson Innovation business models.

We also continue to look at acquisitions and invest for the long term. There are different levers, or focus areas, that we look at consistently. In addition to investing in organic growth opportunities, our team continues to evaluate strategic acquisitions, licenses and other external collaborations that would enhance our current portfolio, build upon our capabilities and enable us to play in higher growth markets, while also delivering strong financial returns.

There are typically two main principles we consider in terms of dealmaking. The first, and most important, is whether a transaction can bring differentiated innovation to the patients that J&J serves. The second is whether it creates shareholder value. These principles have stood the test of time over the years and help us direct where we should focus our time.

A perfect example of our M&A in action is in our acquisition of Abiomed – a world leader in heart recovery. In December 2022, we completed the Abiomed transaction, marking the third-largest deal that J&J has ever done. We saw the cardiovascular space as a potential high-growth area. But, more importantly, we recognized the high unmet medical need for our patients globally. With Abiomed, J&J MedTech now has 12 platforms with over US\$1 billion in annual sales, and we are very pleased with the integration and performance thus far.

GUEST PERSPECTIVE



EY: How does J&J prioritize capital allocation among therapeutic areas, modalities of interest or other corporate initiatives, such as dividends and share buyback?

Van Arsdale: We prioritize capital allocation based on strategic fit and the ability to benefit patients and create value across both our medtech and pharmaceutical areas of focus. We have a well-documented capital allocation framework that our executive vice president and chief financial officer speaks about every quarter on our earnings call. As a result of this framework, our priorities are very clear, and they've been consistent over time.

The first lever, and our highest priority in capital allocation, is supporting our organic business needs and our R&D pipeline across the five focus areas in our MedTech sector and six therapeutic areas of our pharmaceutical business. This is the most efficient use of capital and provides the most reliable return for our shareholders and patients. The second lever is our dividends, and in the first quarter of 2023, we increased our dividend for the 61st consecutive year. As such, we are considered one of approximately 50 dividend kings across all industries. The third lever is M&A. As one of three companies with a AAA-rated balance sheet, we continuously evaluate strategic business development opportunities that enable us to create value for patients, customers and shareholders. And the fourth lever is share repurchases programs, when appropriate.

EY: Is the current interest rate environment shifting your capital allocation strategy? How you are structuring deals? How are you thinking about contingent considerations or minority investments?

Van Arsdale: It's something we're taking into consideration. When we look at the macro environment, we realize the cost of financing is going to be more challenging, and we make our own priority trade-offs to prepare for a potential recessionary environment. We have to consider whether we are deploying resources appropriately across all levers. But it hasn't fundamentally changed how we think about deals and create long-term value for our shareholders – our strong balance sheet affords us the flexibility to pursue multiple capital allocation priorities concurrently.

J&J has always shown the willingness to do creative deal structures where appropriate, like with the Abiomed transaction. We incorporated contingent value rights (CVRs) on a public company, which is not something we had done in the past. This enabled us to make an attractive – yet disciplined – up-front offer and use a CVR structure with simple clinical and revenue-based milestones to clearly align incentives and allow both sets of shareholders to benefit from the potential upside performance of the business in the future.

Regarding minority investments, we don't do them very often. We look at the differentiated value, and so we tend not to invest in assets that already have a presence in the market or to be the third or fourth to market. The goal of our R&D teams is to bring highly innovative and highly differentiated products to market that solve unmet patient needs, which ties back to the goal of our company – to make a real difference in patients' lives and positively impact the health of humanity.



How companies can pursue a strategy that has long-term growth potential



Lorence Kim, MD

Cofounder and Managing Partner
Ascenta Capital

During our recent conversation with Lorence Kim of Ascenta Capital, we explored several topics that are top of mind for investors.

Ernst & Young LLP (EY): What are the major trends you see within the investment market at present?

Lorence Kim: Since late 2021, companies have adapted their long-term strategies in response to a more restrictive market dynamic and the resulting impact on capital availability. This has been a drawn-out process. Amid ongoing challenges, we are in the later stages of a period in which companies are running low on cash and can no longer defer tough strategic decisions.

Though the mood among some investors is downbeat, there are many of us on the venture side who remain energized by innovation and the challenge of seeking out value. There is growing acceptance that trading dynamics might remain challenging in the near term, but in a sense that gives us the opportunity to take a longer view and really focus on identifying companies that are executing on great science and creating great medicines. There are many high-quality companies still out there, and the market fundamentals are resilient: even during the 2009 financial crisis, we still raised equity for some excellent companies with late-stage products. If you've got great medicines, there will generally be capital available.

GUEST PERSPECTIVE



In an industry like ours, there are many factors that are inherently stochastic, and from the earliest days at Moderna, our strategy was to embrace this uncertainty. We knew we could engineer our platform to deliver, for example, many potential vaccines, cancer therapies or rare disease treatments. But the underlying medicines all carried much risk. We chose to remain agnostic about what parts of the development portfolio would ultimately bring success, knowing we could be ready with the capabilities and infrastructure when that first viable product revealed itself.

EY: What are the key targets for your investment strategy?

Kim: Our strategy at Ascenta is focused on identifying platforms that have received investment and undergone technological advancement for some period of time, where the core hypothesis is now crystallizing. We're looking to invest in those platforms as they get to clinical trials and begin to represent meaningful product opportunities; platforms intrinsically have multi-product potential. Many investors have similar goals, but our distinctive value-add – our sweet spot – is our intersection of growth-oriented operational, strategic and financial expertise that we aim to deploy to help companies navigate this world of constrained capital, focusing on making the right decisions to develop and scale their platforms at the right time.

EY: How does your experience with Moderna inform your approach to these platforms?

Kim: We think our past success in building up Moderna into a major platform opportunity is immediately relevant for companies seeking to chart the same course. In the current environment, some platform companies will opt to distill their platform down to a single program as the simplest and most tangible approach in terms of attracting investors. Other companies with wider ambitions will need to take a more nuanced approach to investing in a broader portfolio, as well as the underlying platform value for the long run. One aspect of navigating these waters is that you need to account for randomness.

EY: Is it still possible to pursue this type of more open-ended platform strategy with current capital constraints?

Kim: With any platform, it's important to maintain discipline in terms of capital allocation. Despite having high capital availability at Moderna, we were laser-focused on the balance between boundless ambition on the one hand and careful deployment of capital while the story was being de-risked on the other. With the emergence of new modalities, there will always be important questions around how you handle the scaling up of processes, infrastructure, organizational capabilities and capacity. For example, at Moderna, we developed a manufacturing process, but we outsourced these operations until we had clinical evidence that our technology would work effectively in humans. We waited for evidence before making our major commitment to infrastructure investment.

That exemplifies the dynamic we want to look for and foster in the companies we invest in now. Seeing and pursuing the opportunity is critical, but you also need to remain mindful of what shareholders need: maintaining investment in the long run means effectively communicating to your board and to your investors what it is you are going to explore and why it's worth the capital. Ultimately, the goal is to find and invest in companies that combine platform technologies that can have a big impact on patients, with a focus on value and capital efficiency, and highly motivated and passionate management teams. That shared strategic value framework is what we are trying to achieve.



The path to value creation isn't straight



Jeff Tong, PhD

Partner

Third Rock Ventures

Our recent chat with Jeff Tong of Third Rock Ventures was a deep dive into all things strategy.

Ernst & Young LLP (EY): Third Rock has been creating and investing in companies since 2007. What have you all learned in that time?

Jeff Tong: As an industry, we've experienced a lot in the last 16 years. During this period, there have been waves of scientific innovation, changes in market cycles, hundreds of companies created while others simultaneously were acquired or shut down, and major classes of new medicines introduced at a time when important legacy medicines are going off-patent and becoming broadly available to society, among many other developments. Against that backdrop, there are certain things that remain constant and others that are variable. The important things that have been constants for us in company creation include: (1) focusing on unmet patient need; (2) producing meaningful medicines that make a difference; (3) knowing that the path to value creation is rarely a straight line; (4) understanding that it will cost a lot to achieve these goals; and (5) partnering with great leaders and great teams, which is a critical part of successfully navigating this journey together.

If those are some of our constants, what are the variables? Cost of capital, pharma deal appetite and equity valuations certainly change over time. And so, these variables only reinforce why the constants are so important: you need to be solving for problems that are important in any market cycle, and you need great people who are able to adapt to changing conditions and can therefore plot a course to build a resilient company.

EY: How has your strategy shifted over the years?

Tong: At its core, it hasn't. Third Rock is a firm that aspires to build great companies that tackle important unmet medical needs. And we do so in partnership with incredible entrepreneurs, founders, management teams, pharma partners and other co-investors. Our success metric is the creation of new medicines.

But the implementation of that strategy – the tactics – has evolved. For example, we actively syndicate more these days. We are incubating ideas in-house for longer, letting them mature more before funding a large Series A. And when funding markets are tight, we need to have a greater degree of confidence that our companies will be able to demonstrate meaningful value inflection prior to the next round of fundraising. Sometimes, this approach means having programs closer to the clinic, but it doesn't always have to be solely product-driven. If there are platform proofs of concept (POCs) that generate that kind of value, those POCs are also good.

GUEST PERSPECTIVE



EY: What are the key elements you focus on, regardless of the market environment?

Tong: With unmet need at the core of our thinking, scientific rigor always takes precedent. And that is fostered by building great teams – both internal and external. We find that developing a strong, singularly focused culture often leads to great things in the lab.

EY: Can you give some examples of when that investment strategy resulted in success? Obviously, not every investment is a win. How have you learned from those that didn't pan out?

Tong: We've been fortunate to be part of some great companies that persevered in discovering and developing important new medicines. The common theme to these successful outcomes is that the company focused on addressing important areas of unmet medical need; for example, sickle cell disease, precision oncology, idiopathic pulmonary fibrosis, postpartum depression and so on. Outside of our work, the persistence of others in tackling

obesity as a major risk factor for cardiometabolic diseases is starting to yield meaningful results. That field went through ebbs and flows in popularity, yet it was always an undeniable truth that cardiometabolic diseases have been a major contributor to morbidity and mortality. Even so, it's a field that's still ripe for new approaches and innovation.

On the other hand, companies sometimes don't work out for any number of reasons. Of course, you need a great team that is making progress addressing important areas of unmet need, but beyond being good and working hard, companies need a little bit of luck and a lot of resilience to avoid being caught up in a market cycle.

EY: Are there any specific therapeutic areas or modalities that you are particularly excited about?

Tong: Over the last 5 to 10 years, there have been more ideas and innovations around new modalities than there have been in the last 50 years: gene therapies, cell therapies, nucleic acids and microbial therapies, to name a few. It is all very exciting. And yet, I wouldn't overlook the advances in small molecule drug discovery and protein/antibody engineering, which really demonstrate that nothing is "undruggable" anymore. Also, one can include functionality such as bispecifics, conditional logic and covalency, while revealing cryptic binding pockets, novel models of agonism or inhibition, or newfound sources of selectivity and specificity. With respect to therapeutic areas, large-scale genotype-phenotype databases are enabling us to think about historically common diseases through the lens of precision medicine.

EY: What advice would you give to biotechs that are trying to attract investment in the current environment?

Tong: Start by focusing on the fundamentals: creating medicines that will make a difference in the lives of patients. That's your true north. Then, build a strategy that can accommodate and even capitalize on the inevitable and unpredictable detours as you head to true north. Once you've done that, build a great initial team because great people attract more great people, and it becomes a foundation upon which you can aspire to make important and value-creating advances.

