



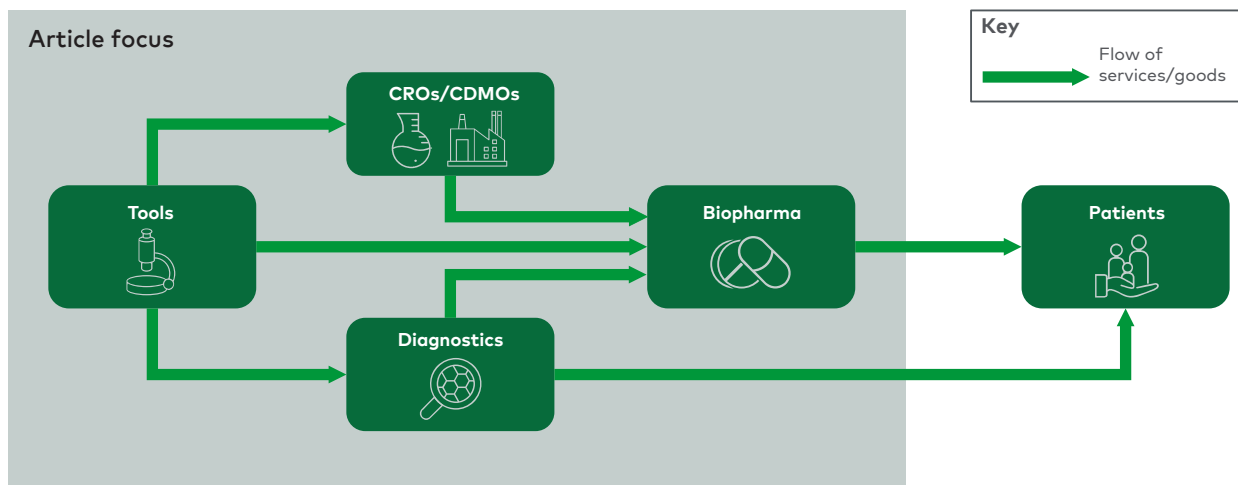
**EXECUTIVE INSIGHTS**

# Navigating the Shifting Landscape in Life Sciences: Trends and Implications

## The life sciences ecosystem and key trends

The life sciences ecosystem is a highly interconnected and dynamic network of stakeholders, all of whom play a vital role in driving innovation, improving healthcare outcomes, and bringing lifesaving therapeutics and diagnostics to patients. At the core, life sciences tools companies provide essential goods and services to contract research organizations (CROs) contract development and manufacturing organizations (CDMOs), diagnostics firms, and biopharmaceutical companies (see Figure 1). These entities collaborate to research, develop, manufacture, and market novel diagnostics and therapeutics that benefit patients.

**Figure 1**  
The life sciences ecosystem



Note: CROs=contract research organizations; CDMOs=contract development and manufacturing organizations  
Source: L.E.K. research and analysis

L.E.K. Consulting has identified several key trends that impact the life sciences ecosystem, resulting in unique challenges and opportunities for each industry stakeholder. These trends are interconnected, with the potential to shape the trajectory of the ecosystem. The following are five of these trends:

- 1. Industry funding normalization:** Recent contractions in funding levels and the potential impact on R&D spending and priorities
- 2. Revenue erosion and policy-driven cost containment:** Anticipated loss of exclusivity for blockbuster drugs alongside U.S. policy changes that could create headwinds for the industry
- 3. Increasing complexity of therapeutic modalities:** Increasing focus on advanced therapeutic modalities (ATMs) and their implications for research, development and manufacturing
- 4. Rise of advanced diagnostics:** Increasing use of innovative diagnostic technologies and their role in precision medicine and patient care
- 5. Increasing globalization:** Increasing importance of Asia-Pacific (APAC) countries such as China, India and South Korea in biopharma R&D and manufacturing

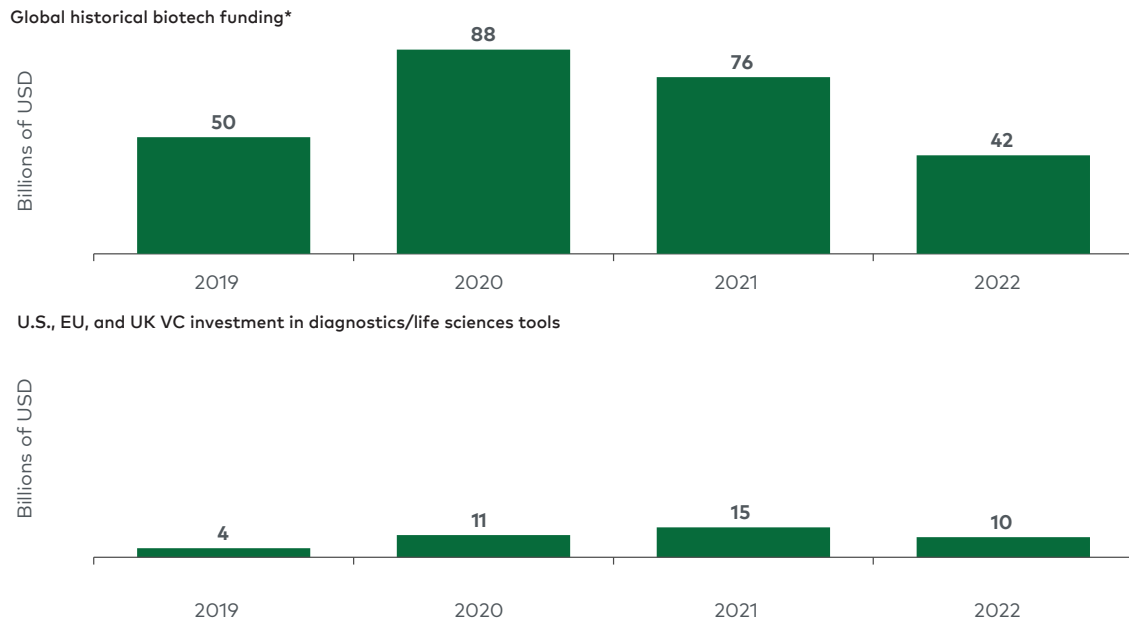
In this rapidly evolving landscape, life sciences companies must adapt and align their strategies with these emerging trends to remain competitive and capitalize on new opportunities. Participants can make informed decisions and thrive in the future ecosystem by understanding the interconnected challenges and opportunities each stakeholder faces.

