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Be brave, be bold Measuring the return from pharmaceutical innovation

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Foreword

Welcome to *Be bold, be brave*, Deloitte's fifteenth annual report in our *Measuring the return from pharmaceutical innovation* series. Our report explores the biopharmaceutical (biopharma) industry's performance and its success in generating returns from investment in innovative pipeline products. This year, we focus on critical pipeline decision making to drive future growth and innovation, exploring industry performance, evolving late-stage pipeline characteristics and understanding opportunities for biopharma companies to stay ahead of the curve.

Since 2010, this report series has provided unique insights into the factors influencing biopharma innovation and financial returns. Our consistent methodology focusses on the late-stage pipelines of the top 20 biopharma companies by R&D spend and enables us to track trends and identify key drivers of success. This year's analysis indicates that the forecast internal rate of return (IRR) has increased to 5.9 per cent, continuing the upward trajectory seen last year. This positive shift is driven by new high-value products entering the late-stage pipeline, including GLP-1s for diabetes and weight-loss, and increased commercial forecasts of returns for late-stage assets with impressive improvements in their trial results data.

Notwithstanding this uptick, our analysis also highlights that to sustain and improve this growth there is a need for a bolder, advanced strategic approach to pipeline development. Our report explores pathways to success, including prioritising areas of high unmet medical need, pursuing novel mechanisms of action (MoAs), and embracing cutting-edge technologies like AI and gene editing across R&D. Our analysis shows that diversifying portfolios into less saturated therapy areas can offer competitive advantages and accelerate innovation. Moreover, a data-driven approach to decision-making is crucial in supporting this shift. Leveraging advanced analytics and real-world data can optimise resource allocation, improve clinical trial design, and enhance the probability of regulatory success. By embracing these strategies, companies can enhance R&D productivity, deliver novel therapies to patients, and achieve sustainable growth.

We invite you to delve into the findings of this report and discover the key trends shaping the future of biopharma innovation. We believe that by understanding these dynamics and embracing bold action, we can collectively drive sustainable growth and deliver impactful therapies to patients worldwide as well as improved returns for their investors at a time when the returns for biopharma companies are under scrutiny.

We welcome your feedback and look forward to discussing the report's findings and implications for your organisation.

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Measuring the return from pharmaceutical innovation

Our annual report series *Measuring the return from pharmaceutical innovation* analyses the internal rate of return (IRR) that the top 20 biopharma companies (our cohort) can expect to earn from their latestage pipelines. After more than a decade of decline in the forecast IRR, followed by the volatility of the COVID-19 pandemic years, our latest analysis shows a continuing uptick from last year with another cohort-level improvement in the IRR. We explore how this progress has been achieved and can be sustained. We identify the importance of being brave and bold in developing innovative pipeline strategies including prioritising novel mechanisms of action (MoAs) to address unmet needs.

About this report

Our report series *Measuring the return from pharmaceutical innovation* has provided insights into the productivity of biopharma R&D since 2010. Our inaugural report analysed the return on investment that 12 large-cap biopharma companies might expect to achieve from their late stage pipelines. Over the past 15 years, the composition of our cohort has evolved and since 2020 has included the top 20 companies by 2020 R&D spend.



We continue to use the same objective methodology, which focuses on each company's late-stage pipeline, using multiple inputs to calculate the IRR, our measure of R&D productivity. The inputs to our calculation include:

- the total R&D expenditure incurred by a company in bringing its assets to launch (based on publicly available information from audited annual reports and readily available data from third party data providers)
- the impact of in-licensing and mergers and acquisitions (M&A) on R&D costs
- forecast estimates of the future revenue that will be generated from the launch of the late-stage assets (revenue forecasts provided by Evaluate Pharma)
- success rates in late-stage development to risk-adjust forecasts
- the cost of failure due to the inherent risks in undertaking R&D
- the impact of clinical trial cycle times.

