Biotech innovation is robust; when will financing return?

Beyond Borders:
EY Biotechnology Report 2024

Texas Edition

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The year in review

The 34th edition of our annual global *Beyond Borders* report reflects continued uncertainty for US and European biotechnology companies, as predicted in our report from last year. After a tough year for the biotechnology sector, 2023 ended on a positive note amid genuine hope that 2024 may be the beginning of a real recovery for biotech. We are watching to see if it can be sustained. Over the last 18 months, biotechs' financing opportunities have presented a "tale of two cities": companies with highly sought after late-stage assets have secured record-high premiums, while others struggle for survival. The "sugar high" of late 2020 and 2021, characterized by high valuations and free money, has been followed by a capital hangover that has continued through 2022 and 2023, punctuated by layoffs and economic uncertainty. Throughout 2023, biotechs continued to see significant challenges around a constrained public financing environment, like those seen in 2022 following the high capital infusions of 2020 and 2021. As a result, many emerging biotechs (particularly those in early stages) have had to rationalize or restructure their operations, cutting staff and narrowing R&D focus from platform to product.

Yet, given the strength of innovation in the sector, biotechs have strong grounds for optimism. Drug discovery and development are entering a new age, bolstered by the emerging possibilities of technologies such as artificial intelligence (AI), generative AI and machine learning (ML), which can significantly improve productivity and help bring the next wave of innovative new medicines to patients. Life sciences companies are now generating new treatments for chronic disease areas that had fallen out of fashion in favor of rare disease; conditions that impact large patient populations, like diabetes, obesity, mental health and metabolic dysfunction-associated steatohepatitis, or MASH, are all benefitting from an R&D renaissance.

Further, we expect fiscal policy to shift toward lower interest rates within the trailing months of 2024, which could potentially trigger a recovery in the biotech investment environment. Biotech's fundamentals remain robust; the pharmaceutical ecosystem's innovation engines are still thriving, as new modalities and exciting scientific innovations continue to drive the sector forward. Moreover, there are early signs of a thaw in the financing and dealmaking environment for biotech.

Finally, Big Pharma is in the midst of a US$350 billion patent cliff,[1] driven by a loss of exclusivity for some of the best-selling biologic products of the last decade. Large pharmaceutical companies are facing a dramatic drop in revenue, especially those that profited most from vaccines and therapeutics made in response to the COVID-19 pandemic. At the same time, many pharma companies are finding it difficult to fill pipelines and will be unable to maintain current revenue levels over the next three to five years without significant M&A.

1. EY analysis.

The good news is that Big Pharma currently commands record levels of firepower — dealmaking capacity — estimated at over US$1 trillion at the end of the first quarter of 2024, some of the highest totals since we began tracking this metric over a decade ago. Unsurprisingly, dealmaking has gained momentum with the pharma industry moving to acquire de-risked assets that can replenish threatened revenues. The dire sentiments that many biotech executives were expressing in mid-2023 when this report was last published were replaced with optimism and enthusiasm as the opening days of 2024 brought a flurry of deal activity.

The US$179 billion spent on biopharma M&A in 2023 — which includes the US$7.5 billion purchase of Texas-based Reata Pharmaceuticals — has boosted confidence that biotech will continue to find the capital investment it needs to advance innovation. Though it remains to be seen if this trend will continue for the remainder of 2024, proceeds from biotech follow-on offerings and initial public offerings (IPOs) also increased in 2023 and continued to show promise in the first quarter of 2024, with private investment in public equity (PIPEs) deals also emerging as another means of meeting the industry's financing needs.[2]

The question is whether these signs of renewed investment will translate into a sustainable trend, despite the US Federal Reserve's delaying action on interest rates in the face of persistent inflation, strong payroll data and the sustained resilience of the US economy. For now, biotech remains in a Darwinian environment, where survival remains an ongoing challenge for many companies. As shifts in macro policy potentially infuse more confidence into public and private financial markets, we can expect to see accelerating activity in biotech in terms of partnerships, acquisitions, financing rounds, follow-ons, IPOs, and more. With innovation at a high and capital on the verge of potentially returning in plenty, the biotech sector is poised to not only survive but thrive in this fast-evolving environment.