## 1. Industry funding normalization

The COVID-19 pandemic (leading to Operation Warp Speed and emergency use authorizations) and governments' fiscal policies (e.g., low interest rates, quantitative easing) drove a significant increase in biotech funding, with total investments growing by approximately two-thirds between 2019 and 2020 (see Figure 2). However, after the investment peak that began in 2020 and continue into 2021, biotech funding had corrected to pre-pandemic levels by 2022.

Life sciences tools and diagnostics experienced similar trends, with investments down from 2020-21 peaks. Interestingly, recent biopharma funding has dipped below pre-pandemic levels, while life sciences tools and diagnostics funding remains more than twofold higher than in 2019, suggesting an accelerated need for tools, services and solutions to enable the biopharma value chain.

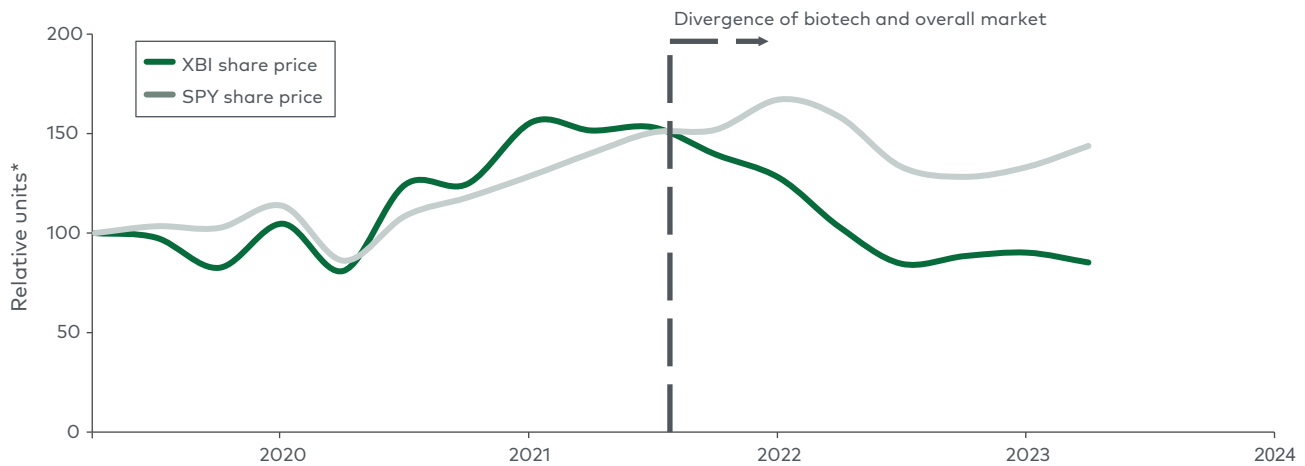
**Figure 2**  
Historical biotech, diagnostics and life sciences tools funding



\*Funding includes venture capital investments, initial public offerings, follow-on offerings and private investments in public equity  
 Note: VC=venture capital  
 Source: Pharmaprojects; TrialTrove; William Blair Report; Torrey; SVB Healthcare and Investments Report; L.E.K. research, interviews and analysis

Beyond the funding decline, market valuation of the biotechnology sector has diverged from the overall market, as evidenced by the XBI index losing over half its value from the mid-pandemic peak and remaining relatively flat, while at the same time, the SPDR S&P 500 ETF Trust (SPY) has continued to regain lost ground (see Figure 3). Market performance may indicate declining investor enthusiasm for value creation within biopharma relative to other sectors, as evidenced by the more than 200 biopharma companies trading below cash balance at the end of 2022.