We consider the late-stage pipeline to be assets in phase II with pivotal or breakthrough designation, in phase III, or filed for regulatory approval. We are working continually to enhance the methodology, modelling and scope of our analysis. Our aim is to achieve greater accuracy and more comprehensive insights while ensuring that a consistent and objective approach is applied across all companies each year. This year, we have expanded our cycle time methodology to cover the full range of clinical trials captured by Evaluate Pharma.



Forecast returns from innovation are on an upward trajectory

Our analysis shows that the 2024 IRR increased by 1.6 percentage points, to 5.9 per cent (see Figure 1), continuing the uptick seen in the previous year's analysis. Thirteen out of the 20 companies in our cohort, experienced growth in their IRR ranging between 0.4 and 6.9 per cent, with three companies exceeding a five per cent increase.

The IRR depends on both efficiency (cycle times and costs) and value creation (risk-adjusted forecast sales), each of which has multiple parameters that can improve outcomes. It is therefore important to understand both the trends in the cost to develop an asset from discovery to launch and also the risk-adjusted forecast revenue of the assets in the pipeline. While R&D costs have continued a year-on-year upward trend, the IRR has nevertheless increased due to new high-value products entering the late-stage pipeline and increased commercial forecasts of returns for late-stage assets due to impressive trial outcomes.



Figure 1. Return on late-stage pipeline, 2013-2024

Source: Deloitte analysis, 2025

The cost of developing a drug from discovery to launch remains high

This year, the average cost per asset increased to \$2.23 billion (see Figure 2), an upward trend observed in 12 out of the 20 companies analysed. While reported costs of pharma R&D, as declared in the cohort's annual returns, continue to increase year on year, since 2020 our cohort has reduced their increase in spend to a compound annual growth rate (CAGR) of 6.44 per cent, compared to 7.69 per cent in the years 2013 to 2020, reflecting the cohort's focus on improving the efficiency of R&D spending.

The rising R&D costs appear attributable to a complex interplay of factors:

- Research complexity. Addressing diseases with intricate biological mechanisms, such as Alzheimer's, coronary artery disease, cancers and rheumatoid arthritis, has required the development of more complex modalities, such as gene therapies, antibody-drug-conjugates, radioligand therapies and trispecifics. This has resulted in more intricate and costly research approaches. Precision medicine further intensifies this complexity.
- Clinical trial challenges. Rigorous clinical trials are essential for ensuring drug safety and efficacy. However, meeting evolving regulatory standards and finding and enrolling eligible patients for trials is time-consuming and costly, especially for rare diseases. As biopharma companies have focused on similar indications and therapy areas,

recruitment and retention for eligible patients is increasingly competitive adding complexity, time and cost. Consequently, cycle times for each phase of development, especially phase III, and in total, continue to rise each year (see Cycle times pull out on page 5).

- High attrition rates. The drug development process inherently carries high failure rates, resulting in significant investment losses on therapies that do not reach the market. Our analysis indicates the cohort has spent \$7.7 billion on clinical trials for assets terminated in this year's analysis timeframe.
- Technological advancements. While promising technologies like robotic process automation and AI offer long-term potential for cost reduction, their upfront research and development costs are significant. Despite this, 42 per cent of the 150 global C-suite life science executives surveyed by Deloitte US in Autumn 2024 for the 2025 life sciences outlook report, said there had been moderate or significant financial return on investment in GenAl in the past year.¹ In the UK Centre's recent Accelerating the future prediction series, we explore *The convergence* of AI technologies and human expertise in pharma R&D and how Interdependent innovations in science and technology are reshaping treatment paradigms.^{2,3}
- Economic factors. General inflation, tax and tariff increases coupled with the rising costs and availability of specialised labour and materials, contributes further to the overall upward trend.



