Deloitte.

Together makes progress

New science, new stakes

The evolving economics of independent biotech commercialization

Independent commercialization has become an increasingly prominent strategic path for emerging biotechs and an increasingly demanding one. In a prior analysis,[1] Deloitte examined approximately 25 first-launch biotechs that brought products to market independently between 2011 and 2020. That work identified two durable findings: higher pre-launch spending correlated with greater probability of success, and the consequences of underinvestment often extended well beyond the launch window.

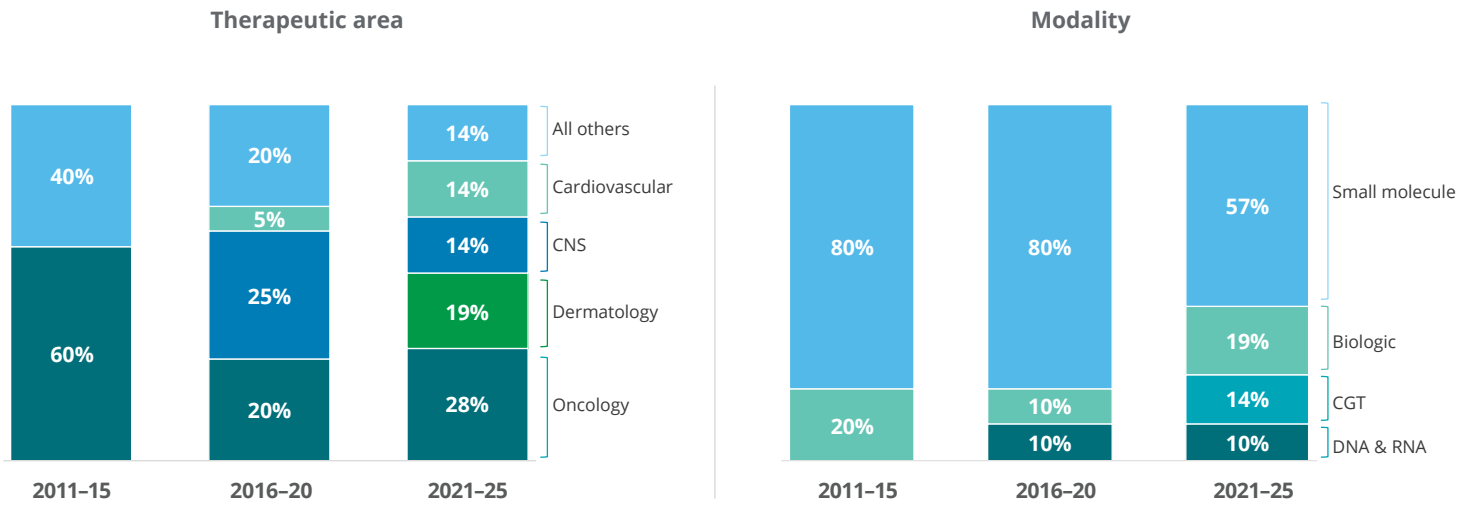
This analysis revisits and extends that data set, now covering 46 companies across 15 years, to examine what has changed and what the patterns suggest for companies approaching this decision today. The scale of the shift is notable, with nearly as many biotechs launching their first product independently between 2021-2025 as in the entire prior decade. A separate IQVIA[2] analysis points to the same broader shift: emerging biopharma companies originated 85% and originated-and-launched 63% of all new drugs in 2024.

First-launch biotechs are entering more scientifically and commercially complex territory.

Over the past 15 years, independent launches have expanded both in scientific sophistication and therapeutic breadth. Cell and gene therapies and DNA- and RNA-based therapeutics have evolved from a negligible share of launches to a meaningful component of the recent cohort. Oncology continues to account for a disproportionate share of activity, increasingly centered on precision medicine and novel modalities, while dermatology, central nervous system (CNS), and cardiovascular therapies are also becoming more prominent.

Many recent launches entered disease areas and modality categories with limited commercial precedent. In these settings, patient identification pathways are often underdeveloped, specialist networks may still be forming, and the infrastructure required to diagnose, educate, and support patients frequently must be built alongside the launch itself. The practical implication is that market shaping and commercial preparation in these settings are less about reaching an established audience and more about helping to constitute one.