These efforts continue to attract investments for R&D and for new biotech companies to relocate to Texas, including Verily, which announced its relocation to the Dallas Forth-Worth area in June 2024.

The past year has been a testament to the sector's tenacity, with Texas biotech companies demonstrating remarkable agility. Against a backdrop of cautious capital markets and a shifting regulatory environment, these firms have continued to advance scientific frontiers. The state's and its educational facilities' investments in life sciences infrastructure and talent has also laid a foundation for growth, attracting both established players and emerging innovators. The state is home to seven of the nation's top 125 medical institutions, contributing to a growing skilled life sciences-oriented workforce.

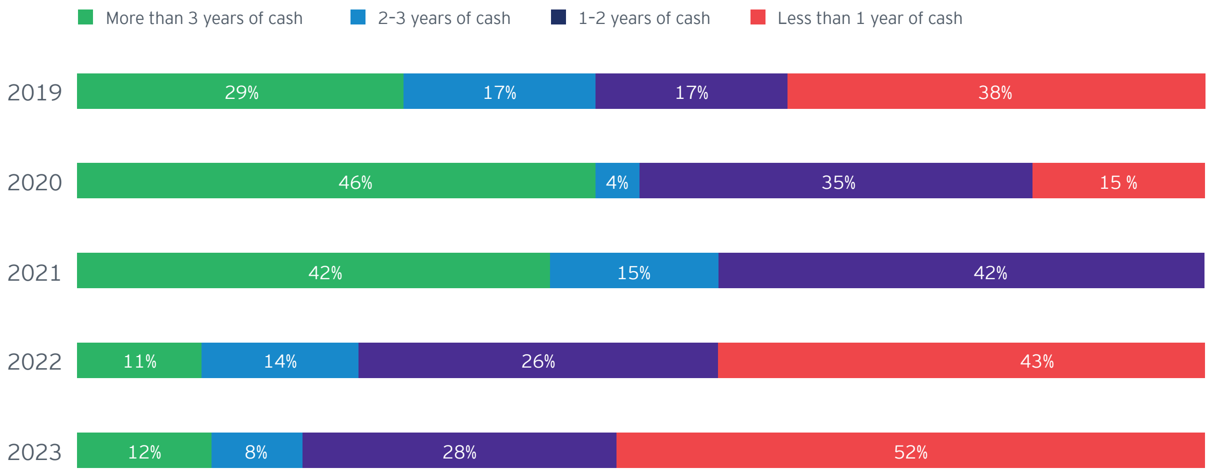
As we explore the data and developments of 2023, we also cast an eye toward the future of biotech. With signs of potential increases in financing and dealmaking, and the potential for a more favorable fiscal policy on the horizon, Texas stands ready to capitalize on the opportunities that recovery may bring. This report aims to provide a comprehensive analysis of where biotech stands and the possibilities that lie ahead for Texas in the industry.

2. "Certain Biotech Investors Get an Early Look at Results. Is That Fair?," *Wall Street Journal website*, https://www.wsj.com/finance/investing/biotech-private-investments-public-equities-9999d99e, April 15, 2024.

Texas by the numbers

As mentioned in our 34th edition of our annual global *Beyond Borders* report, the past 18 months has been challenging for biotech companies. Cash runway continues to be challenging for early-stage companies, with 31% of public biotechs having insufficient cash to maintain their operations for more than one year into the future, and an incremental 25% only having sufficient cash for less than two years. Texas companies reflected additional need for capital with 52% of public biotechs having insufficient cash to maintain their operations for more than one year, and an incremental 28% only have sufficient cash for less than two years.