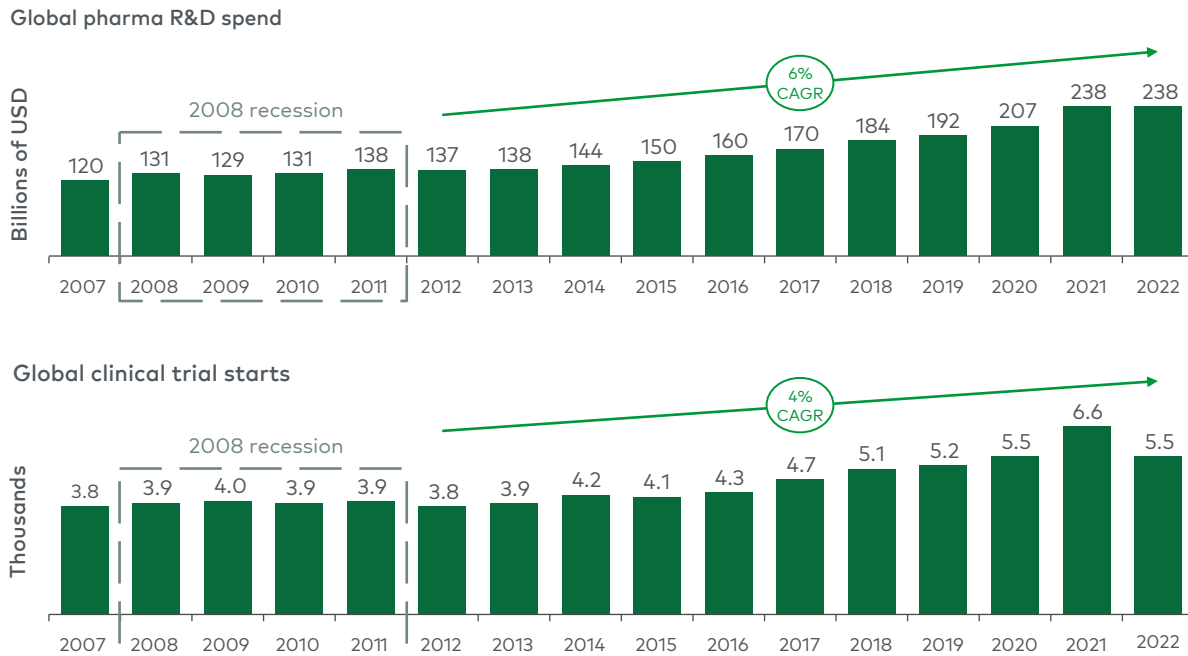
**Figure 3**  
Biotech and S&P 500 performance over time



\*Relative to April 1, 2019; data is reported on a quarterly basis  
 Note: XBI=SPDR S&P Biotech ETF; SPY=SPDR S&P 500 ETF Trust  
 Source: S&P Capital IQ; L.E.K. research, interviews and analysis

As the world continues to emerge from the pandemic and potentially enters a recessionary environment, more challenging access to funding could negatively impact R&D spending behavior. Notably, previous challenging macroeconomic environments led not to a decline in clinical trial activity but rather to a flattening: After the 2007-08 global financial crisis, R&D spending and the number of trial starts remained relatively stable from 2008 to 2011, illustrating that the industry successfully adapted to allocate funds more efficiently, prioritizing continued development of in-flight programs (see Figure 4). Post-recovery, there was sustained growth in spending and trial starts between 2012 and 2021, indicating that the impact of macroeconomic challenges on the life sciences ecosystem can be transitory.

**Figure 4**  
Historical R&D spending and clinical trial starts



Note: CAGR=compound annual growth rate  
Source: Pharmaprojects; TrialTrove; William Blair Report; Torrey; SVB Healthcare and Investments Report; L.E.K. research, interviews and analysis

### Implications of industry funding normalization

In response to more challenging access to new funding, biopharma companies may focus their near-term R&D spend on advancing existing programs toward the next value inflection point rather than increasing early discovery efforts. This change may create a trickle-down effect on life sciences tools and CRO/CDMO businesses, possibly softening near-term demand for discovery-focused products and services, whereas clinical and commercial services may see more consistent demand.

Across the life sciences tools, diagnostics and CRO/CDMO landscape, tightening of funding might also spur consolidation. Valuations for innovative companies could become more attractive to strategic buyers, especially those with cash reserves on their balance sheets from the pandemic years, or to private investors, potentially driving a wave of mergers and acquisitions across the ecosystem.

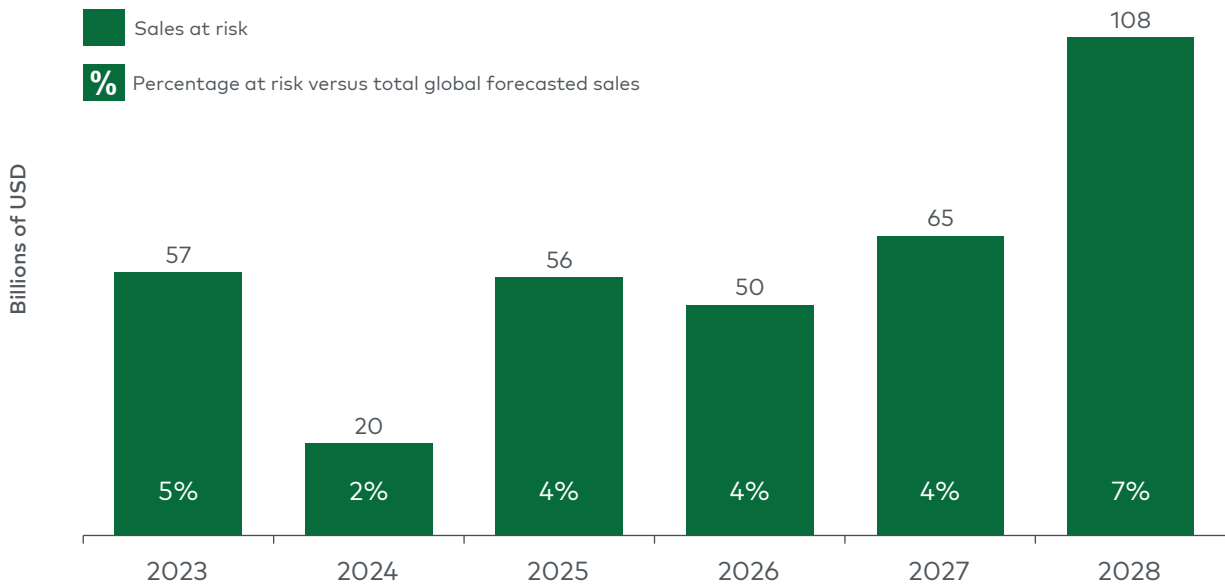
### 2. Revenue erosion and policy-driven cost containment