Figure 2. Average R&D cost to develop a drug from discovery to launch, 2013-2024

Cycle times are increasing year-on-year

Our analysis (see Figure 3) shows that cycle times continue to increase year-on-year, and now exceed 100 months for time in phase I through to filing. While all stages of development have lengthened over the past five years, time in phase III has increased to the greatest extent, by 12.0 per cent. This increasing development time contributes to escalating costs as well as delays in bringing new assets to market, impacting in particular those in areas of unmet need. As explored in the previous edition of this report <u>Unleash Al's potential</u>, leveraging Al to create more flexible and adaptable clinical trial processes, can improve productivity, enable companies to respond more effectively to the rapidly evolving regulatory and commercial landscape, and reduce costs, while bringing products to market more quickly and effectively.

Figure 3. Time in phase I, II, III and filing time, industry benchmarks 2020-2024 (months)



Deloitte view on reducing R&D costs

Escalating costs present a continuing challenge to the biopharma industry. Strategic diversification, early adoption of promising technologies, and a willingness to challenge conventional pipeline composition and approaches to clinical trial management can help to mitigate costs and enhance R&D efficiency. Strategies can include greater collaboration between the biopharma industry, research institutions and regulatory bodies to streamline trial processes and reduce redundancies in patient recruitment and embrace innovative trial designs, such as adaptive trials and decentralised trials, to improve efficiency and reduce timelines. This collaboration can help lower costs by focusing data collection on the most crucial datapoints that drive decision-making for each asset and de-risking future decisions. Biopharma can also invest in advanced data analytics and AI to help optimise trial design and patient selection and explore alternative funding models for novel technologies.

Increases in forecast peak sales drive the growth in IRR

The cohort's average forecast peak sales per asset have increased to \$510 million (see Figure 4), with two companies forecast average peak sales expected to exceed \$2 billion. Notably, if we exclude GLP-1s from our modelling, the average peak sale drops to \$370 million, and also reduces the IRR to 3.8 per cent for 2024 and 3.4 per cent for 2023, an indication of their substantial market influence.

There has been a resurgence in potential blockbusters in the late-stage pipeline in recent years and this has a big impact on the industry's IRR (see Figure 5). The growth in the IRR is driven primarily by new high-value products entering the late-stage pipeline and increased commercial forecasts of returns for late-stage assets due to impressive trial outcomes. Specifically:

- Twenty-nine new blockbuster assets (assets with peak sales forecasts of over \$1 billion) have entered this years late-stage pipeline, comprising 14 per cent of all new products. This is a 53 per cent increase on the previous year's 19 new blockbuster assets. This year, the new forecast blockbusters target a wide range of indications including type 2 diabetes, obesity, hyperlipidaemia, eczema and non-small cell lung cancer (NSCLC).
- Twenty assets (4.2 per cent of existing assets) saw their peak sales forecasts rise by over \$1 billion, eight of which are oncology assets for breast cancer, NSCLC or multiple myeloma. An oral GLP-1 obesity asset with improved production efficiency had the biggest percentage increase due to reducing the cost of production and consequently it is expected to be more accessible in pricing, distribution and ease of administration. The second-biggest increase in forecast sales is for a subcutaneous treatment for NSCLC that will enable a two-to-three-minute administration compared to intravenous administration which normally takes over an hour, benefitting both patients and healthcare providers.



Figure 4. Average forecast peak sales per pipeline asset, 2013-2023

Source: Deloitte analysis, 2025

While promising new and existing assets boost the IRR, these assets move out of the scope of our analysis once they are approved; and there is also a risk that late-stage trial setbacks could lead to reduced peak sales forecasts or terminations, ultimately impacting the IRR. Specifically:

- Nineteen of the blockbuster assets in our 2023 analysis were approved in this 2024 analysis cycle,
 23.75 per cent of all approvals. These span indications including the menopause (specifically the treatment of vasomotor (hot flush) symptoms), respiratory syncytial virus infections, eczema and stomach cancer. Having entered their company's commercial portfolio, and thus no longer being part of our analysis, their successful approval means they now provide a reliable revenue stream for their company.
- Two forecast blockbusters have been terminated, a blood cancer asset that failed to meet its primary endpoint in a pivotal trial and a COVID-19 therapeutic which failed due to recruitment difficulties among reduced COVID-19 cases. Seventy-seven other assets were also terminated during this year, demonstrating the scale of the inherent risks of R&D.
- Ten products have had their forecast peak sale reduced by over \$1 billion, across several therapy areas including diabetes, neurology, oncology and cardiovascular, due to factors including lower-than-expected efficiency in phase III trials, emerging side effects and an evolving treatment landscape with new competitors emerging before or shortly after the expected drug launch. Despite these reductions, five of these assets retain their blockbuster potential.