Figure 1: Proportion of first launches by therapeutic area and modality across 5-year cohorts (2011-2025)



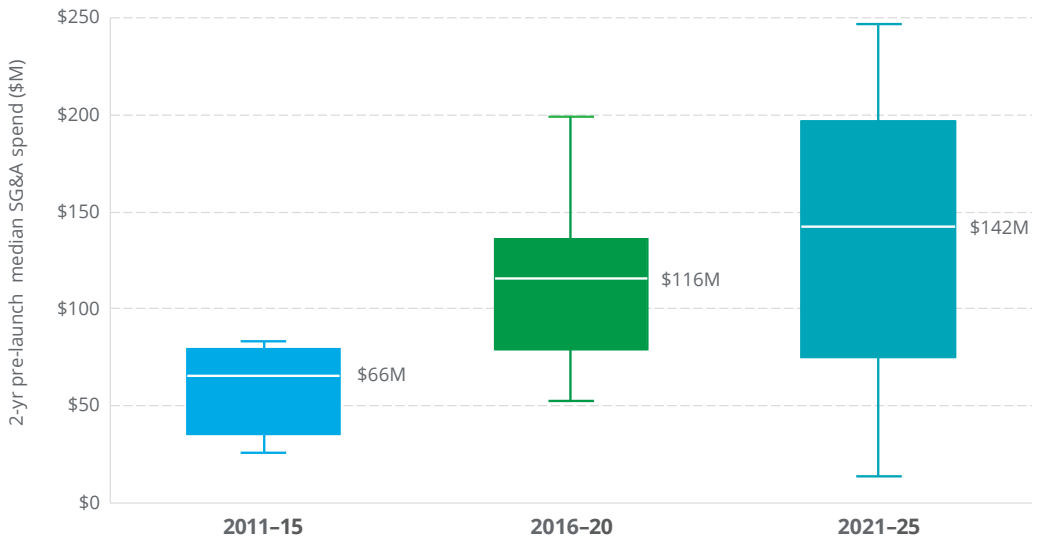
Source: Evaluate Pharma[3]; Deloitte analysis

Rising scientific complexity is reshaping what commercialization requires and what it costs.

Median pre-launch selling, general, and administrative (SG&A) spend among first-launch biotechs reached $142 million in the most recent period, rising substantially versus earlier cohorts. Equally significant, the distribution of spending outcomes has widened considerably, with the gap between the highest- and lowest-investing launches now greater than at any prior point in the data.

At the lower end of the distribution, a subset of predominantly small molecule assets has launched with investments smaller than any previous cohort. These products tend to share structural features that reduce commercial complexity: a naturally concentrated prescriber base, a reformulation or follow-on profile that limits clinical education burden, or a second-mover position that inherits category awareness already established in the market. Their presence has driven the median pre-launch SG&A spend for small molecules down by more than $30 million over the last decade, according to Deloitte analysis, widening the spread between launches that must construct their commercial environment and those that operate within one already in place.

Figure 2: Pre-launch SG&A spend across 5-year cohorts (2011-2025)



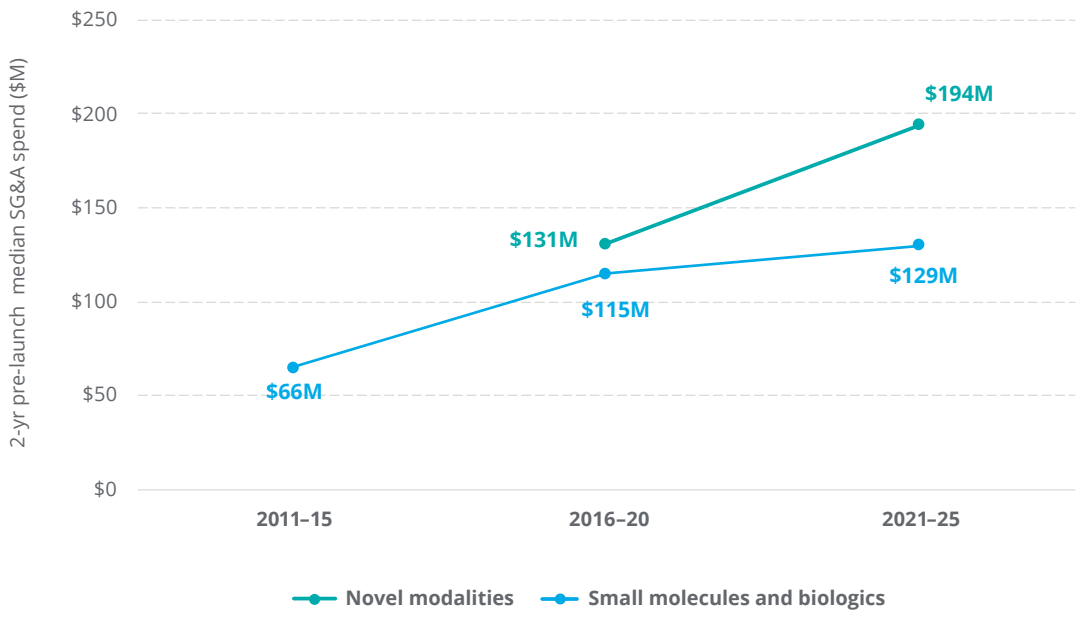
Note: The box represents the interquartile range (IQR), the solid line indicates the median, and the whiskers extend to 1.5x IQR. Data points beyond the whiskers are treated as outliers.

