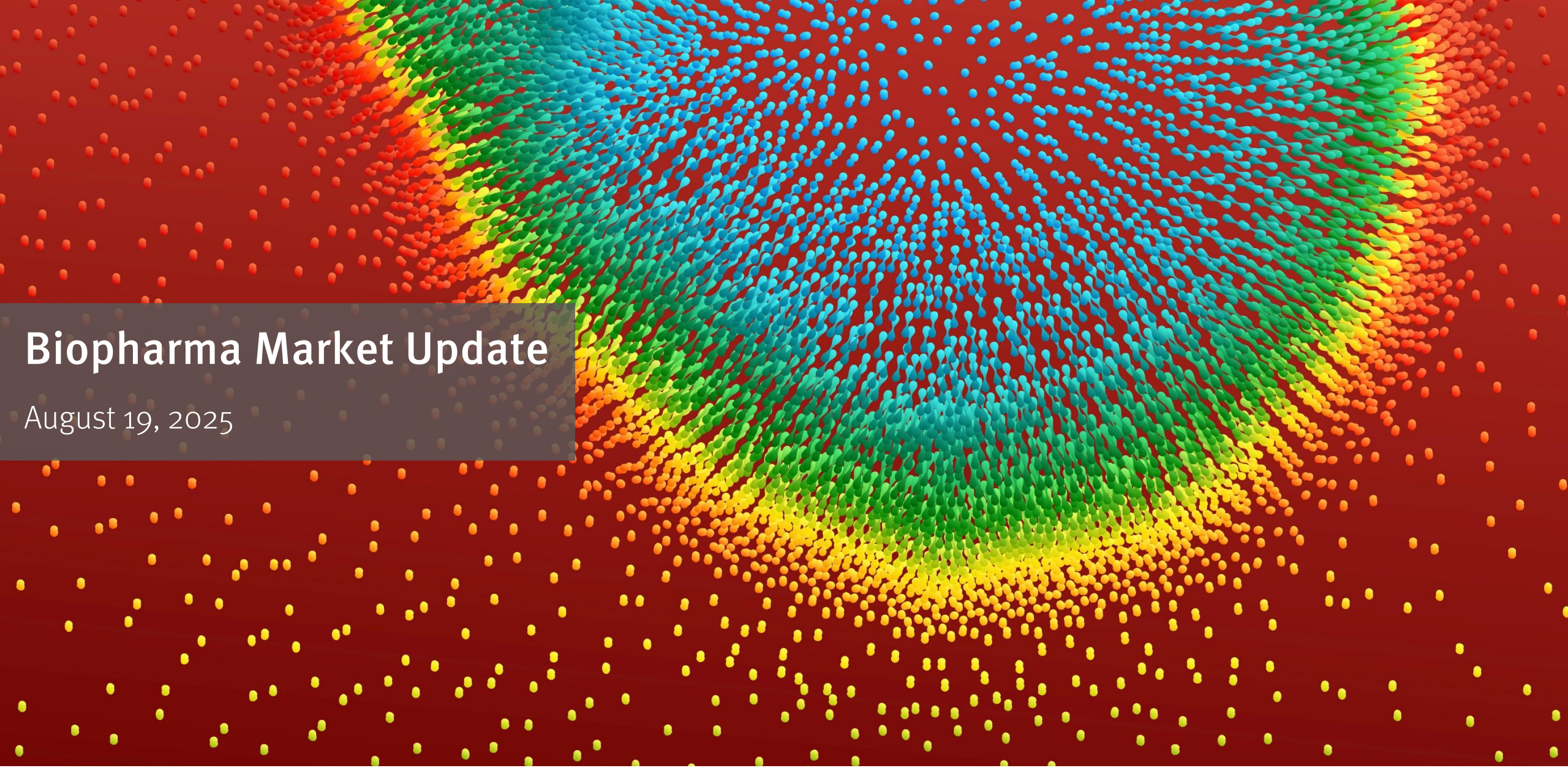

Biopharma Market Update

August 19, 2025

STIFEL | Healthcare

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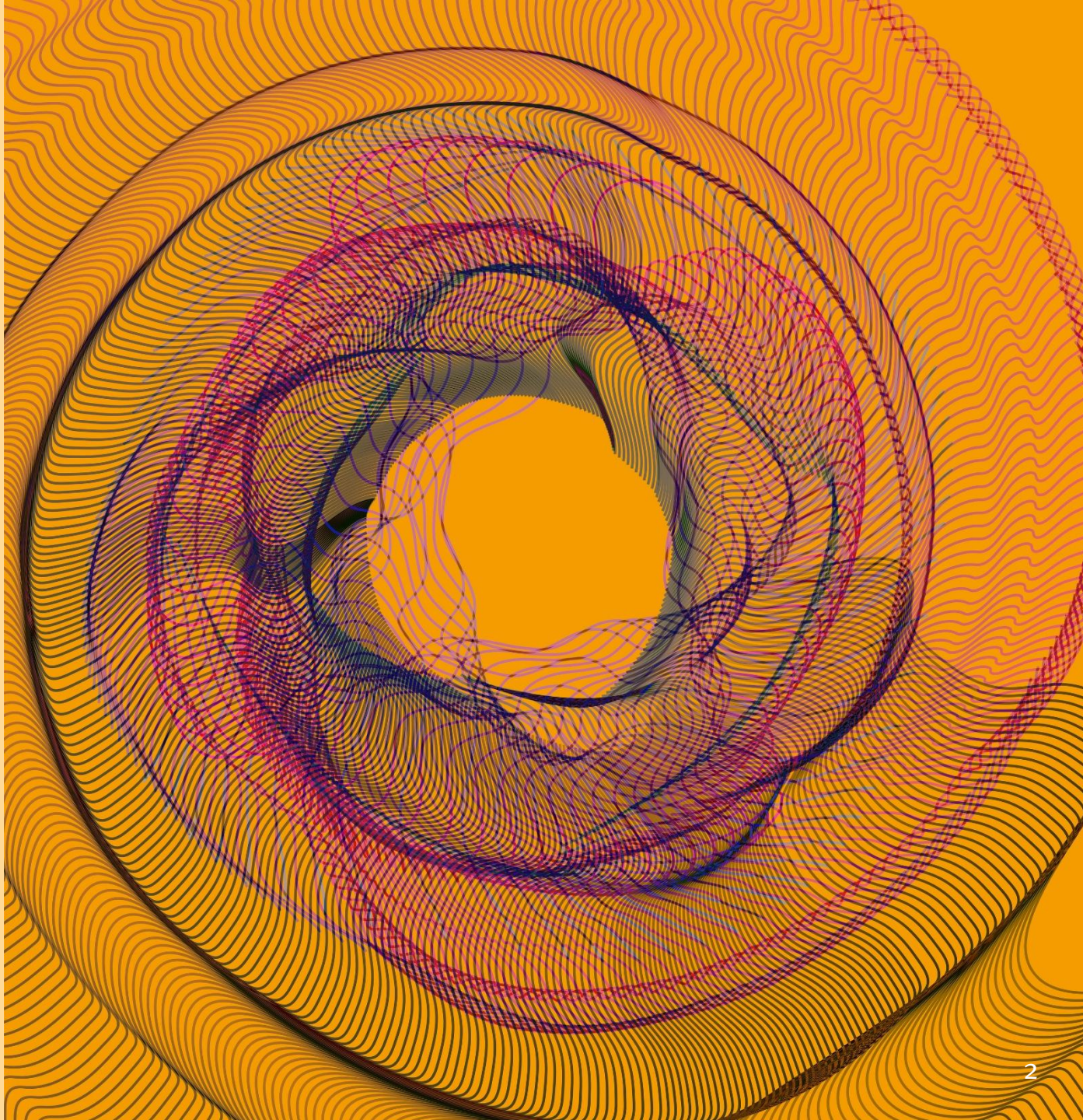

Past Issues

To get on the mailing list for this publication feel free to contact Jenna Hill (hillje@stifel.com). Past issues of this publication can be read online at:

Jul 14, 2025 (Top 40 Pharma)
Jun 23, 2025 (Science and Truth)
May 12, 2025 (MFN Policy)
May 5, 2025 (NIH Cuts, China Tariffs)
Apr 28, 2025 (Eyes on Washington DC)
Apr 21, 2025 (FDA Shifts, Buyside Update)
Apr 14, 2025 (Wild Week in Market)
Apr 7, 2025 (Biotech Market Break)
Mar 31, 2025 (China Biotech Update)
Mar 24, 2025 (Healthcare Reform)
Feb 24, 2025 (Retail Pharma Trends)
Feb 10, 2025 (Pharma Earnings)
Jan 27, 2025 (Women's Health, Obesity)
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May 27, 2024 (GLP-1's)
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May 6, 2024 (Earnings, Obesity)
April 29, 2024 (M&A, Japan)
April 22, 2024 (Pharma Pricing)
April 15, 2024 (AI in Pharma)
April 8, 2024 (The Buyside)
April 1, 2024 (Biotech Balance Sheets)
March 25, 2024 (Women's Health)
March 18, 2024 (Inflammasome)
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March 4, 2024 (Biotech Employment)
Feb 26, 2024 (Biotech Strategy)
Feb 19, 2024 (Big Drugs, Autoantibodies)
Feb 12, 2024 (Fibrosis, Endometriosis)
Feb 5, 2024 (Severe Disease in Women)
Jan 29, 2024 (Pharma R&D Productivity)
Dec 18, 2023 (Expectations for Future)
Dec 11, 2023 (ASH, R&D Days)
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November 20, 2023 (M&A)
November 13, 2023 (AHA, Bear Market)
November 7, 2023 (Unmet Needs)
October 30, 2023 (ADCs)
October 23, 2023 (ESMO Review)
October 16, 2023 (Cancer Screening)
October 9, 2023 (Biosimilars, M&A)
October 2, 2023 (FcRn, Antibiotics)
September 25, 2023 (Target ID)
September 18, 2023 (Pharma Strategy)
September 11, 2023 (US Health System)
September 5, 2023 (FTC, IRA, Depression)

OSAKA EXPO 2025, Official Plush Doll for Sponsor: Shionogi Pharmaceuticals, June 2025.

Links to Stifel Biopharma Special Topic Publications

Obesity Drug Update

[July 9, 2025]

Oncology Update

[Jun 5, 2025]

Aging Biology, Part I

[Mar 26, 2025]

2025 Biotech Outlook

[Jan 8, 2025]

2024 Biotech Mid-Year Outlook

[July 15, 2024]

Obesity Drug Update

[July 8, 2024]

AI in medicine

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Why Invest in Biotech?

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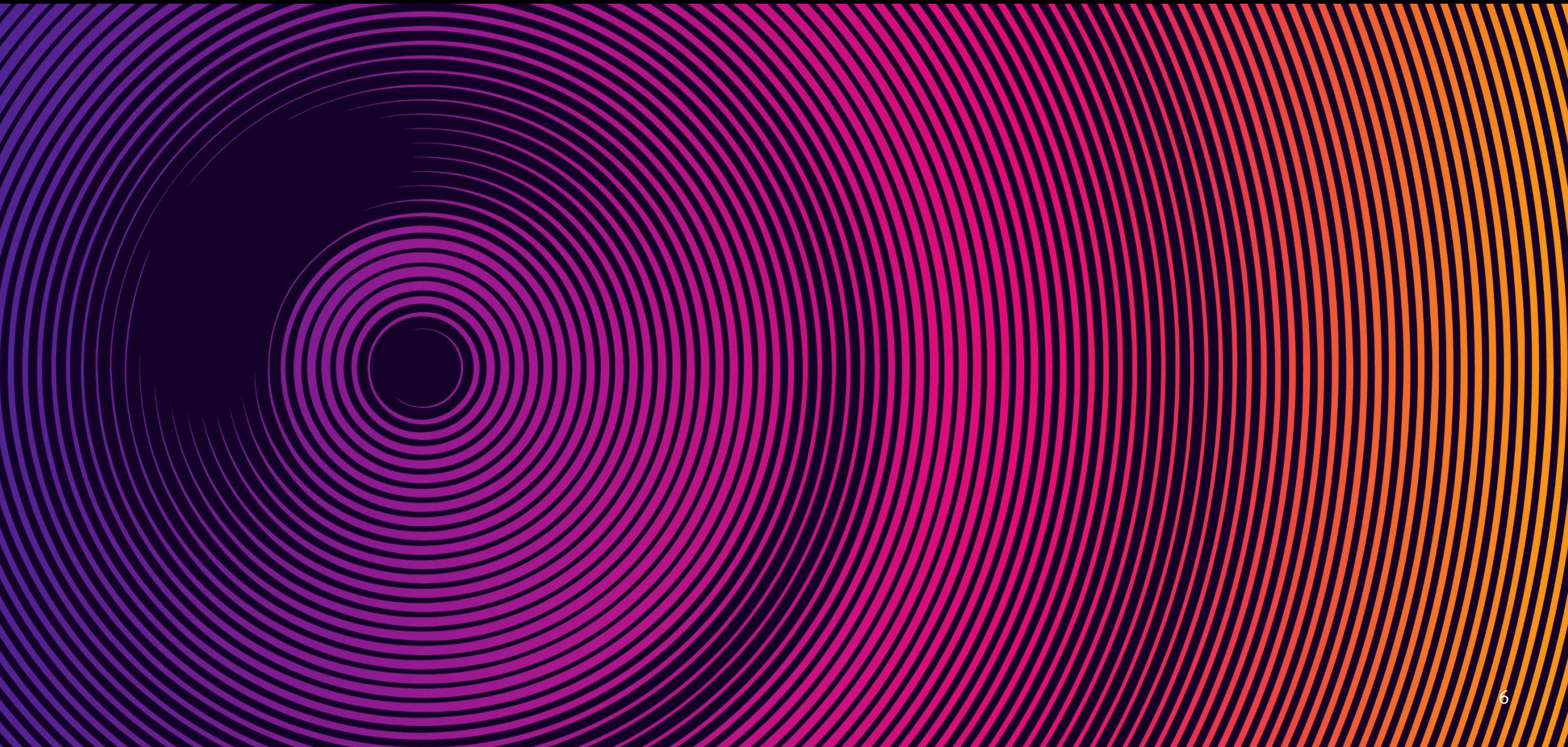
Macro and Political Update