Figure 5. Changes in blockbuster volume in the late-stage pipeline of the top 20 cohort, 2023-2024



Source: Deloitte analysis of Evalaute Pharma data, 2025.

Deloitte view on improving revenue

To sustain this uptick in forecast sales, companies should consider adopting a proactive and bold pipeline replenishment strategy that enables differentiation within the biopharma industry. Fifty-eight per cent of the executives surveyed for the *Deloitte US 2025 life sciences outlook* report, believe that rethinking their overall portfolio strategy is important in 2025.

This involves a two-pronged approach:

- 1. Actively identifying high-growth therapeutic areas and investing in promising assets that could address unmet needs through both in-house development and early external sourcing through mergers, acquisitions, and partnerships
- 2. Rigorously evaluating existing pipeline candidates, using data-driven decision making, to help ensure alignment with evolving market dynamics and strategic priorities, while minimising late-stage terminations

Individual companies should consider how to balance being bold enough to believe they can outcompete the market with their version of a mega-blockbuster and brave enough to innovate at the edges of the science to be first to find the next mega-blockbuster MoA. Leveraging predictive modelling, competitive benchmarking and a deep understanding of patient needs can enable informed decisions about pipeline prioritisation, resource allocation and go-to-market strategies, ultimately maximising returns.



Diversification of portfolios and focusing on less saturated therapy areas can improve returns

Among the top 20 cohort, all but one company are active in five or more of the 15 therapy areas analysed (therapy areas listed in Figure 6). However, this diversification is not uniform.

Oncology for instance attracts significant investment, with 37 per cent of all pipeline assets concentrated in this area (and consistently over 35 per cent for the past five years), leading to intense competition for suitable trial sites and participants (see Figure 6). Only two companies do not operate in the oncology space. Furthermore, fifteen companies are operating in the highly competitive infectious disease space with more than 10 per cent of pipeline assets concentrated in this therapy area.







Source: Deloitte analysis of Evaluate Pharma data, 2025

The remarkable growth trajectory of GLP-1s, particularly in the obesity market, underscores the substantial return potential of addressing unmet needs at a population health level. Forecast revenue from obesity indications has increased from one per cent of total revenue in 2022, to eight per cent in 2023 and 16 per cent in 2024. (see Figure 7). Replicating this success across other indications with high unmet needs presents a significant opportunity for the industry. For example, in the late-stage pipeline there are nine assets targeting Alzheimer's disease, six assets for stroke prevention, and two for preventing relapse and reducing progression of multiple sclerosis, all of which hold similar potential for a transformative impact on patient outcomes and for improving the IRR for the industry.



Figure 7. Forecast revenue for the top 20 cohort by therapy area, 2022-2024

Source: Deloitte analysis of Evaluate Pharma data, 2025

Deloitte view on pipeline diversification

There is a strategic opportunity for companies to diversify portfolios and build expertise in less saturated therapy areas. For example, companies can expand their differentiated modality expertise into new MoAs and indications. Being a first-mover or fast-follower in these under-served areas can offer a competitive advantage and the potential to accelerate innovation for patient benefit. While targeting areas of unmet need inherently involves greater complexity and risk than incremental improvements on launched drugs and are more time consuming both in development and through regulatory approval, the rewards for companies bold enough to pursue them can be substantial, both financially and in terms of improving global health outcomes. To improve patient outcomes and transform the IRR for the industry, it will be important to identify and implement sustainable access models to drive adoption by healthcare systems.