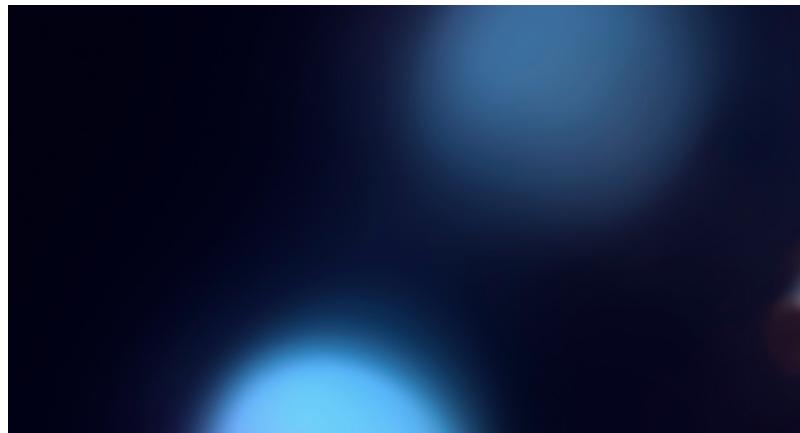


Investing in a more efficient and focused biotech future



Andrew Hack, MD, PhD
Partner
Bain Capital Life Sciences

Bain Capital Life Sciences partner Andrew Hack shared several leading insights on driving innovation, navigating disruption and more.



Ernst & Young LLP (EY): How has the financing landscape for biotech changed over the last 12 months?

Andrew Hack: The longer-term secular trend of accelerating innovation driven by decades of global investment in science and health care remains tremendously exciting. In the near term, however, devaluation of biotech stocks, and a contraction in the amount of public and private capital available to them, is creating headwinds to delivering this innovation to patients. As a result, many companies are reassessing how they allocate their capital, where they are going to get capital and what the cost of capital is likely to be. Despite this, we continue to believe great teams and great therapies will make it to patients, delivering on the promise that we all believe the biopharmaceutical and medical device industries have to make a difference in people's lives globally.

EY: How does the present situation compare to previous market upheavals?

Hack: The present moment most reminds me of the period after the dot-com and genomics bubbles burst in 2000 and 2001, both in terms of the magnitude and duration of the shift in valuations and capital availability. It took a couple of years for the implications of that reset to work their way through the system, and I think that could be the case again. Among the many impacts of 2000 and 2001 was a shift in the amount of focus investors and companies put on medicines vs. platforms, and I think you will see that again this time.

GUEST PERSPECTIVE



EY: What is your advice to biotechs in the current climate?

Hack: We believe that the backbone of value creation in biotech and medtech is tangible products that make a real difference for patients and are economically valuable to stakeholders in the system. Although platforms are vital to generating new product opportunities, the value associated with them inflates and deflates more rapidly than the value associated with the products themselves. Along the same lines, products that are more oriented to proving the concept behind a platform but are of less clinical or economic value are difficult to fund in environments like this. With that in mind, the companies that do the best job of critically assessing which of their activities will deliver the most tangible value for all stakeholders will be rewarded disproportionately.



EY: How has your fund's strategy changed?

Hack: Our core focus has always been evaluating innovative products (generally in clinical development or early commercialization) and teams, their plans to develop these products, and the time and capital needed to get products to important value-inflection points. We think this strategy can work in every market environment because it is focused on high-value products for areas of high unmet medical need. Within that strategy, one area of growing interest for our fund is products in larger therapeutic areas, which by definition have the potential to make a difference for larger populations of patients and hold more relevance for potential acquirers. Having said that, we remain committed to investing in therapies for a wide spectrum of diseases, and the backbone of this approach is always a focus on understanding the patient journey and addressing the real unmet needs for patients.

One silver lining of the current situation is that it will ultimately lead to a more efficient ecosystem of companies that advance truly innovative products. We cannot lose sight of the fact that for many companies, the current landscape will bring challenges. But as an industry, we will ultimately emerge as better stewards of capital, as well as disciplined organizations that deliver more with less. There will never be infinite resources that can be allocated to bringing new treatments to patients. Anything we can do to make that process more focused, efficient and effective is ultimately a good thing.



The new pricing challenges for biotech



On May 11, 2023, the COVID-19 Public Health Emergency in the US officially expired, formally ending a period during which US policymakers played a major role in accelerating the growth of the biotech sector. Public health initiatives such as emergency use authorizations for coronavirus vaccines and treatments supercharged biotech's growth in 2021, and the unwinding of these policies played a role in the industry's slowdown in 2022. However, we can expect US policymakers to continue playing a significant and proactive role in shaping the operating environment for biotech, with companies needing to pay close attention to the shifting regulatory environment as they plot their new path forward.

Policymaker interventions will shape the future of the biotech market in multiple ways, some of which are already emerging:

- ▶ The Federal Trade Commission (FTC) has toughened its antitrust stance, which may have a chilling effect on mega mergers, as illustrated by gene-sequencing giant Illumina's legal struggles over its acquisition of Grail.
- ▶ The Consolidated Appropriations Act (December 2022) brought in provisions enabling the FDA to impose more stringent post-launch demands on companies that leveraged the accelerated approval pathway to market.
- ▶ The US government has also announced intentions to secure national pharmaceutical supply; this may have consequences for globalized industry supply chains in the longer term, with increased onshoring a possibility.

While these policy shifts are all potentially consequential for biotech, the most immediately important regulatory development will be the Biden administration's passing of the IRA in August 2022. The IRA's provisions are set to have a major impact on drug pricing, with profound implications for biotech over the next seven years.



The IRA and what it means for biotech

The IRA contains three key provisions from a biotech standpoint:

- ▶ **Medicare drug price negotiations:** Intended to reduce the price of high-cost single-source drugs, these negotiations between the Centers for Medicare & Medicaid Services and manufacturers are set to begin in the fourth quarter of 2023, with the negotiated maximum fair price (MFP) to be published in September 2024 and applied from 2026 onward.
- ▶ **Inflationary rebates:** Manufacturers will need to provide rebates if their price increases exceed the Consumer Price Index for All Urban Consumers (CPI-U) inflation rate.
- ▶ **Medicare Part D redesign:** With the aim of shifting costs from Medicare and beneficiaries, this provision will place a US\$2,000 cap on the amount patients may pay out of pocket per year by January 2025.

Though many uncertainties remain – for example, the IRA mandates that the pricing provisions come into effect over a seven-year time frame, and legal challenges are anticipated throughout that period – the intent of the legislation is clear. The Congressional Budget Office projected that between 2022 and 2031, the legislation would deliver US\$99 billion in savings from price negotiations, US\$62 billion in savings generated by discouraging drug companies from raising prices and US\$38 billion in rebates paid. Though the effects of the legislation will initially fall on manufacturers with drugs listed under Medicare and will only apply to certain drugs, the long-term results will be broader. Reducing the price of a single high-profile drug will likely have a ripple effect on pricing for other drugs in the same class; cutting prices for originator drugs will have a downstream effect on biosimilars and generics with prices keyed to the branded product. In all, the legislation appears to signal a new era of pricing control in the US, a region where biopharma is the industry's largest national market and has traditionally had considerable leeway to set prices.

The implications for biopharma are not all negative. For example, affordability and access improvements may expand patient populations and prescription volumes, redressing some of the revenue erosion from price cuts.

Nevertheless, companies need to refresh their future commercial strategies in the light of the IRA. They should prioritize four main initiatives:

- ▶ Develop and embed a commercialization framework to identify and address the asset-level impacts of the IRA.
- ▶ Adapt portfolio-level decision-making to the post-IRA landscape, including more detailed assessment of therapeutic area launch sequencing and product lifecycle management approaches.
- ▶ Explore new commercialization strategies, including activating new channels, developing strategic partnerships and assessing the opportunities for volume-driven offsets to revenue erosion.
- ▶ Evaluate price and access trade-offs across indications being considered for launch, in terms of the shifting competitive landscape.

Pursuing these strategies will help companies optimize market launch and commercial strategies to achieve earlier peak ROI from assets. As with other trends affecting biotech, the regulatory developments in the life sciences industry present new challenges. Yet the changing landscape also offers companies opportunities to refine their commercial strategies and find a more efficient and effective path forward in a changing market.





How digital drives connectivity and optimized experience with customers



Over the last decade, the life sciences industry has made a continuous push to be more customer-centric and data-driven, aiming to meet customers where they are and on the channels they prefer. The pandemic only accelerated the need for greater digital connectivity and personalization across the life sciences ecosystem.

The industry has invested in and built the foundational capabilities required to be digital. However, as pharma continues its digital evolution, there is an opportunity to pause, take stock and realign to capture greater value. The question is no longer how the life sciences can become digital; rather, it's how the industry can optimize its digital capabilities to maximize opportunity and keep pace with evolving customer experience expectations and needs. As the industry looks toward a more personalized and connected future, a cohesive, fit-for-purpose commercial strategy that incorporates the power of data and analytics will be critical to success. For instance, large pharmas can streamline communications by eliminating redundant marketing tactics so that physicians don't receive an excessive number of emails from different parts of the brand.

One of the biggest opportunities that aligns the power of digital, data and analytics to impactful commercial efforts is next best action (NBA). While this approach has been embraced by the banking and retail industries, life sciences is beginning to implement it and reap the resulting benefits. NBA is a process that harnesses the power of continuous AI models and tailors them to a specific company's sales cycle. It uses the latest customer data to develop content recommendations for digital channels and sales reps so that the right doctors see the right message at the right time on the right platform to capture the greatest likelihood of increased prescribing at a given point in time. Leveraging the optimal inputs, building the right engine that executes against the right business goal and applying the outputs as part of a broader omnichannel strategy are the keys to unlocking the power of digital and embracing the digital age of the customer. Pharma companies that implement NBA correctly see on average a 5% to 10% increase in revenue for products in their launch or growth stage, according to EY analysis.

Successful implementation and application of the NBA process require strategic alignment around the key opportunities and business questions facing the company. These issues will be derived based on nuances in therapeutic areas and customer or market context based on these disease states. A company with a product type that's already well-represented in a saturated market will face different strategic considerations and testing scenarios than those encountered by a company with a single product in a rare disease therapeutic area.

While companies have built the infrastructure to support digital, NBA requires focused use of that infrastructure to drive targeted results. The first step is to align the company's data sources across internal, external, third-party health care and third-party digital data to serve



as inputs into the AI engine. Understanding business objectives and the hypotheses to be tested will be critical in defining the right inputs into the system. Using too many inputs or not being specific in input selection can confuse the model or deliver results that are not aligned to hypotheses being tested. The model will then work across inputs to deliver optimal recommendations to sales reps, who can then report results back to the model to establish a feedback loop. The feedback loop will help the company ensure that quality data goes into the engine to support quality outputs to reps and customers.

Critical actions to consider in using models like NBA that leverage AI technology include applying the concept and technology to the right product at the right time. Leveraging an NBA approach on end-of-life products or those with limited opportunity or access consistently fails to deliver results. But when applied to product scenarios with significant sales and marketing activity that provides multiple testing opportunities, it can be successful. For example, many large pharma brands that aspire to increase first-time prescribing for a newly launched product use NBA to customize marketing efforts to doctor specialty. By identifying the data inputs that make NBA content recommendations more impactful for each of these specialty target segments, such as the optimal time to engage, pharma companies have an opportunity to change prescribing behavior of these segments and increase overall prescribing by double-digit percentages. In addition, pharma brands that aim to expand total prescriptions for legacy products can use NBA to identify additional doctors with significant prescribing potential who should be targeted. This expanded target audience identified by NBA has the potential to drive millions in increased sales revenue.

AI software needs the right inputs to succeed; it can't be fed random data and come back with the insights your company needs. For AI-driven models to drive revenue, experts in a therapeutic area or an individual product must work with data scientists to develop hypotheses that can be modeled in the data.