Over the next approximately five years, many leading blockbuster drugs such as Humira, Keytruda, Eliquis, Stelara, Eylea and Ocrevus will lose their market exclusivity, putting more than \$350 billion in sales at risk due to generic or biosimilar competition (see Figure 5).

Moreover, despite recent legal challenges from large industry stakeholders, the U.S. Inflation Reduction Act (IRA) is likely to create new headwinds for the world’s largest pharmaceutical market. As per the IRA, the top 50 highest-spend Medicare Part B and Part D drugs will undergo mandatory pricing negotiations nine years after Food and Drug Administration approval for small molecules and 13 years for biologics.

Some drug classes, however, such as single-indication orphan drugs and those derived from plasma or human whole blood, are exempt from mandatory negotiation. Likewise, products with available generics or biosimilars will not be subject to negotiation. For a comprehensive understanding of the IRA’s impact on the biopharma industry, please refer to L.E.K.’s report, “Pharma’s New Normal: How the Inflation Reduction Act Will Impact the Biopharmaceutical Industry.”<sup>i</sup>

**Figure 5**  
Global biopharma sales at risk due to LOE



Note: LOE=loss of exclusivity  
Source: Evaluate; L.E.K. research and analysis

Apart from the changes introduced by the IRA, payers, particularly in ex-U.S. markets, are progressively adopting value-based pricing. At the same time, U.S. payers increasingly rely on value assessment agencies (e.g., the Institute for Clinical and Economic Review) for real-world evidence (RWE) and health economics and outcomes research (HEOR) studies to support pricing negotiations. These shifts underscore the necessity for life sciences stakeholders to effectively demonstrate their products’ value.

## Implications of revenue erosion and policy-driven cost containment

The impending patent cliff and policy-driven cost containment will pressure the life sciences ecosystem to reassess its value creation and delivery. Large biopharma companies anticipating revenue pressure from expiring patents will likely sustain high R&D investment in the near term as they seek to replace lost sales. In the medium and longer term, IRA pricing negotiation may shift the focus toward market segments less exposed to these challenges, such as ATMs and orphan diseases, while increasing the importance of demonstrating value via RWE to support pricing negotiations.

Price negotiation mechanisms outlined in the IRA may create headwinds for small molecule drugs and broad life-cycle management. In some cases, market-entry priorities might shift to generate RWE, with ex-U.S. product launches initially, to support a later U.S. launch.

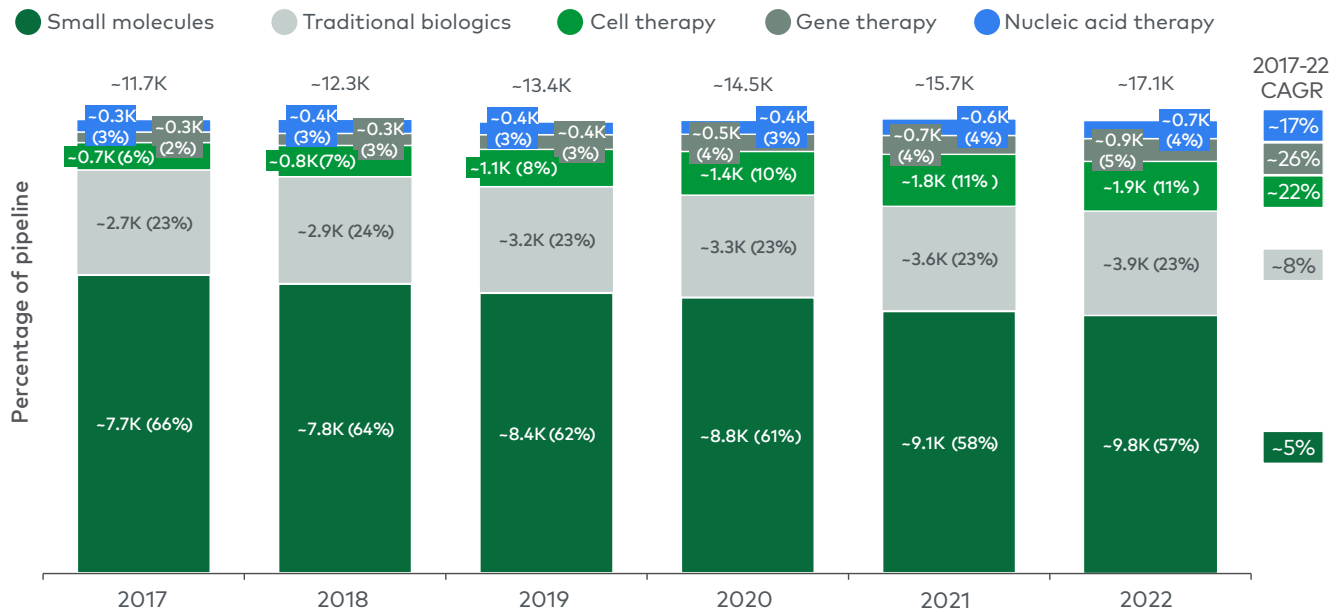
This evolution will likely also impact CROs/CDMOs, which must adapt to shifting biopharma priorities, including demand for offerings supporting value-based care negotiations (e.g., RWE, HEOR). Additionally, the broader emphasis on cost control may be a stronger tailwind for outsourced CRO/CDMO services, particularly those that may increase research efficiency, e.g., artificial intelligence (AI)-based “in silico” tools to accelerate discovery, and clinical development efficiency, e.g., data-enabled synthetic control arms, trial matching and precision enrollment services.