Conscious investment in novel MoAs enables both patient benefit and higher returns

While the concentration of therapeutic areas within the top 20 cohort is clear, this pattern continues when looking at mechanisms of action (MoAs). Over half of the companies in our cohort have late-stage PD-1 antibody assets, further demonstrating the potential saturation within oncology (see Figure 8). This pattern is additionally seen in targeted oncology therapies with five of these being investigated by six companies, these six companies do vary across the inhibitors and are also in development for indications beyond oncology.

Diversifying pipelines to further meet areas of unmet need presents an opportunity for higher returns, and this strategy can be further enhanced by pioneering novel mechanisms of action (MoAs). We define a novel MoA as a one that has not been launched previously anywhere in the world, as per Evaluate Pharma data. These include myeloperoxidase inhibitors for chronic heart failure, coagulation factor XIa inhibitors for acute strokes and glycine transporter type 1 (GlyT1) inhibitors for schizophrenia. Fast-follower MoAs are those under development by our cohort, but approved to market, for the first time, in the three years prior. On-market MoAs are those already approved and undergoing further development by our cohort. While novel and fast-follower MoAs represent a four-year average of 23.5 per cent of all MoAs in development each year, their forecast revenue share is substantially higher with a four-year-average of 37.3 per cent, (see Figure 9).

Opportunities exist for companies to create therapies with novel MoAs. Despite this evidence, only 32 per cent of the biopharma respondents to the *life sciences outlook* survey said they plan to prioritise transformative innovation over sustaining innovation like me-too-drugs.⁴

Alongside an increasing proportion of novel MoAs in the late-stage pipeline, the cohort's focus on rare disease has also increased. In 2024, 37.4 per cent of assets in the late-stage pipeline are targeting a rare disease, compared to 31.1 per cent in 2023. There is, however, a notable concentration of competition in certain disease areas with 50 per cent of all rare-disease assets in the oncology and infectious disease TAs.

Figure 8. Drug targets in the late-stage pipeline of the top 20 cohort, 2024



Source: Deloitte analysis of Evaluate Pharma data, 2025



Figure 9. Volume and revenue split of novel and fast follower mechanisms of action, 2021-2024



Source: Deloitte analysis of Evaluate Pharma data, 2025

Deloitte view on novel MoAs

When multiple companies pursue asset development for the same specific targets, the battle for resources intensifies. This overlap can lead to increased competition for crucial trial sites and eligible patient populations, potentially extending recruitment periods and overall drug development timelines. Furthermore, this concentrated effort on a limited number of targets can stifle innovation in other areas and potentially limit treatment options for patients with unmet medical needs. Despite the inherent greater risks associated with navigating uncharted development territory, prioritising novel MoAs offers compelling advantages: improved efficacy and patient outcomes, greater share of eligible patients due to reduced competition, and ultimately, a higher return on investment.

To balance the risks associated with novel MoA development, biopharma companies need to allocate pipeline resources consciously, ensuring a portion is dedicated to exploring novel MoAs while maintaining a presence in established areas. Furthermore, leveraging existing scientific knowledge and technical capabilities is essential to identify the most promising novel MoAs, optimising the chances of successful development. Establishing robust asset lifecycle governance processes specifically designed for novel MoA development, incorporating rigorous risk assessment, data analysis, and flexible decision-making frameworks, is key to navigating the inherent uncertainties of this approach.

Strategic, early engagement M&A builds a robust and diversified pipeline

As explored in the previous edition of our report, Unleash Al's potential, over the next decade the top 20 biopharma companies are facing over \$200 billion in lost revenue due to the expiration of patents.⁵ This looming patent expiration and loss of reliable revenue is front-of-mind for the C-suite execs surveyed, with 81 per cent seeing this patent cliff as something impacting their organisation's strategy.⁶ Consequently, 7 per cent expect increased M&A activity in 2025.7 Similarly, in the Life sciences M&A 2024 trends and 2025 predictions Deloitte US forecasts that big pharma will leverage bolt-on acquisitions to offset revenue declines due to patent expiries.⁸ This trend is evident in our cohort, with externally sourced assets in the late-stage pipeline rising to 61 per cent, up from 59 per cent in 2023, emphasising the growing reliance on external innovation. We have also found that our cohort is consistently more likely to terminate an externally sourced asset in latestage development compared to those developed in-house (see Figure 10).