Developing the right engine will require a focus on inputs over algorithms. Using different AI algorithms typically drives 10% to 20% improvement in NBA model accuracy, while adding additional relevant data sets can also



drive 60% to 90% improvement in NBA model accuracy, according to EY analysis. Tying data inputs and data sets to business questions is the critical differentiator for companies that achieve measurable impact. Finally, choosing data that changes and refreshes often, along with prediction variables that show shifts in trends or change over time, will compound the recognizable benefit of the engine.

The digital ecosystem requires connectivity and feedback loops between the NBA process and sales reps to accelerate and build on benefits over time and set the foundation for execution of a true omnichannel strategy. Understanding the needs of customers and building a marketing strategy that establishes the best balance will result in the greatest impact. Traditional pharmaceutical sales and marketing tactics that rely on static, unconnected data points are ineffective. Omnichannel approaches put the customer at the center and deliver consistent messaging across channels and moments, driven by a digital-first mindset.

When executed correctly, the use of NBA models together with omnichannel connections drives an engaged, personalized campaign for customers that translates to an increase in prescribing and overall retention, ultimately improving the customer experience.



How technology is making commercial models more impactful



Anthony Mancini
Executive Vice President and
Chief Operating Officer
Genmab

We chatted with Genmab's Anthony Mancini about the key challenges and actions around leveraging a digital-first approach.



Ernst & Young LLP (EY): How is the industry embracing the use of digital technologies in the commercial space? How does this stack up to other sectors and industries?

Anthony Mancini: Progress is being made toward leveraging digital methodologies to bring innovative medicines to patients faster, using high-performance cloud computing, big data and AI, to identify potential targets, better predict efficacy and safety, and accelerate drug discovery. Thanks to these technology-driven solutions, we are also gaining better insights for analyzing different data sets to help understand the care journey and predicting longitudinally how a patient might progress through their disease.

Digital technologies are helping us listen to health care providers and patient insights so that our interactions can be as impactful as possible; the goal is to improve the quality of the dialogue between patients and providers and to maximize the customer experience through a relevant, proactive and coordinated approach that's also responsive as needed.

Biotech and biopharma are still lagging other sectors, but significant strides are being made.

GUEST PERSPECTIVE



EY: What challenges need to be overcome to implement these technologies successfully in a commercial organization? And what challenges or barriers are unique to biopharma?

Mancini: Implementing digital technologies successfully can be challenging due to many factors:

- ▶ **Data complexity and heterogeneity:** Data sets come from various sources (e.g., clinical trials, genomic data, real-world evidence, claims, prescribing data). Integrating and standardizing these data types for analysis, insights and decision-making is complex.
- ▶ **Regulatory:** Digital technologies need to comply with various regulations, including data privacy, patient safety and clinical trial transparency.
- ▶ **Talent and skill gaps:** Highly skilled professionals who deeply understand large data models and apply digital technologies effectively are critical to attract and retain.

▶ **Legacy IT systems:** Often, legacy IT systems that have limited interoperability or scalability can make it difficult to integrate new digital technologies. In some cases, building system architecture from scratch can be significantly more straightforward.

▶ **Costs and ROI:** Effectively implementing digital tech can be costly, and it may be difficult to determine ROI in some cases. In other cases, returns require longer-term investment.

There are several challenges or barriers that are specific to biopharma organizations, including:

- ▶ **Intellectual property (IP) and security:** Highly sensitive data, including IP, requires implementation that drives data security and confidentiality.
- ▶ **Clinical trials and regulatory approval:** Clinical trial data is critical, but recruitment and retention of participants can be a challenge. Digital technologies can help us overcome these challenges and need to be implemented with patient privacy and consent. Data integrity and security are also important to the regulatory approval process.

GUEST PERSPECTIVE



EY: How are patients, health care providers and payers benefiting from the use of data analytics by the pharmaceutical industry?

Mancini: Data and analytics have enabled us to better understand the needs of patients and health care providers; these insights ultimately help us engage with them in ways that are more meaningful. Data is a critical tool in embedding the patient's voice into every decision we make. With skilled talent, the right data and the latest technology, we can gather powerful insights that can help us identify tailored approaches that will potentially yield better outcomes for patients.

The goal is to develop more personalized treatment plans by analyzing patient data at scale and to drive early identification of potential safety issues, both of which can lead to improved patient outcomes. This approach can also help us identify trends to potentially enable both faster and more accurate diagnosis. Ultimately, these actions can help reduce inefficiencies so that payers can proactively manage health care needs and reduce health care costs.



EY: What are the priorities for Genmab's commercial digital transformation over the next three years? How is Genmab relying on digital technologies to compete against larger biopharma companies?

Mancini: Genmab has a legacy of innovative antibody science, and we recently (just over three years ago) made a strategic decision to become an end-to-end biotech company. We are actively working to create an end-to-end digital mindset throughout the company as we believe it is a critical part of achieving our vision of transforming the treatment of immunology, inflammation and cancer by 2030 with our knock-your-socks-off (KYSO) antibody medicines.

Part of our digital transformation has been championing the idea of "digital citizen" development, embedding a digital mindset into new ways of working across R&D, commercialization and enabling functions as well as creating integrated product-based teams to help solve our biggest challenges.

GUEST PERSPECTIVE



We have the benefit of being nimble and relatively light on legacy IT systems, particularly in the parts of our organization that are newer, which has allowed us to integrate data and digital into everything we do from the outset. We also bring patient insights into the drug discovery and development journey even sooner with the goal of unlocking new breakthroughs.

At the same time, we must stay one step ahead with a laser focus on what's next. It is critical that we continue to be mindful of industry trends, partner closely with experts in the ecosystem to keep pace and continue to deliver KYSO medicines to those who need them most.

EY: How do you expect digital technologies to shape the future commercialization landscape?

Mancini: As we have access to more data sets and robust digital capabilities, we will be able to generate actionable insights that can inform our decisions, providing critical information to allow us to bring antibody medicines to patients even faster.

At Genmab, we'll continue to embed digital as a core element of our company operating model, exploring how AI and machine learning can enhance and accelerate the discovery, development and commercialization of our antibody medicines. There is no doubt that we will also see significant improvements in diagnosis, along with more personalized treatment and monitoring, so that ultimately we can have a more meaningful impact on as many patient lives as possible.

Digital isn't an end goal; it's a journey that will continue to be an important part of helping our sector realize positive change and health outcomes.

From advancements in AI and machine learning to telehealth and virtual care, the next five years are likely to bring exciting developments in solutions that can improve patient outcomes, increase efficiency and reduce health care costs. We've only scratched the surface.



How a digital supply chain can drive visibility and improve operations



As AI chatbots and other emerging technologies continue to impact every corner of business and interaction, moving toward more digital operations makes sense for every business, regardless of sector.

Pharmaceutical and biotech companies have been exploring all things digital, AI, machine learning (ML) and data-driven analytics for the last several years. In fact, in a 2020 survey conducted by EY, 70% of executives noted that they had already invested in AI and ML. They have leveraged these technologies to accelerate launches, drive operational efficiencies, automate processes and execute on environmental, social and governance (ESG) initiatives. However, in many areas, the industry is still not realizing the full benefits of digital transformation.

Biopharma executives have been cautious about applying these technologies to manufacturing and the supply chain, even as problems that began during the pandemic persist. Supply chain disruption caused by pandemic-era lockdowns greatly accelerated the need for increased visibility and resilience across the supply chain ecosystem. These disruptions have been further exacerbated by

pressures from government to localize some areas of supply and manufacturing as pharmaceuticals have become a growing part of national strategic calculations; a trend that is expected to only continue as governments emphasize greater national self-reliance. For these reasons, supply chain executives across industries stated in a [2022 EY survey](#) that visibility throughout the supply chain is their top priority.

Geographic shifts are also making supply chains more complex. As a greater number of supply chain partners across the value chain are added – including suppliers, chief manufacturing officers, wholesalers and third-party distributors – it becomes increasingly more difficult for biotechs to track the movement and genealogy of products. Ninety percent of the executives we surveyed in 2020 said their visibility into the extended supply chain network was moderate to low. This general sentiment comes when regulators are also looking for more accountability across the downstream drug distribution framework and expect companies to be able to track their product down to the lot level.



Digital tools, cloud networks and real-time data analytics help organizations capture metrics, set key performance indicators and establish governance. And a holistic, end-to-end view of the supply chain and manufacturing operations helps companies conduct real-time monitoring of the health status of every asset, enabling predictive maintenance and digital handling of exceptions, while also enhancing workforce capabilities. Digital offerings can also help companies identify and achieve greater sustainability across their value chain.

Creating data continuity

For many organizations, piecemeal adoption of advanced technologies such as AI and ML together with the increasing variety of available data sources have created inherent gaps in company data platforms as well as visibility gaps related to third-party provider operations. Digital solutions could change that by linking disparate systems through a single cloud-based network. The goal is to achieve a better understanding of the DNA of the manufacturing value chain so that this intelligence can drive better decision-making.

But transforming the supply chain model will require a new infrastructure and new connection points across the organization. Automation in manufacturing can help create efficiencies and allow humans and machines

to work better together, eliminating redundant tasks and human error, while freeing up resources for value-added activities. Machine-to-machine algorithms can lead to predictive maintenance and automatic corrective mechanisms.

As pharmaceutical companies move toward a digital factory model, they can use digital tools to reduce costs and waste, while increasing production and compliance. A digital factory can allow for paperless operations, data transparency and accessibility, predictive and adaptive manufacturing, and touchless operations – solving the problems of siloed execution and fragmented digital operating models.

New roles will need to be created to help companies take ownership of performance and integration of different functions to realize supply chain strategies from an end-to-end perspective. Existing workforces will need to be upskilled to help accelerate adoption of digital technologies. Third-party providers can help facilitate these changes across the value chain.

Ultimately, digitalizing the pharma supply chain and manufacturing functions will allow for greater sustainability, increased visibility throughout the value chain, easier compliance with regulators and stakeholders, and more efficient internal operations.