US Producer Inflation Heats Up as Prices Soar

Lucia Mutikani, *Reuters*, August 14, 2025 (excerpt)

U.S. producer prices increased by the most in three years in July amid a surge in the costs of goods and services, suggesting a broad pickup in inflation was imminent, posing a dilemma for the Federal Reserve.

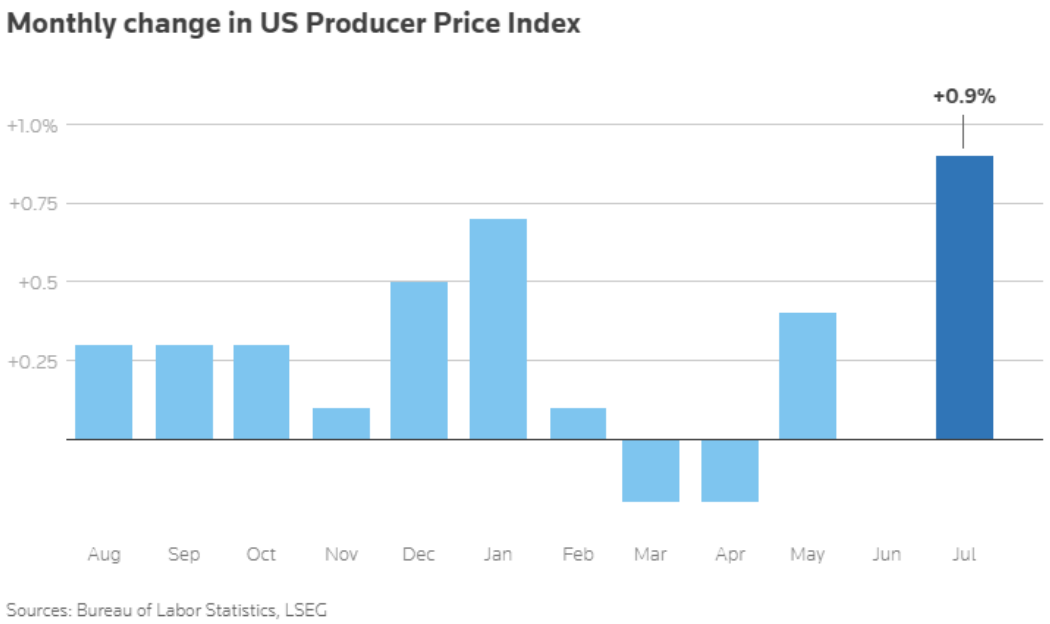
The stronger-than-expected producer inflation report from the Labor Department on Thursday followed data this week showing consumers paid higher prices for services like dental care and airline fares last month. There were also no signs of further labor market deterioration in early August.

Economists had hoped that moderate services price gains would blunt the inflationary impact of higher goods prices from President Donald Trump's sweeping import tariffs.