### 3. Increasing complexity of therapeutic modalities

The global biopharma pipeline expanded substantially from 2017 to 2022, from about 13,500 assets to 19,000 assets (annual growth rate of about 6%). Much of this growth was driven by investment in biologics and a growing interest in ATMs, such as cell, gene and nucleic acid therapy. In contrast, small molecules have experienced slower growth since 2017 (see Figure 6).

Despite the relative decrease in small molecules' share, they remain a critical part of the pipeline, as not all conditions can be targeted with advanced modalities. For example, intracellular targets, such as the MEK and AKT pathways, are inaccessible to traditional biologics and cell therapy.

**Figure 6**  
Growth of ATMs in the global biopharma pipeline



Note: ATMs=advanced therapeutic modalities  
Source: Chief Martec; MarTech Alliance; LXA; L.E.K. research and analysis









While traditional biologics have accounted for most non-small molecule approvals in the past five years, the number of nucleic acid, gene and cell therapy approvals has steadily increased.

Approximately 15 ATMs have been approved since 2020, with multiple additional approvals expected in the next one to two years and beyond (see Figure 7). The increasing prominence of ATMs highlights the growing importance of embracing, and adapting to, the rising complexity of therapeutic modalities in the biopharma industry, which will require equally complex capabilities to successfully support discovery, development, manufacturing and commercialization of these therapies.



**Figure 7**  
Recent and expected approvals of ATMs

FDA drug approvals by year

	2017	2018	2019	2020	2021	2022	2023+ (expected)
<b>Nucleic acid therapy*</b>							<ul style="list-style-type: none"> <li>• Tofersen (Biogen)</li> <li>• Eplontersen (Ionis/AstraZeneca)</li> <li>• Zimura (Iveric)</li> </ul>
<b>Gene therapy</b>							 <ul style="list-style-type: none"> <li>• Upstaza (PTC)</li> </ul>
<b>Cell therapy</b>							<ul style="list-style-type: none"> <li>• Afami-cel (Adaptimmune)</li> <li>• Exa-cel (Vertex)</li> <li>• Lifileucel</li> </ul>

\*COVID-19 mRNA vaccines are listed according to their BLA approval date, not their EUA approval date  
 Note: ATMs=advanced therapeutic modalities,  
 Source: Chief Martec; MarTech Alliance; LXA; L.E.K. research and analysis

### Implications of the increasing complexity of therapeutic modalities

The global biopharma pipeline is anticipated to continue its shift toward ATMs like cell, gene and nucleic acid therapy. Biopharma companies prioritizing these innovative modalities will benefit from generally shorter timelines to clinical development while increasingly emphasizing the importance of improving manufacturing efficiency and reducing cost of goods sold (COGS). Biopharma companies will also need to develop manufacturing and supply chain strategies early (i.e., buy versus build dynamics) and may prioritize partnerships with service providers that can enable cost-effective scaled manufacturing.

The continued growth of the ATM pipeline will increasingly require fit-for-purpose tools and services (e.g., genetic payload construct design and screening) and manufacturing capacity/expertise to bring the pipeline to fruition.

Earlier in the value chain, CROs and CDMOs may need to adapt to increasingly complex R&D requirements from biopharma partners developing ATMs, which have unique needs for discovery (e.g., construct design and screening) as well as unique challenges for process/analytical development.

In drug manufacturing, while there may continue to be a capacity supply/demand gap, an expertise gap is increasingly developing as the industry lags in training key facilities personnel.

Meanwhile, life sciences tools companies and others providing reagents/consumables (e.g., media) and critical inputs (e.g., plasmid DNA) will likely continue to prioritize differentiated offerings that can be designed in, or "locked in," to good manufacturing practice and the

analytical testing of ATMs, with the aim of driving outside growth with future commercial demand for supported programs.

Across both services and tools players, AI and in silico capabilities investments are common themes to drive R&D efficiency and help reduce COGS, though significant wet lab capabilities are still required to support these computational tools.

Private investors seeking to participate in the growth of ATMs should prioritize life sciences tools and service providers that offer the specialized capabilities and unique technology required to support an increasingly complex client base, especially those that may benefit from the high switching costs of the process lock-in dynamic.

#### **4. Rise of advanced diagnostics**

The rise of advanced diagnostics (ADx) is reshaping the landscape of patient care and treatment strategies. Over the past five years, there has been a consistent flow of novel ADx launches, supporting their growing prominence within the life sciences. Much of this focus has been channeled into oncology and traditional molecular diagnostic applications such as therapy guidance, which are one-time tests.