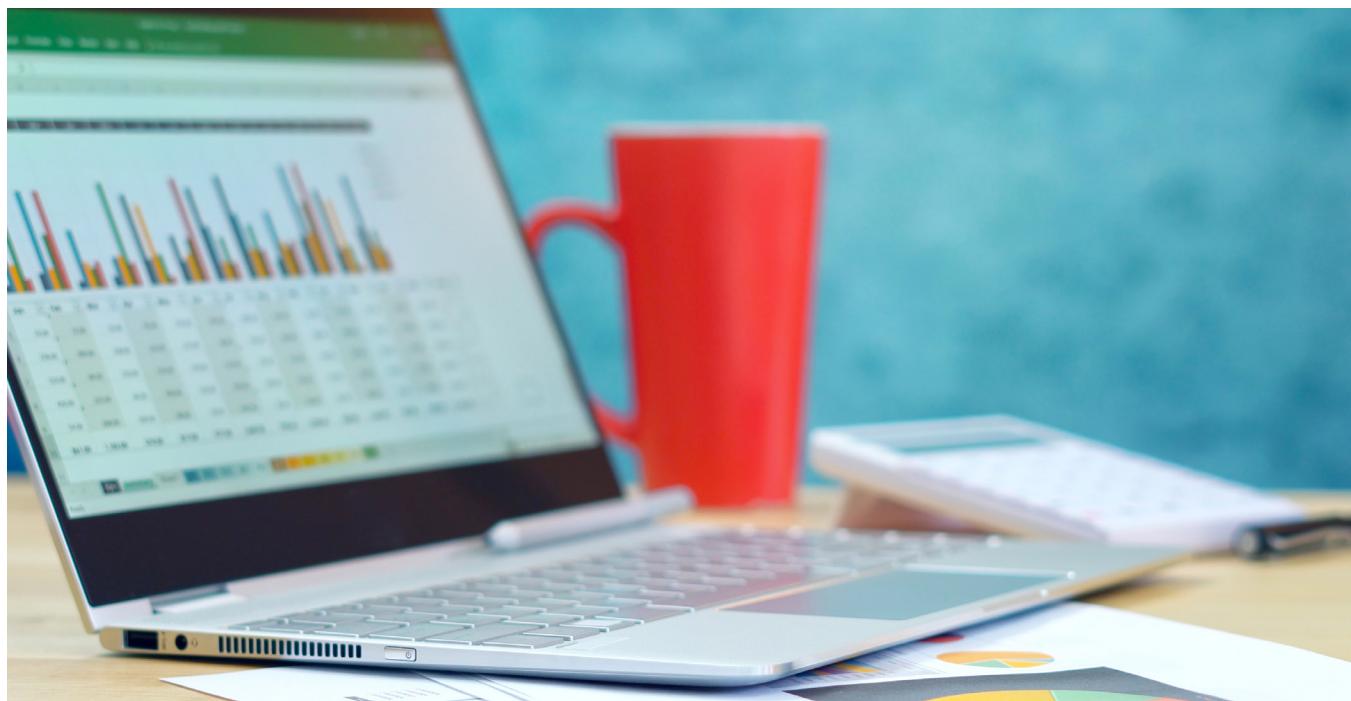
How capital constraints are helping to transform tax and finance in life sciences

While the life sciences sector played a leading role in helping the world navigate the COVID-19 pandemic, many of its organizations are now facing several cost and resource pressures that will require them to transform their operating models. Included in this transformation will be the tax and finance functions, which will have to contend with the tax and reporting implications of supply chain disruption, cost-reduction pressures, shifting industry trends and new global tax legislation. These functions are already stretched thin in many areas, including budgets, technology and talent, and delivering more with less will present challenges. As such, many life sciences companies need to reimagine their tax and finance operating models and current ways of working to enable long-term success.

Looming pressures

Several key trends are impacting the budgets of tax and finance functions within life sciences organizations. These trends include the looming biologics patent cliff (i.e., reduced profits following patent expiration), projected to hit the top line sometime between 2024 and 2026 and likely to create huge pressures on revenue and costs. As IP is a cornerstone of success in life sciences, manufacturers are being challenged by generic competition as patents run their course.

To shore up the innovation pipeline, companies are taking steps to free up capital for R&D and strategic partnerships. For example, according to the [2022 EY M&A Firepower report](#), major biopharmas have deployed





roughly 1.5 times more firepower (i.e., dealmaking capital on hand based on the strength of the balance sheet) on alliances relative to M&A since the beginning of 2020.

These conditions will have a serious impact on the tax and finance function as more capital is directed to R&D and M&A. In fact, the [2022 EY Tax and Finance Operations Survey \(TFO Survey\)](#) found that 87% of companies are planning to reduce their tax and finance budgets – by an average of 5.4%.

As budgets are stretched and reduced, tax and finance functions face an increasingly arduous workload, especially when it comes to data. Also, the trend toward bolt-on acquisitions, joint ventures, strategic partnerships and spin-offs will spark a steep increase in the volume of data sources and requirements around data manipulation.

At the same time, compliance requirements are also escalating. As new global tax legislation is introduced, life sciences companies are likely to face a significant uptick in the volume of tax compliance and controversy issues as they have complex supply chains, legal entity charts and IP structures that make legal entity reporting and forecasting especially intricate.

Life sciences tax departments already perform transfer pricing work as a significant component of their duties related to tax planning and compliance. In addition, the Organisation for Economic Co-operation and Development's base erosion and profit shifting (BEPS) 2.0 initiative and other global tax reforms will have major implications for transfer pricing and every aspect of the tax lifecycle – from provision to planning, compliance and, ultimately, controversy.

Tax departments will also have to navigate disclosures on ESG performance to regulators, shareholders and the wider public in a comprehensive and transparent fashion, along with tax authorities' demands for increasing volumes of digital data, often in real time. Together, these factors will lead to even more challenges around data workload, costs and the risk profile for tax and finance functions.

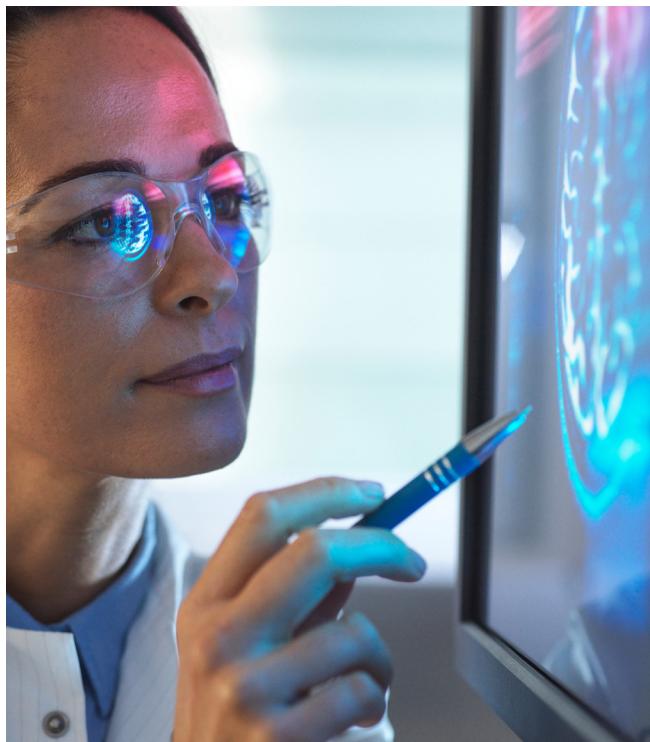


Large multinational companies already have to access, transform and extract insights from significant volumes of data that they've not historically had to think much about. They need to be able to access that data from their current systems in an efficient manner so they can transform and organize it for use across all provision, planning and compliance processes so people can actually make sense of it and draw meaning from it.

All too often, companies don't yet have these capabilities.



Ready to reimagine



Our TFO Survey revealed more about the challenges life sciences tax and finance functions face as they tackle escalating pressures. For example, 32% of respondents cited an inability to identify, evaluate and respond to legislative and regulatory change, while 37% said they lack a sustainable plan for data and technology.

Life sciences organizations tend to have decentralized tax operating models, often with several service providers supporting diverse local country tax and related reporting needs. This approach is complex and often further complicated by the realities of using multiple enterprise resource planning (ERP) systems and lacking a centralized data management strategy. Further, as life sciences companies are now in the process of decoupling their supply chains, decentralizing their operations and building regionalized capabilities, data management becomes even more complex.

It's perhaps no surprise that the majority of life sciences organizations are starting to reimagine their tax and finance functions. The TFO Survey found that 84%

of respondents plan to do so, while 95% said their organization would be reallocating budgets over the next two years, from routine activities such as tax compliance to strategic activities, including legislative planning and controversy.

Automation offers a compelling solution to these challenges, but many life sciences organizations have been slow to leverage and incorporate available technologies. According to the TFO Survey, only 27% of respondents use cloud-based platforms extensively, and only 20% use automation extensively. For many organizations, IT systems and processes were designed and implemented with the finance function in mind, often without consideration of the granularity of the data and reporting required for tax. As such, the TFO Survey respondents still spend, on average, 40% to 70% of their time on gathering data and making it useful.

In addition, our survey respondents are projecting that they will need to spend an average of US\$10.6 million in tax technology over the next five years to bridge the current technology gap.

Yet another factor also may impede the tax and finance function's response to escalating legislative, data and compliance requirements: talent. Ninety-two percent of respondents to our TFO Survey said that their personnel will have to moderately or significantly augment their tax technical knowledge with data, process and technology skills in the next three years to add value to the organization. In addition, 24% said they have struggled to hire and retain the required talent.

Many life sciences organizations are still suffering from the impacts of the Great Resignation (i.e., the pandemic-era trend that saw employees leaving roles for a change of lifestyle or to seek greater purpose and fulfillment). Some fear that, when tasked with tackling deeper volumes of increasingly arduous compliance tasks on smaller budgets, talented personnel may simply head for the exit. In addition, several companies are experiencing significant turnover and a challenging and competitive recruiting environment, and that revolving door is another strain on the department.



Bespoke co-sourcing solutions



Rather than relying solely on their own in-house capabilities and building customized technology platforms, many tax and finance functions are opting for third-party support to navigate all this change. For instance, data and compliance work can easily be co-sourced, enabling talent to spend more time on high-value activities such as communicating with stakeholders, tax planning and risk management.

Indeed, 82% of respondents to the TFO Survey said they are more likely than not to co-source select tax and finance activities in the next 24 months, with reduced risk and costs the most commonly cited benefits.

Even the biggest organizations, with well-funded and resourced IT and technology infrastructures, are relying much more heavily on external advisors and third-party tools, especially in light of the requirements of BEPS 2.0 Pillar Two. The tax rules are too complex and are changing quickly. As a result, it is often expensive and too risky to build and maintain custom in-house solutions.

It's worth noting that co-sourcing is not a one-size-fits-all proposition. Rather, it's a unique response to the needs and challenges of each organization. For example, life sciences companies with a large international footprint are likely to co-source their corporate income tax and

indirect tax compliance work for value-added tax (VAT) and goods and services tax (GST), as well as work on other ancillary and local filings that are often required.

A company's co-sourcing strategy will depend on a myriad of factors, including geographical footprint, complexity, turnover rate, headcount and retention goals for the tax and finance function, the skill sets and experiences of the company's tax and finance professionals, the current state of its technology and systems (including the number of ERP systems it operates), its ability to access reliable data and any investments already made by the company.

But regardless of these metrics, success for all companies will require proactive but careful planning.

Life sciences organizations are facing an unprecedented confluence of challenges, including the patent cliff, complex new compliance requirements, and a distinct set of sector-specific cost and data pressures. In the face of tighter budgets, many organizations in the sector are turning to co-sourcing models to navigate the risk and cost of compliance and to free up their tax and finance talent to focus on more critical tasks. With the right model in place, these functions will be better equipped to manage risk and add genuine value to their organization.



Business models are shifting, and tax compliance models are, too



Peter Schreiner
Global Head, Tax and Insurance
Novartis

Peter Schreiner, Global Head of Tax and Insurance at Novartis, sat down with us recently to discuss the benefits of centralization.

Ernst & Young LLP (EY): What are some of the biggest tax challenges Novartis is facing in the current environment, and how have you adjusted your tax strategy in response?

Peter Schreiner: Novartis operates in a rapidly changing business environment, and our tax team is navigating the risks and opportunities of technological disruption and digitalization, changes in the regulatory environment, and changes in workforce dynamics and hybrid working.

We've focused closely on several tax transparency initiatives across jurisdictions. While most of these are mandatory, some jurisdictions require us to do what is called horizontal monitoring, a contemporaneous process that allows taxpayers to share their reasoning for certain tax items and the controls they have with tax authorities.

To better help us respond to these challenges, Novartis Tax has made the shift from being a decentralized tax compliance function, where the team in each country independently ensures compliance with local country requirements, to being a more centralized, outsourced tax compliance service with a single outsource partner under which we have greater visibility at the headquarter level.

EY: Why was it important for Novartis to move to a centralized tax compliance model with a single outsource partner?

Schreiner: We had several goals across different time frames, from short term to long term. Our immediate aims were to gain visibility at the headquarter level of the company's tax status across the countries in which we operate and to establish baseline quality standards.