The U.S. central bank puts more emphasis on services inflation given the economy is services-driven. Though financial markets continued to anticipate the Fed would resume rate cuts in September, some economists urged caution.

"This is a kick in the teeth for anyone who thought that tariffs would not impact domestic prices in the United States economy," said Carl Weinberg, chief economist at High Frequency Economics. "This report is a strong validation of the Fed's wait-and-see stance on policy changes."

Source: https://www.reuters.com/world/us/us-producer-inflation-heats-up-goods-services-prices-soar-2025-08-14/



Beware the Return of Inflation

The Editors, *National Review*, August 15, 2025 (excerpt)

President Trump seems to think the Bureau of Labor Statistics' jobs reports are made up, but what about the inflation reports? The BLS's consumer price index last month registered a 2.7 percent year-over-year increase overall, with a 3.1 percent rise in core prices (excluding food and energy). The producer price index for final demand surprised on the upside, rising 3.3 percent year-over-year.

The surge in the producer price index is not due to tariffs. The BLS says three-quarters of the increase was due to higher prices for services, not goods. And that should worry the administration more than if it were caused by tariffs.

"The index for final demand services moved up 1.1 percent in July, the largest advance since rising 1.3 percent in March 2022," the producer price index report says. March 2022 was in the lead-up to 9 percent inflation in the summer of that same year, the tip of the spike in prices that made the Democrats who were in power at the time so unpopular.

There was, of course, a confluence of other circumstances in 2022 that do not obtain today, and 9 percent inflation is unlikely to reemerge. But 3 or 4 or 5 percent? Perhaps. Inflation has been stuck around 3 percent since June 2023, despite Federal Reserve rate hikes to get it back down to the 2 percent target. And the administration isn't doing much to help.

Voters are unlikely to be interested in a technical conversation about the difference between relative price increases and inflation. They'll likely see tariffs that raise prices (that is their purpose, to discourage imports by raising prices) and blame Republicans for any inflation that occurs. Recent polls already show Trump underwater on the issue, a bad sign for someone who won the election last year in part because of inflation.

Source: https://www.nationalreview.com/2025/08/beware-the-return-of-inflation/

The Economy Is Starting to Pay for Trump's Chaos

Jared Bernstein and Ryan Cummings, Editorial, *New York Times*, August 10, 2025 (excerpt)

Since President Trump took office, economists have been waiting for his policies to work their way through the U.S. economy and reveal their consequences. The soft data, mostly surveys of consumers and businesses that track how people feel about the economy, turned down sharply months ago, while the hard data — jobs, G.D.P. growth, inflation — all seemed fine. But recently, a telling series of hard economic data rolled in that has rightfully raised alarm bells about slowing growth and increased inflation — a dreaded economic combination known as stagflation.

Mr. Trump's tariffs are now clearly fueling inflation, particularly in goods such as home appliances, cars and food. In the first six months of the year, real (that is, inflation-adjusted) consumer spending, the main driver behind business cycles and robust economic expansion, barely grew, after rising 3 percent last year. G.D.P. growth slowed by about half, to 1.2 percent this year from 2.5 percent last year. When overall growth falls that sharply, the labor market tends to follow, which is precisely what happened: Job growth, at 35,000 per month on average between May and July, is dangerously close to stall speed.