Figure 1. Eighty percent of Texas-based public biotechs have two or less years of cash in 2023



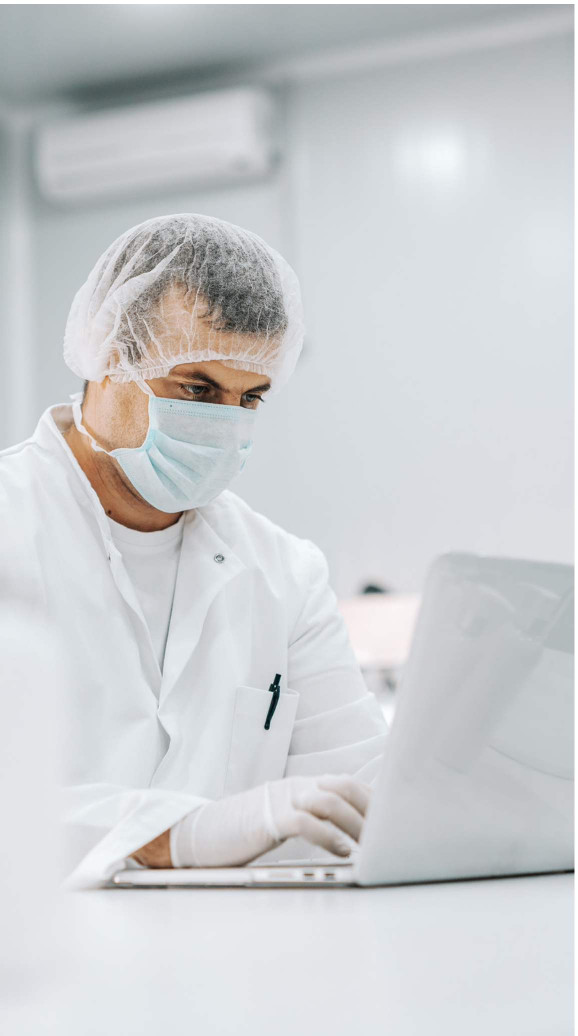
Sources: EY analysis, Capital IQ and company financial statement data.
Chart shows percentage of biotech companies with each level of cash.
Numbers may appear inconsistent because of rounding.

With continued constraint on capital and reduced ability to access the public markets for funding (as reflected in Texas with zero companies experiencing an initial public offering (IPO) in 2023), employment at biotech companies is down for the first time on a global basis, with headcount reductions of almost 2% seen in the US and European Union (EU). This is felt more acutely at early-stage R&D companies and is reflected in our Texas data, which identified a decline of 29% from 2022 to 2023.

Figure 2. Texas biotechnology at a glance (US$m)

	2021	2022	2023	H1 2024	% change (2021-22)	% change (2022-23)
Public data company						
Revenues	238.3	197.5	324.3	211.7	-17%	64%
R&D expense	1,042.2	1,132.7	875.7	356.9	9%	-23%
Net income	(1,497.9)	(1,808.9)	(1,438.6)	(426.8)	21%	-20%
Market capitalization	10,256.9	5,004.8	4,303.3	4,395	-51%	-14%
Number of employees	2,479	2,255	1,606	880	-9%	-29%
Financing						
Capital raised by public companies	1,392.7	306.6	1,039.7	87.1	-78%	239%
Number of IPOs	2	2	0	0	0%	-100%
Number of companies						
Public companies	26	28	26	24	7%	-8%

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



Similarly, the number of publicly traded companies decreased by approximately 5% across the US and EU, with a 7% decrease experienced in Texas between 2022 and 2023. In addition, market capitalization of companies continued to decline in 2023 by 14%. With increasing inflation, the US Federal Reserve hiked interest rates 11 times, which have correlated negatively and consistently with falling biotech valuations.[3]

However, it is expected that the US Federal Reserve will begin to reduce the interest rates in late 2024, creating a favorable scenario for companies to increase their valuations in the current year.[4]

Public biotech companies in Texas recorded an average annual revenue growth rate of 50% in 2023 compared to the previous year to total revenues of US$333 million. Net losses increased US$300 million, from US$(1.8) billion in 2022 to US$(1.5) billion in 2023.