A longer-term goal was to leverage this consistent external interface to drive increased standardization within our own internal processes and procedures. This allowed us to incorporate automation, with the main objective of limiting manual and human interventions in some data collection from different sources and in our reporting systems. This standardization and automation allowed us to relieve some of the pressure on our people, giving them the room to focus on the controls.

GUEST PERSPECTIVE



This approach involved internal changes to our tax governance and mandated an external independent preparation or review of the tax returns.

EY: You mentioned that governance, methodology and visibility were important factors in deciding to shift to a centralized compliance model. What other benefits or considerations were important to you?

Schreiner: Given the scale of the project and the existing strains on our tax department from managing numerous other projects, including BEPS 2.0, we needed additional people. A centralized compliance model provided us the additional resources we needed. In addition, our outsource partner brought their systems and technology expertise, along with a technology stack that would have been too costly and time-consuming for us to develop and build internally.

This model has been especially helpful around M&A. It is much easier to change business models when the underlying tax governance follows basic principles and the processes on compliance are well-established and well-tested. Externalizing this model has allowed us to free up our qualified tax resources in-house to focus on risk management and value-add activities.

We also have access to other clients of our service provider, allowing us to have conversations with peers who work on similar platforms and learn from their experiences. That is an important dimension as tax directors and peers spend a lot of time in forums where they're discussing experiences and the resources needed to address complex and emerging issues.

EY: Now that your centralized tax operating model is implemented, what's next and what additional benefits would you like to realize?

Schreiner: Our work on the tax compliance engagement continues to develop. From the initial focus on specific compliance objectives, we have worked to gain a more granular view of our processes. Instead of seeing only whether we filed our tax returns on time, we now look at how early we filed them, how long it took to gather the necessary information to complete the tax filings and whether information needed additional processing. This helps us to identify potential delays and inefficiencies in our processes, resource constraints within certain countries, and areas where automation and integration of technology might improve accuracy, reduce administrative workload, enable support from centralized subteams and save time.



DATABOOK

Financials
Financing
M&A
Alliances
Data exhibit index

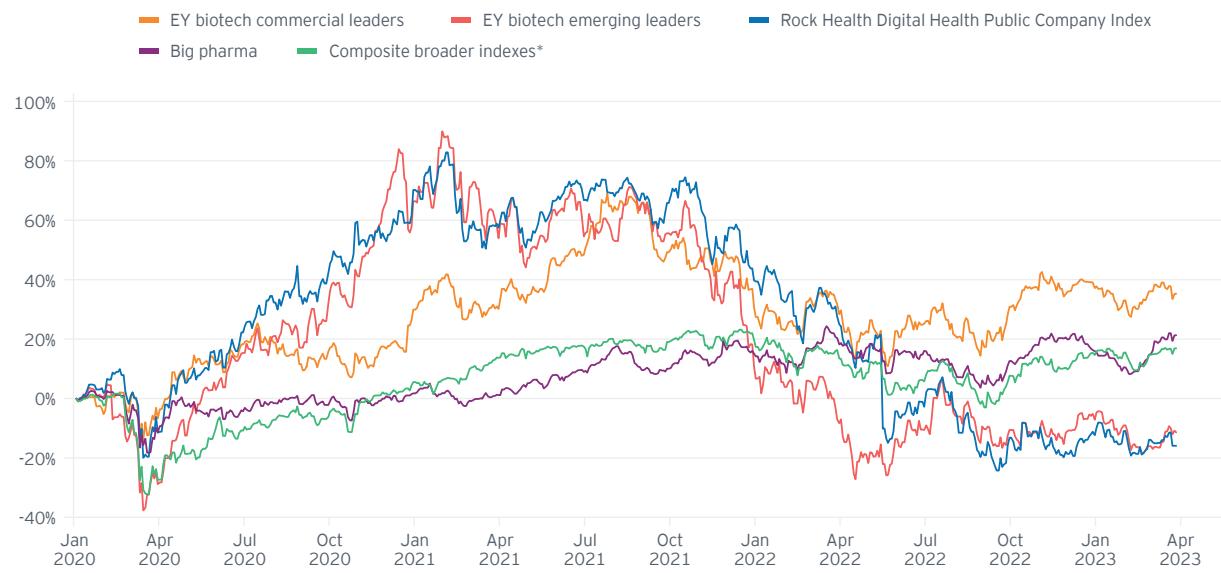
US and European biotechnology at a glance (US\$b)

	2022	2021	% change (2022-21)
Public data company			
Revenues	\$215.2	\$217.3	(1%)
R&D expense	\$91.1	\$91.0	0%
Net income	\$(29.6)	\$(0.1)	(19,887%)
Market capitalization	\$1,305.1	\$1,311.2	(0.5%)
Number of employees	284,200	266,600	7%
Financing			
Capital raised by public companies	\$35.5	\$ 92.4	(62%)
Number of IPOs	22	160	(87%)
Number of companies			
Public companies	949	971	(2%)

Sources: EY analysis, Capital IQ and company financial statement data.
Numbers may appear inconsistent because of rounding.

- ▶ Total revenues for public biotech companies dropped 1% in 2022 following the huge pandemic-driven increase in industry sales in 2021. Commercial leaders – defined here as the companies that capture more than US\$500 million in annual revenue, of which there were 49 in 2022, up 3 from the previous year – generated 88% of the year's US\$215.2 billion total, up 1%, while collective revenues for all other companies fell 11%. Net income also fell sharply, from -US\$148 million in 2021 to -US\$29.6 billion in 2022, with the biggest drops coming from accounting charges and operational challenges.
- ▶ Only two out of the top six public biotechs, and just 53% of all public biotechs with revenues, improved their top-line growth; only 42% of companies increased bottom-line growth. Three of the biggest drops were recorded by Regeneron (down US\$3.9 billion, 24%, as REGEN-COV lost US authorization), BioNTech (down US\$3.1 billion, 14%, amid falling vaccine demand) and OPKO Health (down US\$770 million, or 43%, with reduced demand for COVID-19 testing). The largest stand-alone biotech, Gilead Sciences, saw a US\$1.7 billion drop in sales for its Veklury COVID-19 treatment offset by growth in the rest of its portfolio, with overall company revenues at US\$27.3 billion (down just 0.1%). Approximately US\$2.3 billion of 2021 biotech revenue from 2021 disappeared as a result of delistings, bankruptcies or acquisitions (e.g., Pfizer's acquisition of Biohaven removed US\$462 million in 2021 revenue from the biotech industry).
- ▶ Nevertheless, other companies continued to see strong revenue performances built on COVID-19 portfolios, including Moderna, which saw its Spikevax drive revenues up 4% to US\$19.3 billion; Vir, which grew 48% to US\$1.6 billion from its share of revenues from the Xevudy coronavirus treatment; and Novavax, with US\$1.6 billion sales from its COVID-19 vaccine helping boost total revenues, which were up by 73%. Outside of the COVID-19 market, other strong performers in 2022 were Vertex, which achieved US\$8.9 billion in revenues (up 18%) largely on the strength of its Trikafta/Katario cystic fibrosis therapy, and Genmab, which reached US\$2.1 billion (a 62% increase) on the strength of royalties from collaborations with Janssen and Novartis.

US and European biotech market capitalization relative to leading indexes



Sources: EY analysis and Capital IQ.

Chart includes companies that were active on 30 December 2022.

*Composite broader indexes refers to the daily average of leading US and European indexes: Russell 3000, Dow Jones Industrial Average, NYSE, S&P 500, CAC-40, DAX and FTSE 100.

- ▶ Following the market correction in mid-2021, stock prices have recovered for the commercial leaders group. Valuations for these companies are now 37% higher than they were at the beginning of 2020, prior to the pandemic surge and subsequent dive in industry market capitalization. This increase is greater than the valuation growth for composite indexes (up 18%), big pharma (up 22%) and the Rock Health Digital Health Public Company Index, which fell 17%. The growth in biotech valuations in 2020 and 2021 was driven by the emerging leaders group, which is now less favored by investors, down 12% compared with January 2020.

Quarterly breakdown of US and European biotechnology financings (US\$m), 2022

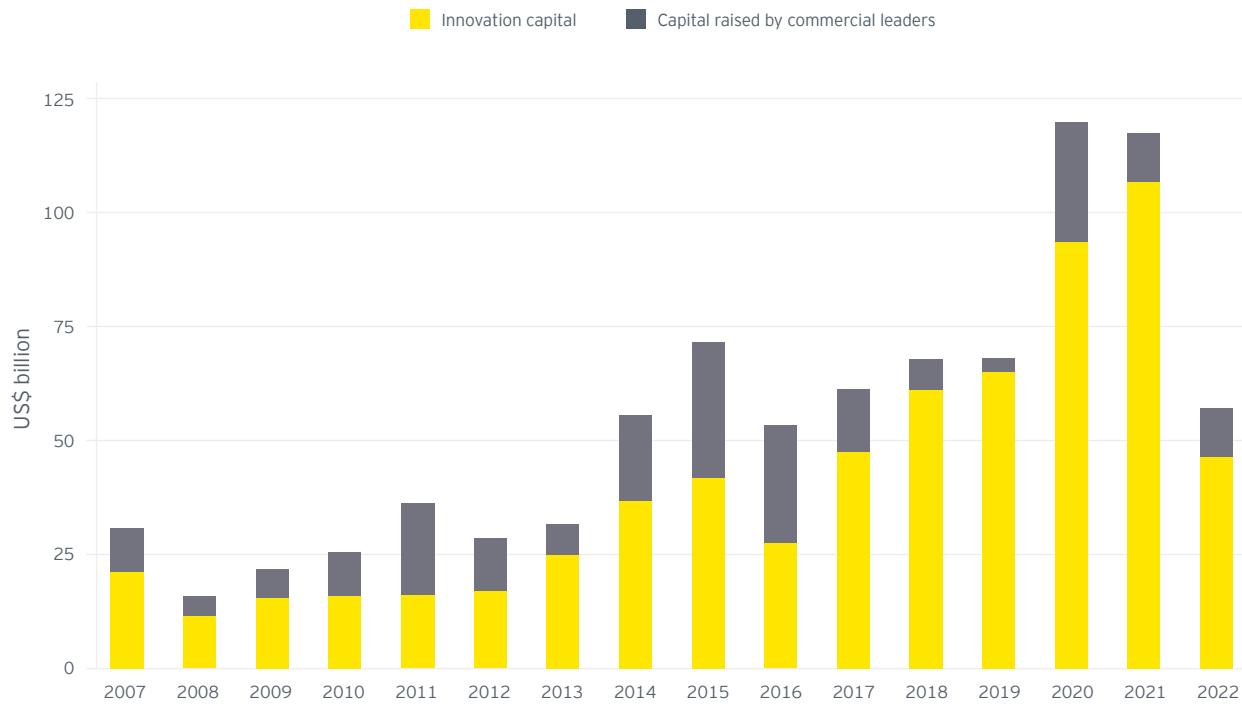
	First quarter	Second quarter	Third quarter	Fourth quarter	Total
IPO	\$342	\$607	\$228	\$302	\$1,479
	(8)	(6)	(3)	(5)	(22)
Follow-on and other	\$3,631	\$3,312	\$7,115	\$6,487	\$20,544
	(53)	(72)	(101)	(91)	(317)
Debt	\$4,871	\$1,289	\$6,615	\$895	\$13,670
	(17)	(7)	(16)	(6)	(46)
Venture	\$8,541	\$3,687	\$3,403	\$3,268	\$18,899
	(255)	(194)	(178)	(178)	(805)
Total	\$17,385	\$8,749	\$17,507	\$10,952	\$54,592
	(333)	(278)	(299)	(280)	(1,190)

Sources: EY analysis, Capital IQ and Dow Jones VentureSource.