Source: Deloitte analysis

At the upper end of the distribution, the increasing presence of novel modalities in the independent launch landscape is the primary driver of rising median spend. Based on our analysis, novel modalities (cell and gene therapies, DNA & RNA therapeutics) carried median pre-launch SG&A of approximately $190 million, compared with approximately $110 million for small molecules and biologics, reflecting the more specialized commercialization infrastructure these therapies require, from patient identification and diagnostic pathways to provider education, care coordination, and market access support.

The same dynamic is evident at the therapeutic area (TA) level. Median SG&A spend for cardiovascular and oncology first-launchers has climbed notably over the past decade, driven by the specific commercial demands of the products emerging from each space. In cardiovascular, recent launches exemplify a new generation of cardio-metabolic therapies targeting disease states that were previously untreatable or underserved. In oncology, the pattern is similar but further compounded by the rise of advanced cell therapies and precision modalities. In these settings, commercial investment precedes and enables the market, rather than simply reaching one that already exists.

Figure 3: Pre-launch SG&A spend by modality type



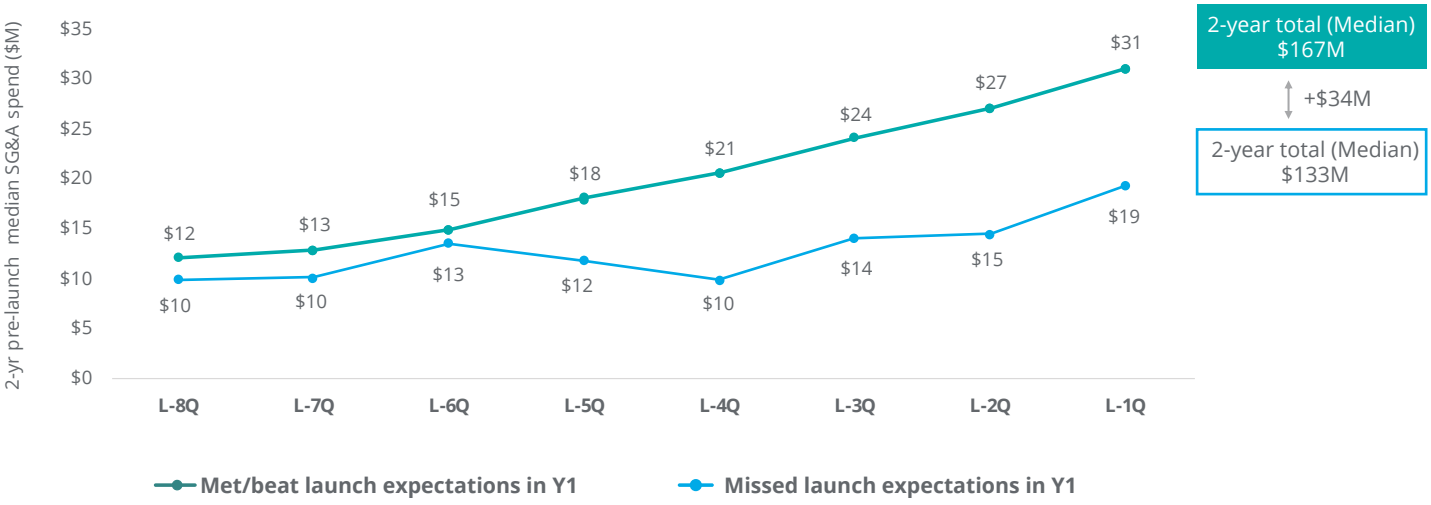
Source: Deloitte analysis

First-launch success rates have improved, reflecting a more disciplined understanding of when and where investment creates commercial impact.

First-launch success rates have risen from 60% in 2011–15 to just over 80% in the most recent cohort.[4] On average, successful launchers invested more in the pre-launch period than their unsuccessful counterparts.

The pattern of investment relative to launch timing offers an additional lens. At the two-year mark prior to approval, spending levels across successful and unsuccessful launchers were broadly comparable. Divergence began to emerge around 18 months before launch and built steadily from there, reaching its widest point in the quarter immediately preceding approval. This is the period when many launch-critical activities typically move from planning to execution: key opinion leader and health care provider engagement, patient identification, diagnostic readiness, access preparation, field deployment. The data cannot establish causation, but the alignment between investment timing and execution milestones is consistent with the view that earlier commitment to these activities may be a meaningful differentiator.

Figure 4: Quarterly pre-launch SG&A spend, 2021-2025 cohort



Source: Deloitte analysis

Against a more demanding launch environment, how companies finance independent commercialization is becoming a more strategic question.

As launch requirements increase and independent commercialization becomes more prevalent, the question of how to finance that investment is becoming a more prominent strategic and capital allocation consideration, and the environment in which companies are making that calculation has shifted.