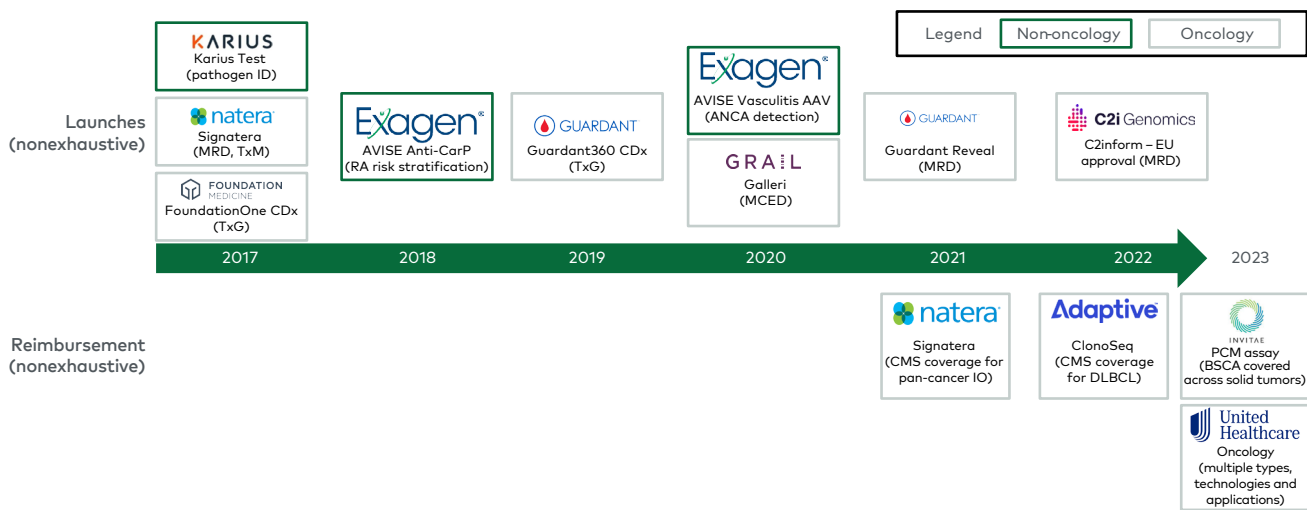
Step changes in technology have allowed for the detection of analytes in blood, enabling novel, minimally invasive diagnostic applications, including circulating tumor DNA (ctDNA) tests such as Guardant360 and multicancer early detection (MCED) technologies like those developed by Thrive and GRAIL.

These blood-based diagnostics have also unlocked novel use cases, including therapy monitoring and resistance mutation detection (e.g., EGFR T790M) and minimal residual disease (MRD) detection, like Signatera and ClonoSeq. These novel use cases offer a wide-ranging value proposition to physicians and patients, primarily for disease monitoring, and to biopharma, by incorporating surrogate endpoints in clinical trials and helping identify label expansion opportunities with RWE.

Importantly, payer coverage for novel diagnostic technologies, traditionally a challenge for diagnostics commercialization, is evolving. Notable examples include the Centers for Medicare & Medicaid Services' coverage for Natera's Signatera in pan-cancer immuno-oncology since 2021 and Adaptive's ClonoSeq for diffuse large B-cell lymphoma since 2022. This year, Blue Shield of California has approved the Invitae Personalized Cancer Monitoring assay across solid tumors, while UnitedHealthcare has issued broad coverage guidelines for oncology ADx (see Figure 8).

Although oncology has been the primary beneficiary of these advancements, blood-based tests may continue to expand the diagnostic toolkit into other areas, such as infectious diseases, immunology and neurology. Examples include pathogen identification using next-generation sequencing for infectious diseases, risk stratification and diagnosis for immunology, and using P-tau and synucleins to diagnose neurodegenerative diseases.

**Figure 8**  
Recent launches and coverage announcements of ADx



Note: ADx=advanced diagnostics; MRD=minimal residual disease; TxM=treatment monitoring; TxG=treatment guidance; AAV=ANCA-associated vasculitides; MCED=multicancer early detection; RA=rheumatoid arthritis; ANCA=antineutrophilic cytoplasmic antibody; CMS=Centers for Medicare & Medicaid Services; IO=immuno-oncology; DLBCL=diffuse large B-cell lymphoma; PCM=personalized cancer monitoring; BSCA=Blue Shield of California  
Source: Food and Drug Administration; company websites and press releases; 360Dx; L.E.K. research, interviews and analysis

Despite this progress, market penetration and coverage outside oncology remain nascent, necessitating significant investment in R&D and market development for many innovative diagnostics. For more on ADx outside oncology, see L.E.K.'s recent report, "Move Precision Medicine Beyond Oncology: Keys to Successful Enterprise-Level Strategy." Continued challenges, such as slower commercial ramp-up as compared to drugs, inconsistent reimbursement (e.g., variance by plan, reliance on self-pay), and the high costs associated with both wet lab research and clinical trials for many novel products, may serve as headwinds to broad commercial adoption and improved profitability for ADx.

### Implications of the rise of advanced diagnostics

In the near term, scale in diagnostics is likely to continue to be driven by oncology, particularly from the increasing penetration of MRD and other liquid biopsy tests, with longer-term potential from blood-based early cancer screening assays. Beyond oncology, ADx companies

will continue to seek revenue- and evidence-generating partnerships with biopharma to demonstrate utility and unlock opportunities in challenging therapeutic areas such as the central nervous system and immunology. Thus, biopharma partnerships are likely to serve as a critical funding source and testing ground for the next wave of ADx.