Figures in parentheses are number of financings. Numbers may appear inconsistent because of rounding.

- ▶ While the industry raised US\$13.7 billion in debt financing, equity investment (venture, follow-on financing and IPO fundraising) fell 60% to US\$40.9 billion, the lowest level since 2016. Venture spending took less of a hit than IPO and follow-on financing; though venture investment fell 29% to US\$18.9 billion, the lowest level since 2019, this was still the fourth-highest total raised in the last decade and well above the previous decade's average of US\$14.2 billion. From a geographic perspective, US companies attracted 86% of all financing, including 78% of venture, 83% of follow-on, 88% of IPOs and 99% of debt.
- ▶ Just over half of the total investment in the sector came in the second half of the year (52% of the total and 51% of all equity financing). While this suggests a stable or positive trajectory, the majority of funding in July to December 2022 came from follow-on investment, with just 36% of IPO fundraising and 35% of venture spending coming in the second half of the year. Of the venture total, 45% was raised in the first quarter alone, with just US\$10.4 billion coming over the last nine months of the year.
- ▶ Despite negative trends, financing levels in 2022 were impressive in a broader historical perspective. In the five-year period following the onset of the financial crash in 2007, the industry raised an annual average of US\$25.7 billion, with equity investment accounting for just over half of this amount. The subsequent decade from 2013 to 2022 has seen average investment surge to US\$66.4 billion, with equity investment accounting for 70%. This change represents a 781% increase in average annual value of IPOs, a 395% increase in follow-on funding and a 258% increase in venture financing. Aside from IPO investment (which sank to its lowest level since 2012), the financing picture in 2022 aligned far more closely with the rest of the decade than it did with the preceding lean years for biotech.

Innovation capital in the US and Europe by year



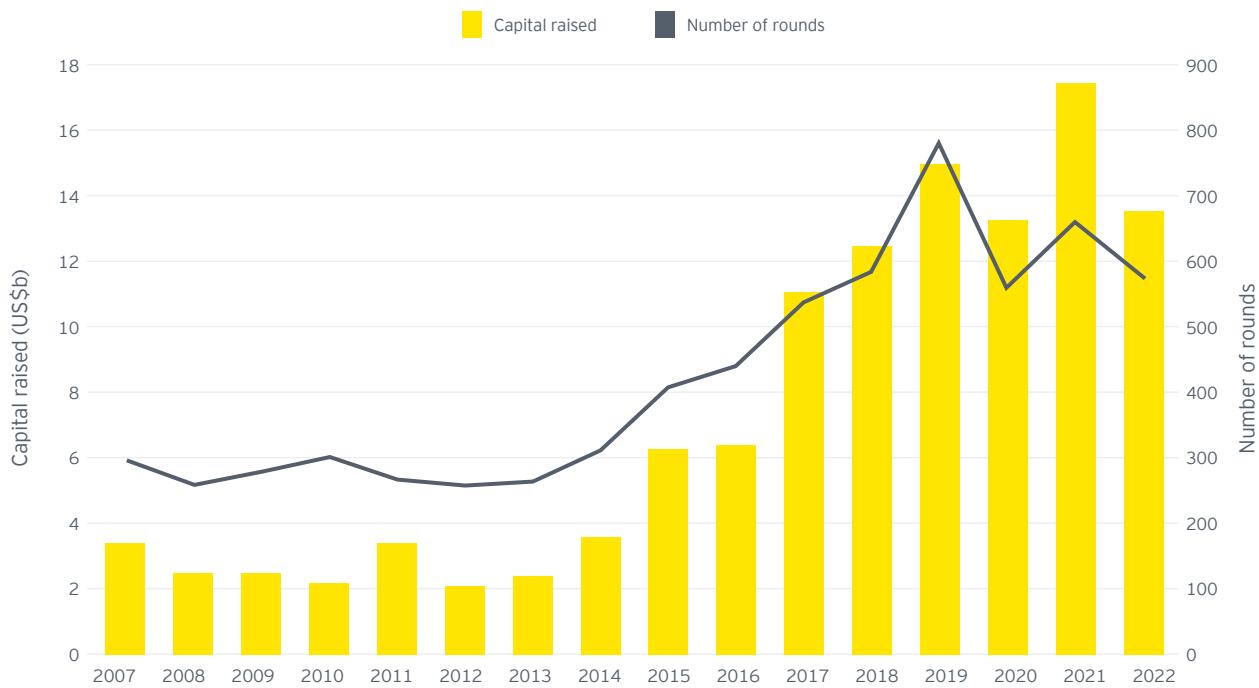
Sources: EY analysis, Capital IQ and Dow Jones VentureSource.

Innovation capital is the amount of capital raised by companies with revenues of less than US\$500 million.

Commercial leaders are companies with revenues that are equal to or greater than US\$500 million

- We define innovation capital as the amount of capital raised by companies with revenues of less than US\$500 million. As a result of the sharp decreases in venture, IPO and follow-on funding, innovation capital slid 59% from a record high of US\$107 billion in 2021 to US\$44 billion in 2022 – this was the lowest total amount of innovation capital invested since 2016 and well below the previous decade's average of US\$52.4 billion.

US and European early-stage venture investment



Sources: EY analysis, Capital IQ and Dow Jones VentureSource.
Early stage includes venture capital investments that occur in the first or second venture rounds.

- ▶ Despite the drop in venture spending overall, it was notable that US\$13.7 billion (72% of total investment) went to early-stage companies (i.e., to seed, first or second financing rounds).
- ▶ Though the total of 567 early-stage deals was down compared with 2021, it was nonetheless well above the whole-decade average of 472 early-stage deals, as was the average deal size (US\$24.1 million compared with US\$17.4 million over the past decade).
- ▶ It must be noted, however, that 22% of the early-stage total came from the proposed commitment of US\$3 billion first-round investment in Altos Labs. This represented by far the largest ever venture round in the history of the industry, 2.5 times greater than GRAIL's record US\$1.2 billion round in 2017 and higher than the next 15 top venture funding rounds of 2022 combined.

Top US and European venture capital rounds, 2022

Name	Region	Therapeutic focus of lead candidate	Clinical stage of lead candidate	Gross raised (US\$m)	Quarter	VC round type
Altos Labs	US – Northern California	N/A	Preclinical	\$3,000	Q1	1st round
Areteia Therapeutics	US – New Jersey	Respiratory	Phase III	\$350	Q3	1st round
Kriya Therapeutics	US – Southern California	Multiple	N/A	\$270	Q2	3rd round
Kallyope	US – New York	Gastrointestinal	Phase I	\$236	Q1	Late stage
Orna Therapeutics	US – Massachusetts	Multiple	Preclinical	\$221	Q3	2nd round
Alumis	US – Northern California	Dermatology	Phase II	\$200	Q1	2nd round
DNA Script	France	N/A	N/A	\$200	Q2	3rd round
FogPharma	US – Massachusetts	Oncology	Preclinical	\$178	Q4	Late stage
Affini-T Therapeutics	US – Massachusetts	Oncology	Preclinical	\$175	Q1	2nd round
Metagenomi	US – Northern California	Metabolic	Preclinical	\$175	Q1	2nd round
LifeMine Therapeutics	US – Massachusetts	Multiple	Unknown	\$175	Q1	3rd round
Frontera Therapeutics	US – Massachusetts	Ophthalmology	Early clinical	\$160	Q3	2nd round
Carmot Therapeutics	US – Northern California	Diabetes	Phase II	\$160	Q3	Late stage
MOMA Therapeutics	US – Massachusetts	Oncology	Preclinical	\$150	Q2	2nd round
Dewpoint Therapeutics	US – Massachusetts	Multiple	Preclinical	\$150	Q1	3rd round
Inari Agriculture	US – Massachusetts	N/A	N/A	\$150	Q3	Late stage
Apogee Therapeutics	US – Northern California	Immunology	Preclinical	\$149	Q4	2nd round
Leyden Laboratories	Netherlands	Infectious disease	Preclinical	\$140	Q1	2nd round
Ventus Therapeutics	US – Massachusetts	Multiple	Preclinical	\$140	Q1	3rd round
Rivus Pharmaceuticals	US – Virginia	Obesity	Phase II	\$132	Q3	2nd round

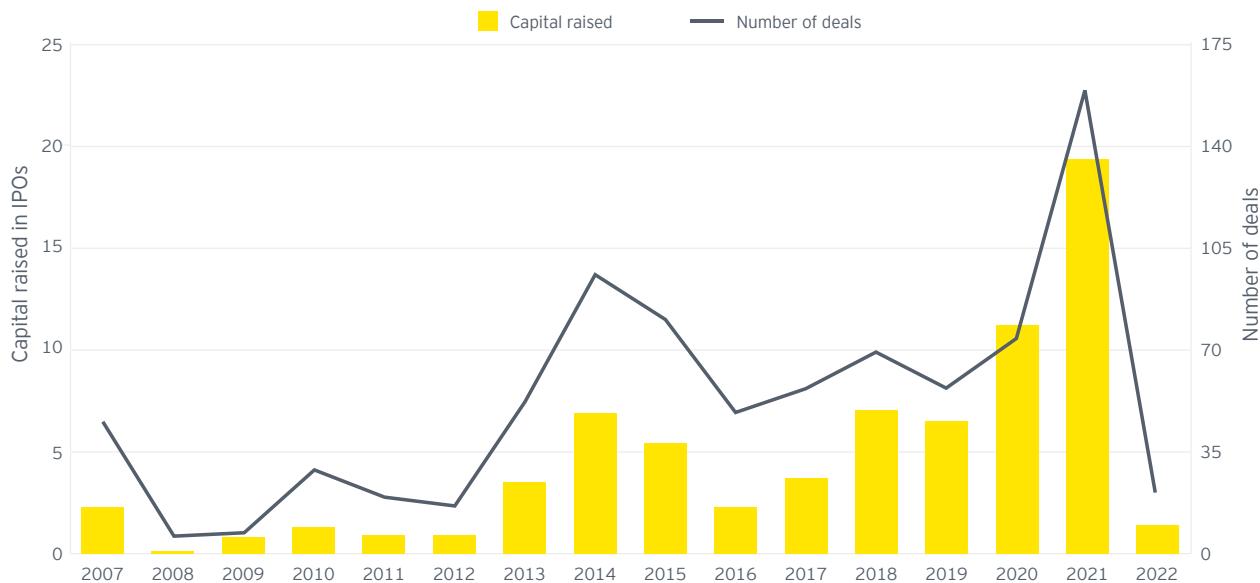
Sources: EY analysis, Capital IQ and Dow Jones VentureSource.

Early stage includes venture capital investments that occur in the first or second venture rounds. Late stage include third and additional rounds.

- ▶ Based in the San Francisco Bay Area, San Diego and Cambridge (UK), and organized into distinct units (the Institute of Science and the Institute of Medicine), Altos Labs' stated mission is to "restore cell health and resilience to reverse disease, injury and the disabilities that can occur throughout life."⁴ The company is supported by a founding leadership team of established industry figures and investors, including Jeff Bezos and Yuri Miller. As noted, Altos Labs' US\$3 billion in venture investment is an industry record by a considerable margin, achieved in spite of the fact that the company's R&D is currently at a preclinical stage.
- ▶ Companies with preclinical or early-stage platform technologies figured prominently elsewhere in the biggest venture funding rounds. These enterprises included Kriya Therapeutics, which secured US\$270 million to expand its SIRVE machine learning platform, intended to support a gene therapy pipeline in multiple therapeutic areas; Kallyope's drug-discovery platform, which raised US\$236 million in Series D funding; and Orna Therapeutics, recipient of US\$221 million in Series B funding to help extend its oRNATM platform, which is intended to improve immunotherapy technologies. DNA Script of France raised the largest European funding round, with US\$200 million invested in its DNA synthesis platform.
- ▶ Areteia Therapeutics, co-created by Knopp Biosciences and the private equity firm Population Health Partners, raised US\$350 million to develop its dexampramipexole molecule for eosinophilic asthma, with Bain Capital Life Sciences among the investors. This was the only Phase III lead candidate among the highest funding rounds, but this pattern may change if, as anticipated, investors increasingly turn their focus to late-stage assets rather than products with revenue potential only in the longer term.