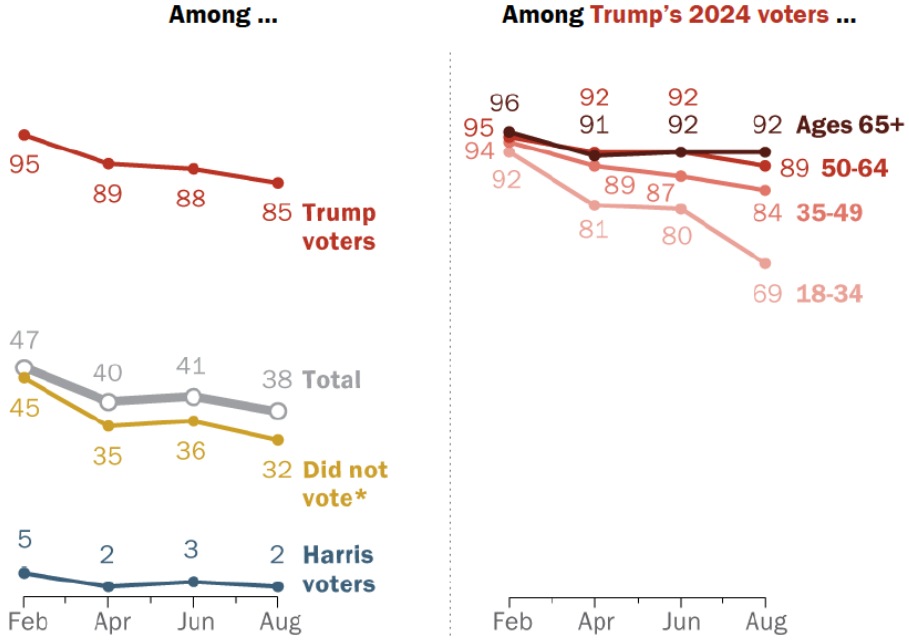
While presidents always take credit for good economic news and try to deflect bad news (in this president's case, by firing the messenger who delivered it), it's often hard to link what's going on in the economy to the current administration. Not this time. Whether it's historically high tariffs that never quite seem to stabilize, deportations that threaten to seriously disrupt labor supply in sectors like construction and health services, or a reverse-Robin Hood, budget-busting bill that takes money away from those most likely to spend it, Mr. Trump's policies have pushed economic uncertainty to levels last seen during the onset of the pandemic. This uncertainty has damped investment, hiring and consumption, while the tariffs increase prices. In other words: stagflation.

Source: https://www.nytimes.com/2025/08/10/opinion/stagflation-trump-economy.html

Trump Approval Ratings Have Not Improved in the Last Two Months

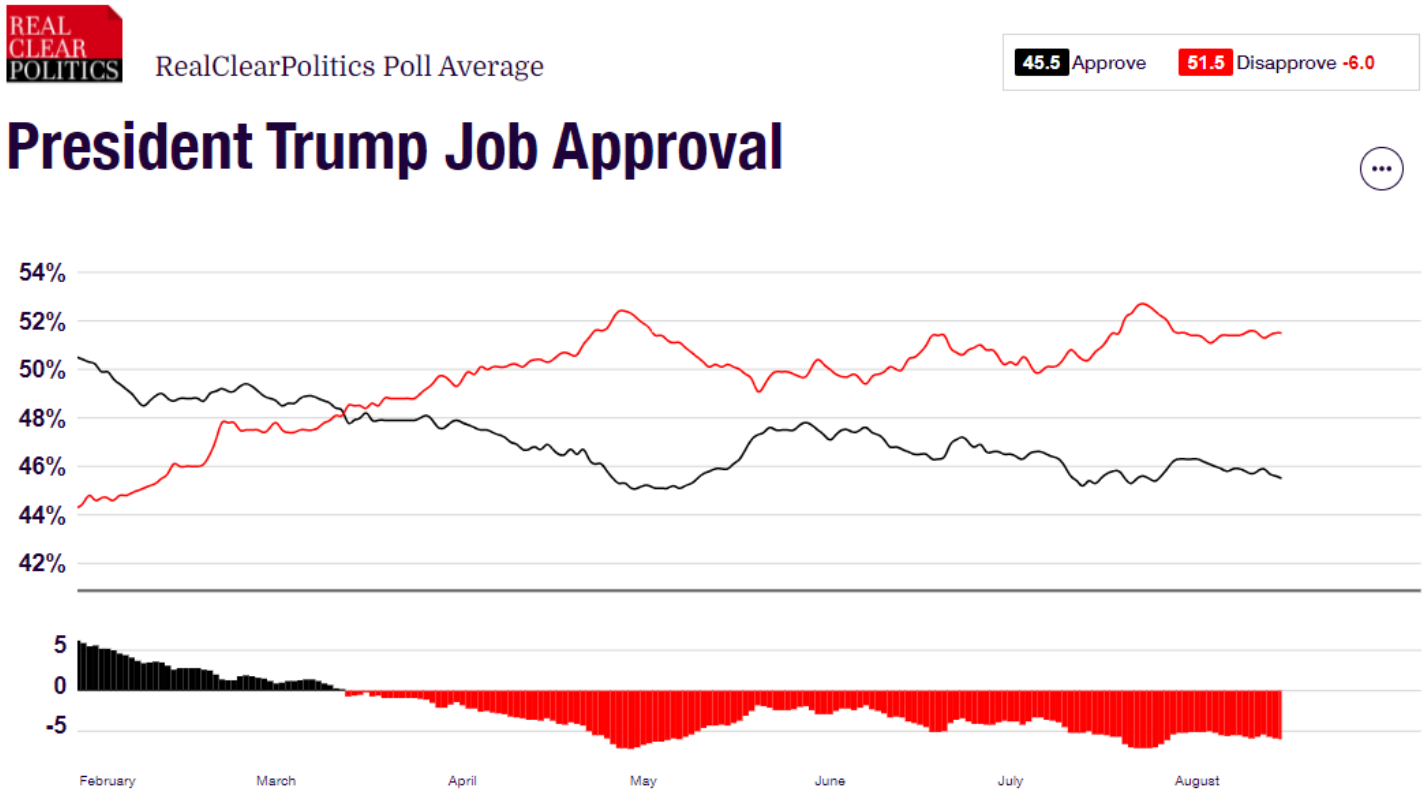
Trump's approval rating declines among his 2024 voters, especially those under 35