Please refer to our annual global *Beyond Borders* report, where we highlight three key focus areas for biotechs that seek to maintain and grow their operations in a capital-constrained market, including the following:

- **Financial resilience:** how can biotechs improve their operational efficiency and contain costs during the ongoing "capital hangover" and beyond?
- **Commercial models:** with biotechs increasingly seeking to explore commercialization opportunities without the guarantee of partnering with large pharma companies, how can companies optimize their approaches?
- **Tax efficiency:** what strategies can biotechs deploy to improve their tax positions (e.g., moving clinical trials to geographies with better tax incentives)?

3. "Fed's interest rate history: The federal funds rate from 1981 to the present." *The Bankrate website*, July 31, 2024, https://www.bankrate.com/banking/federal-reserve/history-of-federal-funds-rate/.
4. "Fed to cut rates twice this year, with first move in September, economists say: Reuters poll." *Reuters website,* July 23, 2024, https://www.reuters.com/markets/us/fed-cut-rates-twice-this-year-with-first-move-september-economists-say-2024-07-23/.

However, the high levels metrics of Texas public companies do not tell the full story. While capital has been constrained since the cash-flush years of 2020 and 2021, Texas biotech companies saw a substantial rise in capital inflow in 2023, rebounding from a sharp decline in 2022. The total capital raised amounted to US$1.569 billion, marking a 251% increase from the previous year, and exceeding levels of capital inflow from any year prior to 2020.

While funding has increased significantly in 2023, the method of funding has changed over the past two years, with a focus in 2023 on cash obtained primarily through follow-on and private investment in public equity (PIPE) offerings, as well as debt offerings. Specifically, follow-on and PIPE transactions represented approximately 60% of the total financing for 2023 at US$938 million and 73% of the total financing for the first half of 2024 at US$337 million. This 18-month period includes two major rounds of follow-on offerings (including PIPE) by Lexicon Pharmaceuticals, Inc. (US$389 million) and Aeglea BioTherapeutics, Inc. (US$210 million), which together accounted for 47% of the total amount raised through follow-on offerings. In 2023, debt funding reached a record high with a total of US$440 million raised. Caris Life Sciences, a molecular science and technology company actively developing and delivering innovative solutions to revolutionize healthcare, was responsible for raising US$400 million of this amount.

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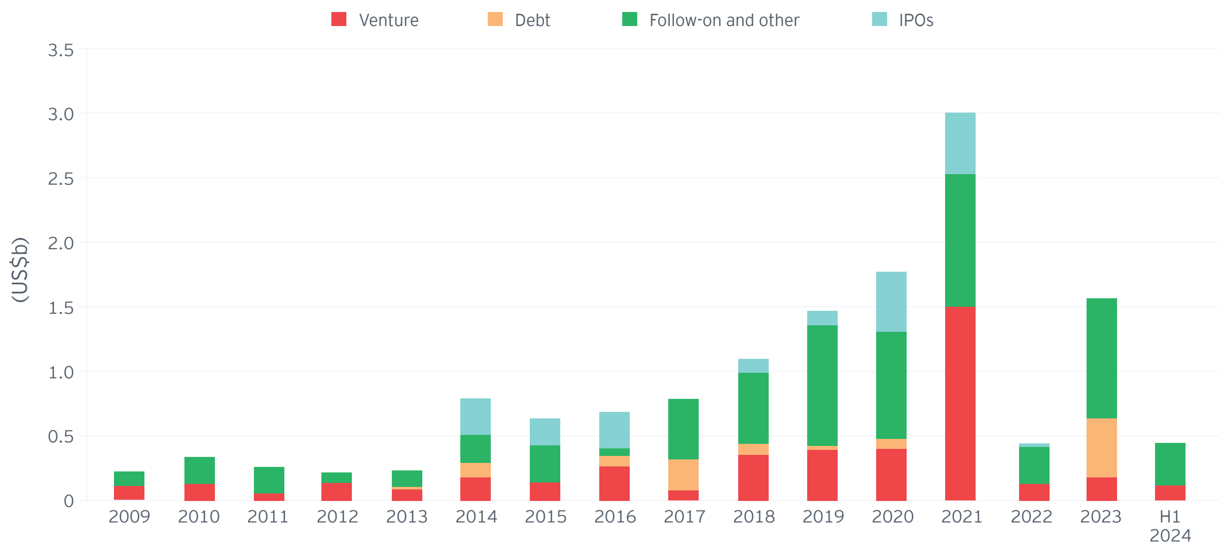
Figure 3: Behind the scenes: funding the growth of Texas biotechs, 2009-H1 2024