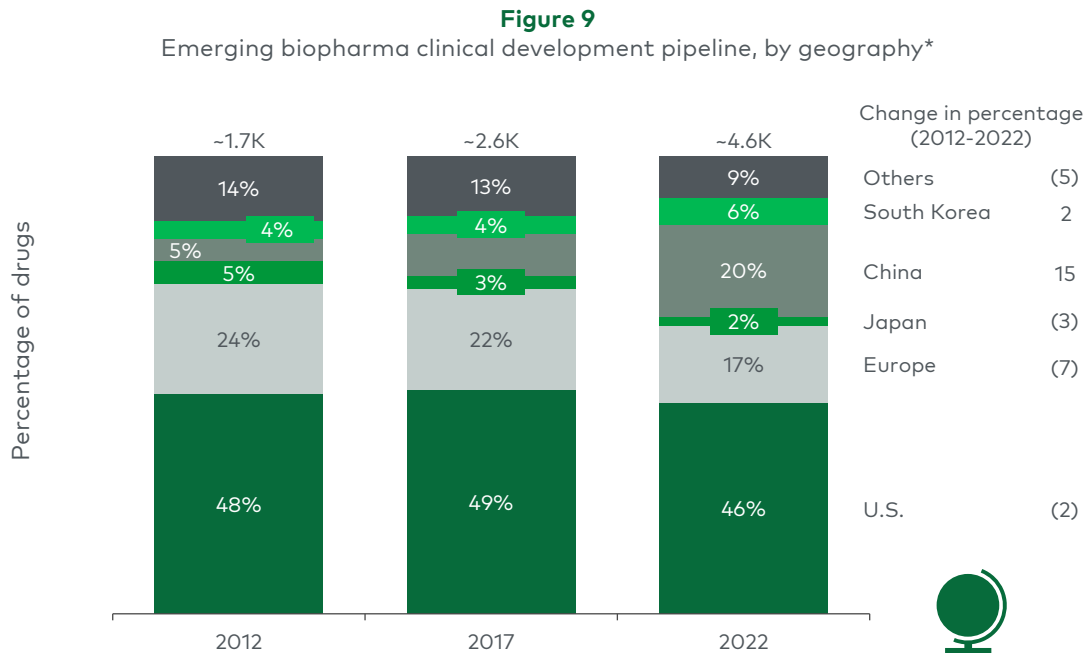
The changing funding dynamics in the market may also lead to changes in the life cycle of ADx companies in comparison to the recent past, and large special-purpose acquisition or initial public offering exits may be less common going forward. Furthermore, shifting market emphasis on profitability versus growing revenue at all costs may impact ADx company strategy and drive application focus, as opposed to broad menu development and the associated significant R&D expenses and market development costs to commercialize new ADx tests.

Private investors should consider not only the technology and market potential of innovative diagnostics but also the potential evidence (e.g., prospective trials) and market development and support (e.g., above-the-test services) costs of successfully commercializing new ADx tests.

## 5. Increasing globalization

Over the years, the clinical pipeline of emerging biopharma companies has witnessed a notable shift in geographical representation (see Figure 9). In 2012, U.S.- and EU-based companies accounted for over 70% of the global pipeline, which decreased to 63% by 2022. During the same period, China and South Korea experienced a significant increase in their pipeline share, growing by 17 percentage points to reach a combined 26%.

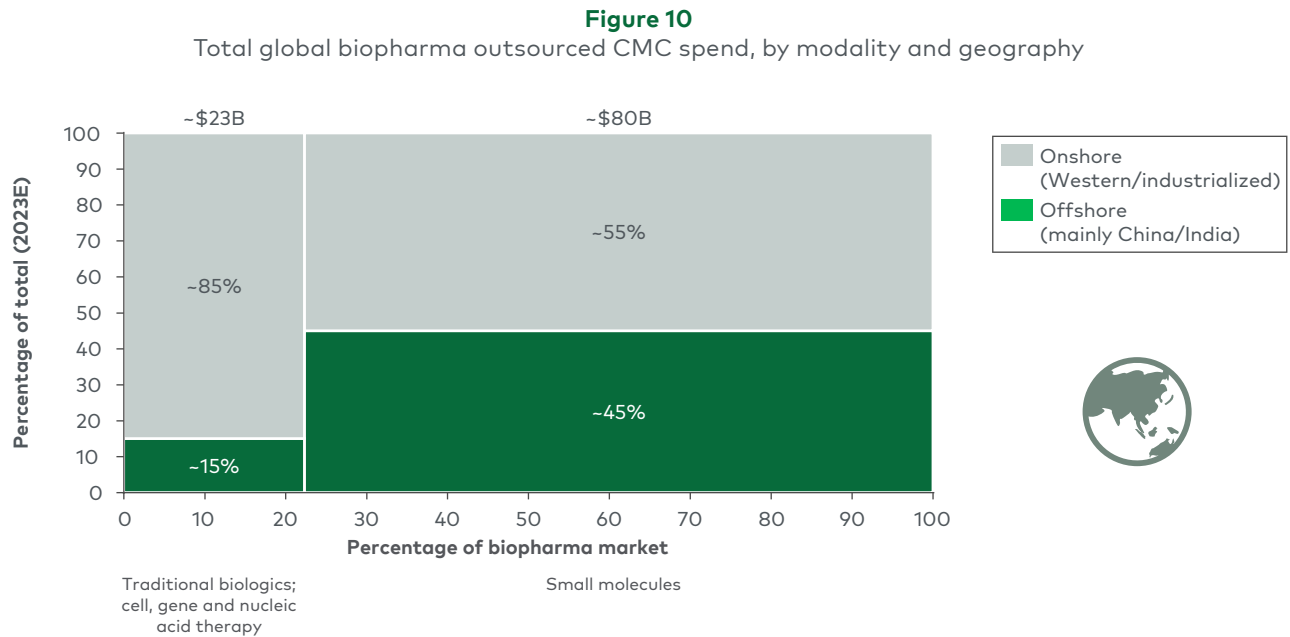
This shift reflects the rising presence of APAC countries in the global biopharma industry, while Europe's pipeline share declined from 24% to 17%. Notably, emerging biopharma companies in the U.S. have been relatively less affected by this trend. Factors such as talent accessibility, cost-efficiency and supportive regulatory environments have contributed to the growing prominence of drug development activities in the APAC region.