Deloitte view on M&A

This emphasises the importance of building a sustainable, integrated M&A strategy that goes beyond plugging pipeline gaps and focuses on long-term strategic fit. While large-scale, late-stage acquisitions can provide a quick revenue boost, a more sustainable approach would prioritise smaller-scale, early-stage M&A that targets promising innovation. This could enable large biopharma companies to capitalise on breakthrough therapies or technologies developed by smaller, more agile firms, helping to maximise long-term returns and creating a more robust and diversified pipeline. By integrating these acquisitions into their existing R&D infrastructure, companies can leverage their expertise and resources to progress assets with the same scrutiny and skill as their internally sourced pipeline while mitigating the risks associated with large, late-stage acquisitions.



Figure 10. Proportion of terminated assets developed internally and externally, 2021-2024

Source: Deloitte analysis of Evaluate Pharma data, 2025

🛑 External 🛛 🔵 Internal

Brave companies taking bold action should improve returns

The evidence from our analysis is clear: maintaining the status quo in pipeline strategy can limit biopharma returns on investment in R&D. This is also reflected in the <u>2025 life</u> <u>sciences outlook</u> survey findings where 56 per cent of the R&D executives believe that re-thinking their overall portfolio strategy is important if they are to improve their returns.⁹

Among those executives who plan to re-think their portfolio strategy, pipeline product decisions are front-of-mind with 58 per cent planning to explore new therapeutic areas and indications, 47 per cent planning to explore new modalities and platforms and 40 per cent planning to prioritise transformative innovation (pursue novel therapies) over sustaining innovation (like me-too drugs).

Deloitte view on the need for a bold approach

To continue the uptick in returns and meet the growing demand for novel therapies, a bolder approach is needed.

Prioritise areas of high unmet need: Dedicating resources to diseases with high unmet medical need and targeting novel MoAs rather than incremental improvements on existing drugs could mitigate the challenges of crowded therapeutic areas, streamlining clinical development and serving a greater share of eligible patients, bolstering returns while improving global health outcomes.

Embrace cutting-edge technologies: Investing, and scaling investment, in emerging fields such as building in-house expertise in gene editing, developing AI-powered drug development platforms, and building the lab-of-the-future has potential for identifying breakthrough therapies, enabling preclinical studies to be accurate and predictive and, alongside first-mover advantage, can attract top talent in these increasingly competitive fields.

Adopt an evidence-driven approach to decision-making: Leveraging automation, advanced analytics, cloud-based data management, and connected lab instruments will help enhance efficiency, collaboration and predictivty. Further, utilising real-world data to identify patient subgroups, decentralising trials and monitoring treatment response in real-time, and utilising digital biomarkers to inform R&D decisions should result in more efficient and targeted drug development, reduced development costs, and improved chances of regulatory success. Additionally, robust data analytics can guide investment decisions, M&A activity, resource allocation and progression no-go decisions.

Pursue novel collaboration and acquisition models: Moving beyond traditional partnerships engaging in open innovation initiatives with academia, pre-competitive industry collaboration, or patient-centric networks, can give access to diverse expertise and accelerated research timelines, and identify critical areas of unmet need.

To be bold, companies first should address their:



Risk tolerance - Bold decisions often come with higher risk. Companies should carefully assess their risk appetite and ensure they have the resources to support these ventures.



Organisation agility - Adapting to new technologies and approaches involves a flexible and responsive organisational structure with bold, exploratory leadership.



Long-term vision - Transformative R&D takes time. Companies need a clear long-term vision and the commitment to see these initiatives through.

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