Sources: EY analysis, EY Strategy Edge, Capital IQ and venture source.

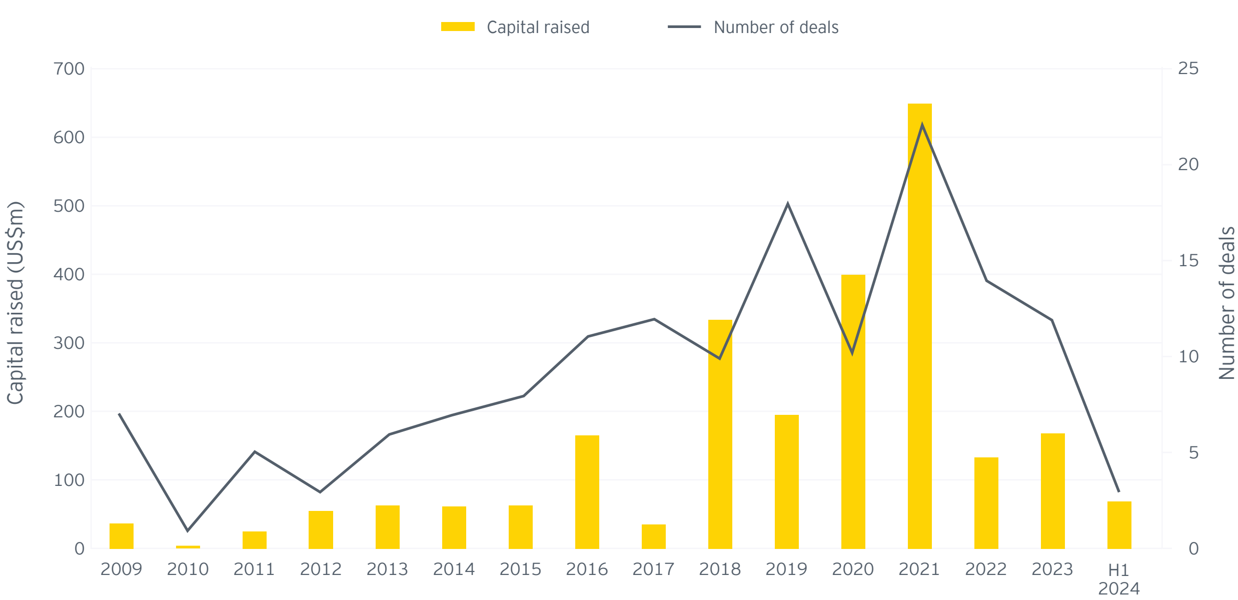
This is in sharp contrast to previous years, which experienced increased levels of venture funding and IPOs. This trend has continued into 2024, which reflects high funding through follow-on and PIPE offerings accounting for 73% of the total amount raised through the first half of 2024.