Equity and debt have historically been the primary vehicles for biotechs pursuing independent commercialization. Since 2021, however, both have become more expensive. Higher interest rates have increased the burden of debt, and compressed valuations have made equity more dilutive while pre-launch investment requirements have been rising.

Against this backdrop, non-dilutive instruments, particularly royalty financing, have become more relevant. A separate Deloitte analysis of the royalty funding market[6] found market volume more than doubled between 2015–19 and 2020–24, and synthetic royalties represented more than 50% of the market for the first time in 2024. Additionally, our data suggests that capital providers are increasingly willing to engage with pre-commercial assets when the commercial plan and underlying asset conviction are credible. Several first-launch biotechs in this data set used royalty financing as part of their pre-launch capital strategy, suggesting that asset quality and the credibility of the commercial plan may be as important as revenue track record in accessing these instruments.

Looking ahead, artificial intelligence (AI) may begin to shift what lean commercial organizations can realistically execute.

For first-launch biotechs operating with lean teams, AI represents a potential lever to extend commercial reach without a proportional increase in headcount or spend. Deloitte estimates that commercial functions account for 25% to 35% of total AI value in life sciences,[7] with the greatest revenue impact concentrated in patient conversion and speed to therapy.

For emerging biotechs, however, the opportunity is less about replacing talent than amplifying it. Experience, judgment, and relationships remain central to commercial success, particularly in areas such as market access and launch execution. AI is likely to create the greatest value in areas constrained by scale and data intensity, including physician/provider targeting, patient identification, content generation, and contract analytics, allowing smaller organizations to execute more targeted and operationally intensive launches than may previously have been feasible.

This creates a consideration that extends beyond near-term efficiency. Established pharmaceutical companies are, in many cases, integrating AI into commercial models built around different assumptions and legacy infrastructure. First-launch biotechs designing their commercial operations today are not constrained in the same way as they can build AI-enabled workflows, data foundations, and processes from the outset rather than retrofitting them. Whether and how that structural flexibility translates into durable commercial advantage is a question worth examining as AI capabilities continue to develop.

Conclusion

Taken together, the data suggests an evolving landscape for independent biotech commercialization. Launch success rates appear to be improving even as first-time launches become more scientifically and commercially complex. This may reflect not only increased discipline in capital deployment, but also a growing recognition that different asset archetypes require differentiated commercial approaches.

What remains less certain is the pace and degree of these changes. The continued rise of novel modalities is likely to sustain upward pressure on launch investment at the upper end of the market.

AI-enabled commercial capabilities, still early in adoption, have the potential to expand what lean organizations can realistically execute. What the data does suggest is that the companies approaching their first independent launch today are doing so in a materially different environment than those of a decade ago, one where the range of commercial archetypes, financing structures, and operational tools available to them is broader than it has ever been. How well those tools are understood and deployed, and how early, may increasingly shape which companies are able to translate a strong asset into sustained commercial performance.

Methodology

Our data set included 46 companies spanning across nine distinct therapeutic areas and five technologies. We set four key parameters in defining the scope of our analysis: (1) publicly traded companies that commercialized their first innovative product in the US in the last 15 years; (2) solo market entrants who did not license out their technology or leverage a commercialization partner; (3) leveraged SG&A as a proxy for first-launch spend, as first-launch companies tend to focus commercial operations on their lead asset; and (4) characterized launches as "successful" or "unsuccessful" based on the product achieving at least 90% of analysts' consensus sales estimates for first year of launch.

Continue the conversation

Deepak Singla
Senior Manager
Deloitte Consulting LLP
desingla@deloitte.com

Mathias Cousin
Managing Director
Deloitte Consulting LLP
mcousin@deloitte.com

Teresa Leste
Principal
Deloitte Consulting LLP
tleste@deloitte.com

Kriti Wahi
Senior Manager
Deloitte Consulting LLP
krwahi@deloitte.com

Akanxa Swami
Consultant
Deloitte Consulting LLP
akaswami@deloitte.com

Endnotes

1. Deepak Singla, Mathias Cousin, and Teresa Leste, "Biotechs with first-launch assets: Penny-wise, pound-foolish?," Monitor Deloitte, February 29, 2024.
2. IQVIA Institute for Human Data Science, *Global trends in R&D 2025*, March 2025.
3. Evaluate Pharma (accessed March 2026)
4. S&P Capital IQ (accessed March 2026)
5. SEC filings, company annual reports.
6. Terese Leste, Deepak Singla et al., *Role of royalties in funding biopharma innovation* Deloitte, September 2025.
7. Aditya Kudumala et al., "Realizing transformative value from AI & Generative AI in life sciences," Deloitte, 2024.

Deloitte.

Together makes progress

15589412