\*Drugs with an active research program and drugs with more than one developer counted for each company  
Source: IQVIA Global Trends in R&D report

In addition to drug development, global biopharma outsourced chemical, manufacturing and controls (CMC) spending (estimated at roughly \$100 billion in 2023) has increasingly been off-shored, particularly for small molecule therapeutics, as a mechanism to manage costs. This shift has allowed some APAC CROs/CDMOs, such as WuXi, to become global players, competing for high-value R&D spending as companies seek to reduce COGS. However, this off-shoring trend has primarily impacted small molecule therapeutics, with around 15% of global outsourced CMC spending for biologics and ATMs in China/India (see Figure 10).

Off-shored manufacturing helps balance capacity and geographic footprint to support supply chain resilience; however, the benefits have proved more challenging for ATMs to achieve, given their additional complexity and need for specialized expertise. Beyond that, increasing geopolitical tensions and the pandemic have highlighted the risks associated with an off-shoring approach. Whether companies will on-shore more capacity in response to these challenges remains to be seen.



Note: CMC=chemical, manufacturing and controls  
Source: L.E.K. research, interviews and analysis

### Implications of increasing globalization

Increasing globalization, marked by the rising representation of APAC in drug development and outsourced CMC spending, implicates diverse stakeholders in the life sciences ecosystem. As biopharma companies expand their geographic footprint and spending, particularly in APAC, they will need to navigate complex local regulations and market dynamics while managing potential geopolitical risks.

While APAC CROs and CDMOs are already servicing a significant proportion of synthesis and CMC spend for small molecules, the same trend has not yet occurred for biologics. Within the ATM segment, key barriers remain for off-shoring many services, including overall manufacturing and supply chain complexity, intellectual property control, and issues related to international shipping of biological products, particularly for patient-derived and genetic materials. In the life sciences tools domain, ongoing pressure from low-cost APAC competitors will likely create additional pressure to differentiate with unique offerings/technology and necessitate strategies to drive customer stickiness in the increasingly price-sensitive global market.

## Next steps for life sciences stakeholders and investors

Understanding and adapting to key trends are imperative for stakeholders' success as the life sciences industry evolves. From funding normalization to globalization, the future demands agility, foresight and strategic execution. L.E.K. partners with life sciences leaders and private investors to decipher these complexities and create forward-thinking strategies. We encourage industry leaders to engage in meaningful conversations on how these trends might shape your unique trajectory, strategic priorities and investment choices.

For more information, please contact [lifesciences@lek.com](mailto:lifesciences@lek.com).

## Endnotes

<sup>1</sup>Lek.com, "How the Inflation Reduction Act Will Impact the Biopharmaceutical Industry."  
<https://www.lek.com/sites/default/files/PDFs/inflation-reduction.pdf>

<sup>2</sup>Lek.com, "Move Precision Medicine Beyond Oncology: Keys to Successful Enterprise-Level Strategy."  
<https://www.lek.com/insights/ei/move-precision-medicine-beyond-oncology-keys-successful-enterprise-level-strategy>

## About the Authors



### **Peter Rosenorn**

Peter Rosenorn is a Managing Director and Partner in L.E.K. Consulting's Boston office and specializes in the life sciences and pharmaceutical sector with a focus on growth strategy and organization and performance. Peter advises clients on a range of critical business issues including organizational scale-up and development, launch planning and commercialization, transaction support, forecasting and valuation, and post-merger integration.



### **Jeff Holder**

Jeff Holder, Ph.D., is a Managing Director and Partner in L.E.K. Consulting's San Francisco office and a member of the firm's Life Sciences practice. Jeff has expertise in the life sciences tools, bioprocessing, biopharma services and diagnostics space with a particular focus on growth strategy, portfolio planning, new product opportunities and business development support.



### **Alex Vadas**

Alex Vadas, Ph.D., is a Managing Director and Partner in L.E.K. Consulting's Los Angeles office and a member of the firm's Life Sciences practice. Alex focuses on diagnostics, precision medicine, research tools and bioprocessing. He joined L.E.K. in 2000 and works with corporate, financial and not-for-profit clients on strategy and transaction support.



### **Spencer Robertson**

Spencer Robertson is an Engagement Manager in L.E.K. Consulting's New York office and a member of the firm's Biopharma and Life Sciences practice. Spencer is helping to lead the firm's efforts in generative AI and has extensive experience advising biopharma executives on a wide range of critical topics, including portfolio optimization, therapeutic area strategic planning and business development strategy/commercial due diligence.

## About L.E.K. Consulting

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