After a spike in 2020 and 2021, IPO activity faced a significant decline as investors became more cautious amid pandemic-related uncertainties and economic downturns. The total capital raised through IPOs was US$453 million in 2021, which decreased to just US$25.1 million in 2022. The IPO market remained largely inactive during 2023 due to market pressures from continue elevated interest rates. While Texas biotech companies have not experienced any IPOs in 2023 or to date in 2024, it is important to note that the broader US market has seen an increase in IPO activity since 2022. This minor recovery, alongside the rise in PIPEs, suggests a level of optimism in the sector.

Venture financings experienced a marginal growth of 36% in 2023, raising a total amount of US$192.2 million, that was US$1.339 billion less than the record high of US$1.531 billion set in 2021. Furthermore, in 2023, these financings represented just 12% of the total amount raised. While not included in the above numbers, Texas-founded ReCode Therapeutics also raised US$260 million in venture capital funding in Q3 2023.

The first half of the year registered a promising start to the year, raising US$459 million primarily through follow-on and venture offerings, amounting to 29% to the total amount raised in 2023.

Figure 4. Texas early-stage venture investment, 2009-H12024



Sources: EY analysis, EY Strategy Edge, Capital IQ and venture source.

Early-stage Texas biotech companies (defined as companies that have raised their first or second round of funding) raised capital in 2022 of US$134 million across 14 deals. This amount increased from 2022 to 2023 by approximately 26% to US$168 million, raised across 12 deals.

For the first half of 2024, early-stage biotech companies raised $69 million. While at first glance this may reflect less investment in the sector, it should be noted that $150 million of the 2023 total early-stage investment of $168 million related to one deal.

The first half of 2024 has already seen an increase in funding with US$122.4 million raised to date.

Figure 5. Top Texas venture rounds of 2023 and the first half of 2024

Year	Name	Therapeutic focus of lead candidate	Clinical stage of lead candidate	Gross raised (US$m)	Quarter	Round type
2023	Colossal Biosciences Inc.	Other	NA	$150.0	Q1	Early
	Osteal Therapeutics, Inc.	Infectious	Phase II	$23.0	Q3	Late
	FibroBiologics, Inc.	Multiple	Phase II	$5.0	Q1	Early
	March Biosciences, Inc.	Cancer	Phase I	$4.8	Q4	Early
	ImmunoGenesis, Inc.	Cancer	Phase II	$4.5	Q2	Early
	Aperiam Bio, Inc.	Other	NA	$4.0	Q3	Early
2024	Osteal Therapeutics, Inc.	Infectious	Phase II	$50.0	Q2	Late
	ImmunoGenesis, Inc.	Cancer	Phase II	$44.4	Q2	Early
	CoRegen Inc.	Cancer	Pre-clinical	$14.5	Q1	Early
	PranaX Corp	Other	NA	$10.0	Q1	Early

Sources: EY analysis, Capital IQ

In 2023, Texas biotech companies, regardless of their funding stages, successfully closed a total of 16 venture deals, raising a cumulative of US$192.2 million compared to 20 deals in 2022 generating US$141million. The first half of 2024 has already seen an increase in funding with US$122.4 million raised to date, including US$50 million raised by Dallas-based Osteal Therapeutics, bringing its total funding to $73 million over the past year.

The majority of the venture rounds in 2023 and H1 2024 focused on cancer (oncology) as a key therapeutic area, with the drug candidates being in Phase I or II of the development stage.