4. "Altos Labs launches with the goal to transform medicine through cellular rejuvenation programming," PR Newswire website, www.prnewswire.com/news-releases/altos-labs-launches-with-the-goal-to-transform-medicine-through-cellular-rejuvenation-programming-301463541.html, 19 January 2022.

US and European biotechnology IPOs by year



Sources: EY analysis, Capital IQ and Dow Jones VentureSource.

- ▶ The record-breaking biotech IPO market of 2021, which raised US\$20.5 billion in investment, disappeared almost entirely in 2022, with only US\$1.4 billion generated in biotech IPO revenue. This total was the lowest since 2012, as was the number of IPOs (22) and the average round size (US\$65 million). This activity reflects the turn away from the sector among generalist investors and the plunge in valuations, which meant that only one in five of the companies completing an IPO in 2021 were valued at or above their float price by the end of that calendar year.⁵ Rather than seeking an early IPO, biotechs can now be expected to prolong the capital raised in early VC rounds or pursue additional private funding (or seek other alternatives such as reverse mergers) before attempting a public market debut.
- ▶ The surge of generalist capital investment into the sector in 2020 and 2021 led to an IPO bull market, which arguably disregarded historic industry fundamentals. For example, biotechs would traditionally be unlikely to seek an IPO with no validated clinical-stage assets. The disappearance of this capital inflow to the sector is compounded by the simultaneous near disappearance of the special purpose acquisition company (SPAC) biotech market since the second half of 2021. Moreover, the SEC's March 2022 announcement of new restrictions on SPAC deals decreased the likelihood of a recovery in this investment source.
- ▶ The shift away from biotech as a focus for investment means that the IPO market is now in much the same position as it was a decade ago, dependent on specialist investors (as described at the time in the 2013 Beyond Borders report). The second half of 2022 saw IPO numbers dip again (with eight IPOs completed for US\$558 million, compared with 14 for US\$918 million in the first half). Nevertheless, the hope is that with an anticipated fall in interest rates, a rebalanced IPO market may recover in the near future, with the focus back on fundamentals, including clinical validation of assets.

5. "Biopharma and Medtech Review 2021," Evaluate website, info.evaluate.com/rs/607-YGS-364/images/jn371-vantage-2021-review-report.pdf, February 2022.

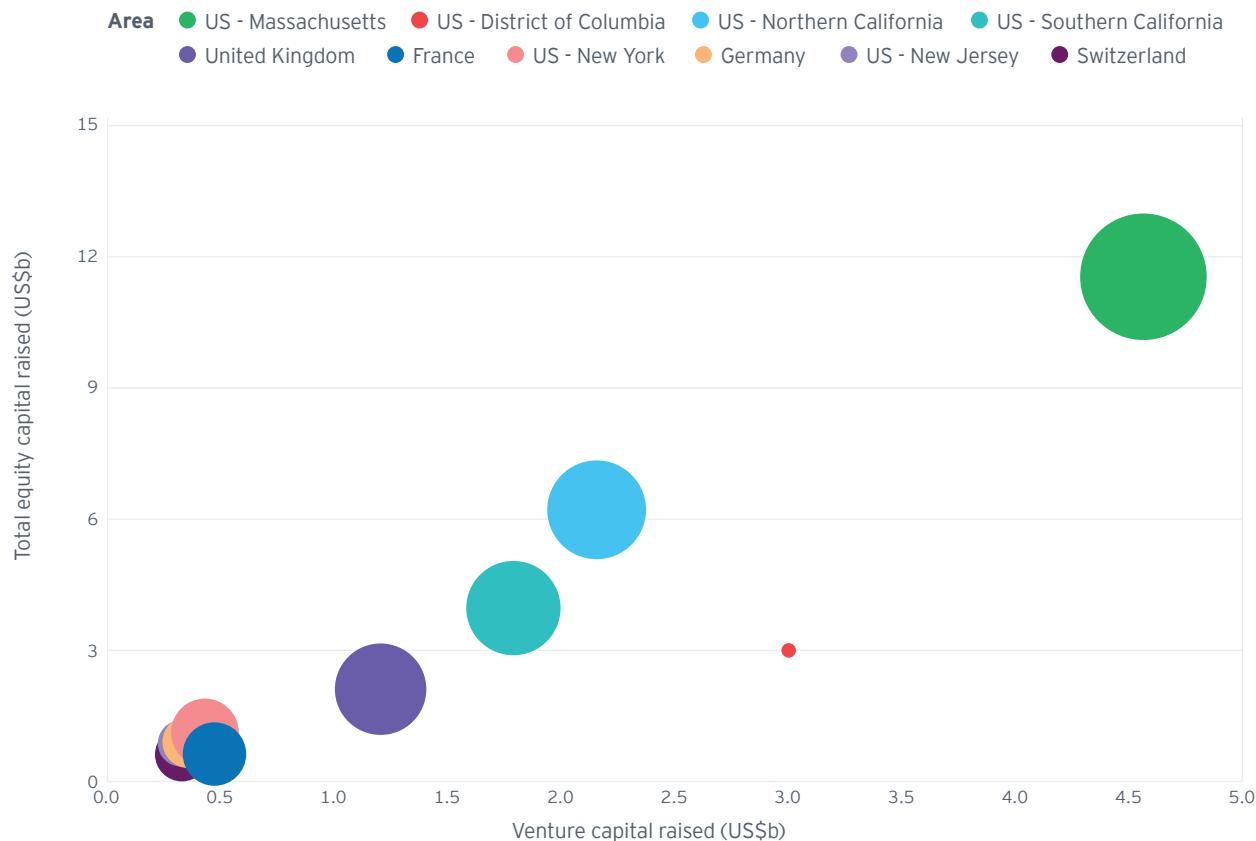
US and European IPOs, 2022

Name	Region	Therapeutic focus of lead candidate	Clinical stage of lead candidate	Gross raised (US\$m)	Quarter	Post-IPO performance (31 Dec 2022)
HilleVax	US – Massachusetts	Infectious disease	Phase II	\$230	Q2	(2%)
Third Harmonic Bio	US – Massachusetts	Multiple	Phase I	\$213	Q3	(75%)
Prime Medicine	US – Massachusetts	Multiple	Preclinical	\$175	Q4	9%
Arcellx	US – Maryland	Oncology	Phase II	\$142	Q1	107%
MoonLake Immunotherapeutics	Switzerland	Inflammatory disease	Phase II	\$115	Q2	-
PepGen	US – Massachusetts	Neurology	Phase I	\$108	Q2	11%
Vigil Neuroscience	US – Massachusetts	Neurology	Phase I	\$98	Q1	(11%)
Acrivon Therapeutics	US – Massachusetts	Oncology	Phase II	\$94	Q4	(8%)
AN2 Therapeutics	US – Northern California	Respiratory	Phase II/III	\$79	Q2	(36%)
Belite Bio	US – Southern California	Ophthalmic	Phase III	\$41	Q2	402%
Aelis Farma	France	Neurology	Phase II	\$28	Q1	(9%)
Blue Water Vaccines	US - Ohio	Infectious disease	Preclinical	\$20	Q1	(88%)
TC Biopharm	UK	Oncology	Phase I	\$18	Q1	(9%)
Coya Therapeutics	US – Texas	Multiple	IND-enabling	\$17	Q4	(5%)
Nuvectis Pharma	US – New Jersey	Oncology	Phase I	\$16	Q1	50%
Hillstream Biopharma	US – New Jersey	Oncology	IND-enabling	\$15	Q1	(90%)
MAIA Biotechnology	US – Illinois	Oncology	Phase II	\$10	Q3	(30%)
Bullfrog AI	US – Maryland	Oncology	Phase I	\$8	Q4	(100%)
bioAffinity Technologies	US – Texas	Oncology	Unknown	\$8	Q3	(74%)
Lipella Pharmaceuticals	US – Pennsylvania	Women's health	Phase II	\$7	Q4	(46%)
Genflow Biosciences	UK	Genetic	Preclinical	\$5	Q1	(74%)
OKYO Pharma	UK	Ophthalmic	Phase I	\$3	Q2	(99%)

Sources: EY analysis, Capital IQ and Dow Jones VentureSource.
IND - investigational new drug

- ▶ Roughly two-thirds of 2022 biotech IPOs were executed by companies with lead products at the preclinical or Phase I development stage. These included the year's largest IPO, carried out by Third Harmonic Bio (based in Cambridge, Massachusetts), which raised US\$238 million. The company's lead asset is a KIT inhibitor licensed from Novartis and currently seeking Phase Ib proof-of-concept data as a therapy for allergic skin disorders. Notably, this IPO would have ranked only 20th in size had it been executed in the surging biotech IPO market of 2021.
- ▶ In all, six of the eight top IPOs in terms of capital raised went to companies headquartered in Massachusetts, including the second-largest public offering (HilleVax, spun out from Takeda and developing a norovirus vaccine candidate, which raised US\$230 million) and the third (Prime Medicine, which owns a gene-editing technology platform and captured US\$175 million in IPO investment). Arcellx, the fourth-largest IPO of 2022, is based in Gaithersburg, Maryland, and has Phase II clinical studies underway in multiple myeloma. Oncology was the most common therapeutic area overall for biotechs that executed IPOs in 2022.
- ▶ US biotechs were responsible for 17 of the 22 IPOs completed in 2022, and 88% of the total US\$1.5 billion invested. The largest European IPO was actually a SPAC carried out by Switzerland's MoonLake Immunotherapeutics, which has three clinical-stage therapies targeting inflammatory diseases. Originally announced in October 2021, MoonLake's IPO was completed in April 2022.

Capital raised by leading US and European regions excluding debt, 2022



Sources: EY analysis, BMO Capital Markets, Dow Jones VentureSource and Capital IQ.
Size of bubbles shows relative number of financings per region.

- In line with historic patterns, Massachusetts, Northern California and Southern California dominated all other regions in terms of equity financing (collectively accounting for 53% of the total) and VC funding raised (46%). Massachusetts led all regions with US\$11.6 billion in total equity, VC raised (US\$4.6 billion) and total equity rounds (167). The US accounted for 81% of equity fundraising and 78% of VC, with the UK, France and Germany leading the European regions.

Select US and European M&As, 2022

Company	Country	Acquired or merged company	Country	Total potential value (US\$m)	CVRs/milestones (US\$m)
Amgen	US-Southern California	Horizon Therapeutics	Ireland	27,800	-
Pfizer	US-New York	Biohaven Pharmaceutical	US-Connecticut	11,600	-
Takeda	Japan	Nimbus Therapeutics	US-Massachusetts	6,000	2,000
Pfizer	US-New York	Global Blood Therapeutics	US-Northern California	5,400	-
Bristol Myers Squibb	US-New York	Turning Point Therapeutics	US-Southern California	4,100	-
Amgen	US-Southern California	ChemoCentryx	US-Northern California	3,700	-
GlaxoSmithKline	UK	Affinivax	US-Massachusetts	3,300	1,200
GlaxoSmithKline	UK	Sierra Oncology	US-Northern California	1,900	-
UCB	Belgium	Zogenix	US-Northern California	1,900	-
Sumitovant Biopharma	UK	Myovant Sciences	UK	1,700	-
Incyte	US-Delaware	Villaris Therapeutics	US-North Carolina	1,430	1,360
Merck & Co.	US-New Jersey	Imago BioSciences	US-Northern California	1,350	-
Novo Nordisk	Denmark	Forma Therapeutics	US-Massachusetts	1,100	-
Abbvie	US-Illinois	Syndesi Therapeutics	Belgium	1,000	870
Alcon	Switzerland	Aerie Pharmaceuticals	US-North Carolina	930	-

Sources: EY analysis, Capital IQ and company news.

Total potential value includes up-front, milestone and other payments from publicly available sources.

- ▶ Amgen's US\$27.8 billion purchase of Ireland-based Horizon, to bolster its rare autoimmune and inflammatory disease portfolio, was the largest deal of 2022, with Pfizer's US\$11.6 billion acquisition of the remaining shares in Biohaven and its migraine treatment portfolio the second. Amgen's acquisition of Horizon has since been called into question by the FTC, and the deal is unlikely to close before the end of 2023, if at all. Both Amgen and Pfizer were featured twice in the year's top six deals, with Amgen also paying US\$3.7 billion for ChemoCentryx and Pfizer spending US\$5.4 billion for Global Blood Therapeutics. Pfizer, breaking US\$100 billion in 2022 revenues with 30% top-line growth driven by its COVID-19 portfolio, has continued using its capital to set the pace for M&A in 2023, with its US\$43 billion takeout of Seagen the biggest biotech deal of recent years.
- ▶ Elsewhere, Takeda spent US\$4 billion up front (and potentially up to US\$2 billion more in milestone payments) to acquire Nimbus Therapeutics' subsidiary Nimbus Lakshmi's Phase III-ready psoriasis drug. Oncology was a focus for other companies, with Bristol Myers Squibb paying US\$4.1 billion to acquire Turning Point Therapeutics and GlaxoSmithKline paying US\$1.9 billion for Sierra Oncology; the British biopharma also paid US\$3.3 billion for Affinivax and its pipeline vaccines for pneumococcal diseases.
- ▶ The eight largest deals, as described above, accounted for 76% of the total 2022 deal value. The Amgen-Horizon and Pfizer-Biohaven deals alone accounted for 47% of the total US\$83.6 billion invested in biotech M&A. The 45 other deals completed in 2022 accounted for US\$44.2 billion, averaging US\$983 million per deal, and the overall deal volume, though down on the 2021 record of 57, was nonetheless significantly above the past-decade average of 38.

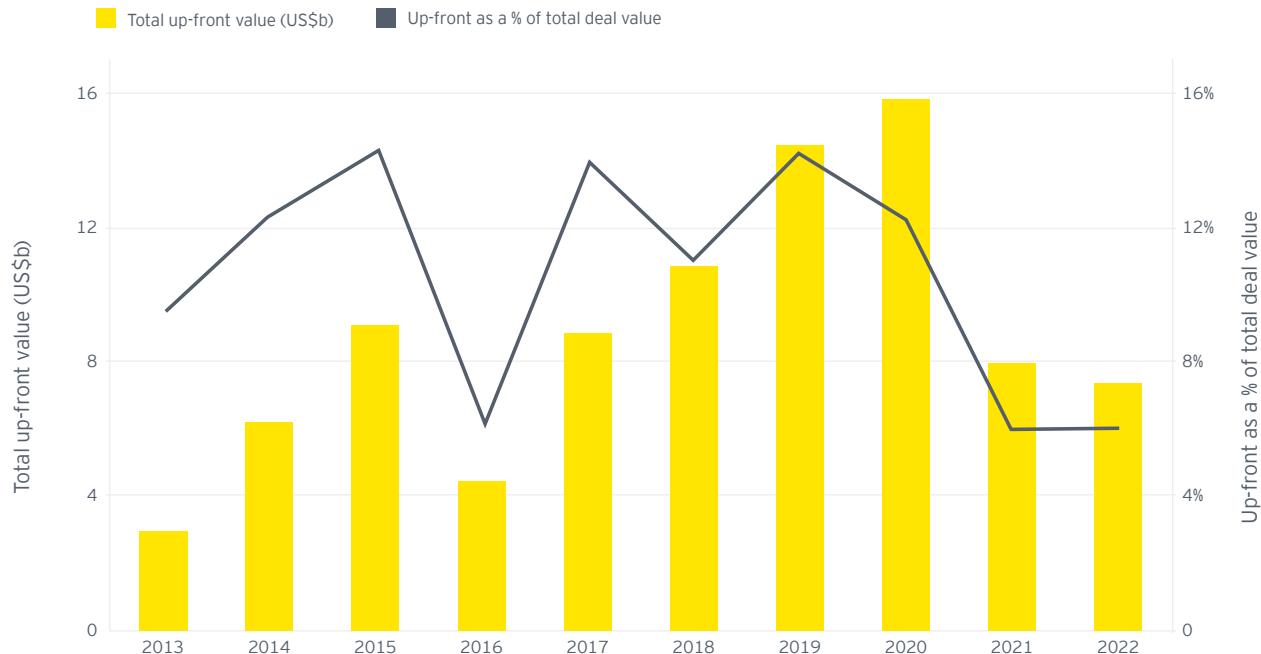
Leading US and European biobucks alliances, 2022

Company	Region	Partner	Region	Lead therapy area	Total potential value (US\$m)	Up-front payments (US\$m)
Roche	Switzerland	Poseida Therapeutics	US – Southern California	Oncology	6,220	110
Sanofi	France	IGM Biosciences	US – Northern California	Oncology	6,165	150
Sanofi	France	Exscientia	UK	Oncology	5,300	100
Bristol Myers Squibb	US – New York	Evotec	Germany	Central nervous system	5,000	200
Summit Therapeutics	UK	Akeso	China	Oncology	5,000	500
CSL	Australia	Arcturus Therapeutics	US – Southern California	Infectious disease	4,500	200
Bristol Myers Squibb	US – New York	Immatics	Germany	Undisclosed	4,260	60
Gilead Sciences (Kite Pharma)	US – Northern California	Arcellx	US – Maryland	Oncology	4,125	225
Merck & Co.	US – New Jersey	Orna Therapeutics	US – Massachusetts	Infectious disease	3,650	150
GlaxoSmithKline	UK	Wave Life Sciences	Singapore	Oncology	3,645	120
Bristol Myers Squibb	US – New York	Century Therapeutics	US – Pennsylvania	Oncology	3,100	100
Sanofi	France	Skyhawk Therapeutics	US – Massachusetts	Central nervous system	2,054	54
Roche Holding AG	Switzerland	Jnana Therapeutics	US – Massachusetts	Metabolic	2,050	50
Regeneron	US – New York	CytomX Therapeutics	US – Northern California	Oncology	2,030	30
Takeda	Japan	Code Biotherapeutics	US – Pennsylvania	Multiple	2,000	–

Sources: EY analysis, Biomedtracker and company news.

- ▶ In 2022, there were 182 announced alliances involving US and European biotechs, down 22% from 2021 and almost 40% compared with the pre-pandemic high of 301 alliance deals completed in 2019. Despite the relatively low volume, the average deal size (US\$698 million) was the highest in the past decade, with 42 alliances with potential payouts of US\$1 billion or more. The total potential deal value ("biobucks") reached US\$132.1 billion, the third-highest annual total during that period.
- ▶ Further, 7 of the top 11 alliance deals by total biobucks were focused on the oncology space, including all of the top three deals: Roche's US\$6.2 billion biobucks deal with Poseida Therapeutics to develop CAR-T therapies, and two major Sanofi deals: a potential US\$6.1 billion transaction to secure a stake in six IGM Biosciences antibodies and US\$5.2 billion biobucks invested in Exscientia and its AI drug development platform. Sanofi was involved in 12 alliance deals, the highest overall, with the company agreeing to pay both the highest biobucks (US\$21.4 billion) and the largest guaranteed up-front payments (US\$794 million) of any company. Bristol Myers Squibb was involved in 10 alliances, including 4 of the top 16 deals by potential value.
- ▶ Among the biggest recipients of these alliance investments were Germany's Evotec, which signed four deals with disclosed terms (worth US\$6.5 billion, with US\$200 million up front) giving access to its multimodal R&D platform, and two companies developing antibody-drug conjugate (ADC) technologies (the same modality Pfizer paid US\$43 billion to acquire in 2023, via Seagen). ADC developer Mersana Therapeutics signed three 2022 deals for US\$170 million up front and a potential US\$3.4 billion overall, and Merck & Co.'s deal with Kelun-Biotech (the third partnership agreement between the two) was worth nearly US\$9.5 billion in biobucks. This transaction is second only to Roche's US\$12.2 billion deal with AI drug development company Recursion Pharmaceuticals as the highest potential value partnership deal of all time.

US and European strategic alliances based on up-front payments



Sources: EY analysis, Biomedtracker.

Leading US and European alliances with big up-front payments, 2022

Company	Region	Partner	Region	Lead therapy area	Up-front payments (US\$m)
Summit Therapeutics	UK	Akeso	China	Oncology	500
Pfizer	US – New York	Beam Therapeutics	US – Massachusetts	Rare diseases	300
Gilead Sciences	US – Northern California	Dragonfly Therapeutics	US – Massachusetts	Oncology	300
Gilead Sciences (Kite Pharma)	US – Northern California	Arcellx	US – Maryland	Oncology	225
Pfizer	US – New York	BioNTech	Germany	Infectious disease	225
Vertex Pharmaceuticals	US – Massachusetts	Entrada Therapeutics	US – Massachusetts	Musculoskeletal	224
CSL	Australia	Arcturus Therapeutics	US – Southern California	Infectious disease	200
Bristol Myers Squibb	US – New York	Evotech	Germany	Central nervous system	200
Mayne Pharma	Australia	TherapeuticsMD	US – Florida	Women's health	153
Sanofi	France	IGM Biosciences	US – Northern California	Oncology	150
Merck & Co.	US – New Jersey	Orna Therapeutics	US – Massachusetts	Infectious disease	150
Oxford Biomedica	UK	Homology Medicines	US – Massachusetts	Rare diseases	130
Roche	Switzerland	Poseida Therapeutics	US – Southern California	Oncology	110
Sanofi	France	Exscientia	UK	Oncology	100
Bristol Myers Squibb	US – New Jersey	Century Therapeutics	US – Pennsylvania	Oncology	100
GlaxoSmithKline	UK	Mersana Therapeutics	US – Massachusetts	Oncology	100

Sources: EY analysis, Biomedtracker and company news.



- ▶ Of the US\$132.1 billion of announced biobucks, just US\$7.5 billion (6% of the total) came in the form of guaranteed up-front payments: the smallest up-front annual alliance investment since 2016 and down 59% from 2020's US\$15.9 billion high-water mark.
- ▶ In all, there were 24 alliances with at least US\$100 million invested up front. This figure was down from 30 in 2021 and 38 in 2020 when there were 8 up-front payments of at least US\$500 million and 4 over US\$1 billion. Pfizer invested the most up-front capital overall with US\$585 million. Pfizer's biggest single up-front investment was for US\$300 million (US\$1.35 billion total) with gene editing company Beam Therapeutics.
- ▶ The lack of up-front investment is indicative of the leverage large biopharmas have in creating these alliance deal structures during a time when capital is relatively scarce for smaller biotechs, and a lack of IPO exit routes gives these companies fewer alternatives.

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