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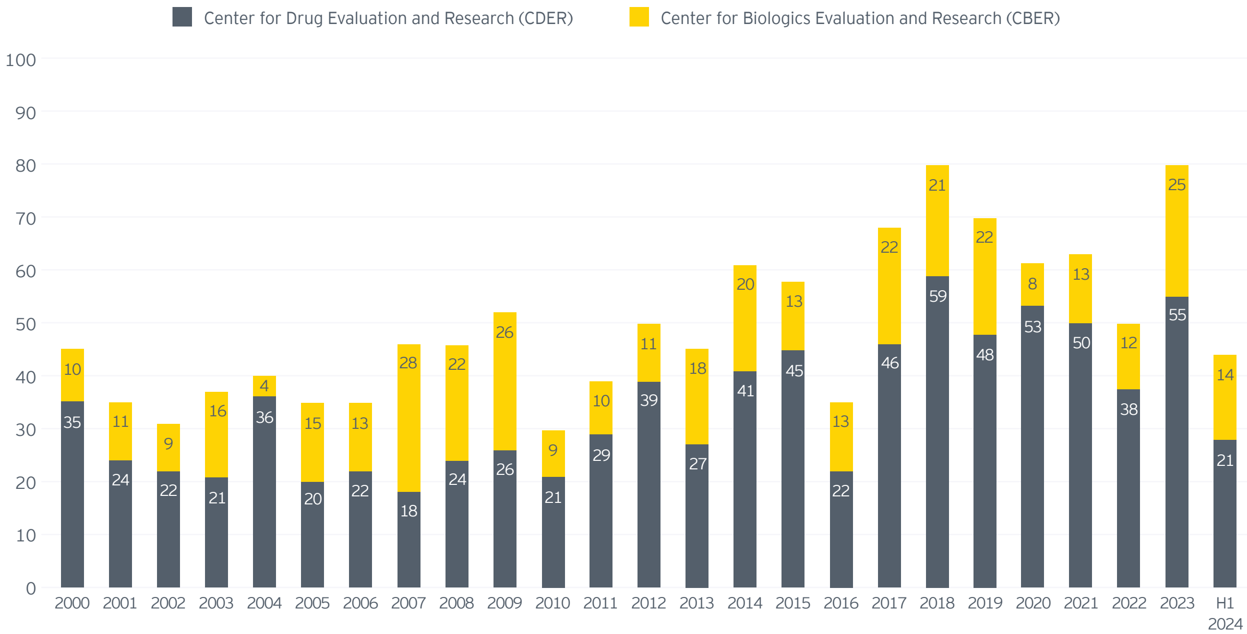
Figure 6. FDA product approvals, 2000–H1 2024



Sources: EY analysis, FDA website.
*Data for CBER and Center for CDER from 2000 to June 2024.
Note: For 2000 to 2011, CDER include new biologics, but exclude new indications, new formulations and generic drugs.

Figure 7. Texas Biotech FDA Approvals, 2023

Drug name	Approval date	Year	Name of company	FDA - approved use on approval date
Skyclarys	28-02-2023	2023	Reata Pharmaceuticals	To treat friedrich's ataxia
Inpefa	26-05-2023	2023	Lexicon Pharmaceuticals	To treat heart failure

Sources: EY analysis, FDA website.

As mentioned in our 2023 *Beyond Borders Texas Edition* report, we were hopeful that the U.S. Food and Drug Administration's (FDA) would soon regain the momentum they lost during the pandemic crisis. This became reality in 2023, when the FDA approved 80 new biopharma products, the most approved this century (tying with 2018). This notable number of approvals highlights the trend of increased regulatory approvals over the past decade, and research indicates that this upturn is driven in substantial part by biotech. For example, one report shows that biotech R&D accounted for 47% of new products launched by the 20 biggest biopharmas between 2015 and 2021, with only 38% coming from internal R&D. Texas-based companies had two new FDA approvals in 2023, as shown in the table above, and there could be more on the horizon as Lexicon has shared a Prescription Drug User Fee Act date in December 2024 for its sotagliflozin type 1 diabetes NDA resubmission.

Despite a challenging period, the Texas biotech industry has shown resilience with a continued increase in capital inflow and robust innovation. With interest rates anticipated to decline, a revitalized investment landscape in the near future is likely. Given the state's commitment to fostering both biotech hubs and a skilled workforce, along with a reinvigorated FDA approval process, Texas is poised to remain at the forefront of biotech innovation, driving the industry toward a future of groundbreaking discoveries and enduring growth.

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