*% who **approve** of the way Donald Trump is handling his job as president*



* Nonvoters include those who did not vote in 2024 but were eligible to do so, as well as those who were not eligible to vote.
Note: Validated Trump and Harris voters are adult citizens for whom a record of voting was found in official state election records. Vote choice was collected in a survey conducted in the month after the 2024 election.
Source: Survey of U.S. adults conducted Aug. 4-10, 2025.

PEW RESEARCH CENTER



Sources: https://www.pewresearch.org/politics/2025/08/14/trumps-job-approval-and-views-of-his-personal-traits/pp_2025-8-14_trump-approval_1-04/, https://www.realclearpolling.com/polls/approval/donald-trump/approval-rating

Stocks Keep Climbing Past Bad News

Strong corporate earnings, mostly stable tariff rates and the expectation of interest rate cuts have eased worries of a market reckoning.

Joe Rennison, *New York Times*, Aug 16, 2025 (excerpt)

To the casual observer, the rally in the stock market may seem baffling.

The effective tariff rate on U.S. imports is the highest it has been since the 1930s, upending supply chains, stoking inflation concerns and underpinning an intensifying war of words between President Trump and Jerome H. Powell, chair of the Federal Reserve.

But the S&P 500 has continued to hit new highs. The index has recovered all the ground it lost in the global market sell-off in April, after Mr. Trump announced sweeping tariffs. It is now more than 5 percent above its last peak, in February, and almost 10 percent higher for the year.

For the time being, the economic reality of tariffs has yet to catch up with the market's earlier worries.

Corporate profits remain strong, and the economy, despite worries about what's to come, is still solid. There are pockets of weakness, but the biggest companies that drive the S&P 500's performance have been largely insulated against further impact from tariffs, propelled instead by the growth of artificial intelligence.

With most companies in the S&P 500 having already reported earnings for the three months through June, the average growth rate of the companies in the index nudged into double digits for the third quarter in a row, according to data from FactSet.

Big tech companies again led the way, helping to justify their high stock prices. A further contraction in the energy sector, alongside the continued malaise for manufacturers, paled in comparison with the growth of the tech juggernauts.

And while retailers and other companies that deal directly with consumers have complained about tariffs, the broad message among the big businesses that make up the S&P 500 is that they are manageable.

"This earnings season has allayed a lot of fears," said Nelson Yu, head of equities at Alliance Bernstein.

But this quarter, more than 40 percent of companies in the index raised their earnings estimates, anticipating a more favorable environment than previously expected.

Source: https://www.nytimes.com/2025/08/15/business/tariffs-stock-market-records.html

Biotech Stocks Did Well Last Week

Investors are snapping up buy opportunities in the downtrodden sector.

Noah Weidner, *The Street, Yahoo Finance*, Aug 15, 2025 (excerpt)

After a whirlwind week of economic data, stocks are taking a chill pill on Friday, ending off the week on a low note. The Russell 2000, Nasdaq Composite, and S&P 500 are down 0.44%, 0.41%, and 0.16% respectively. The Dow is the only major U.S. index in the green for the moment, up 0.21%.

At face, those moves aren't very dramatic. On Tuesday, U.S. equities jumped dramatically after the release of the Consumer Price Index (CPI) showed that inflation moderated in July, with the growth-centric Russell 2000 soaring nearly 3%. But by Thursday, things were all topsy-turvy, with the release of the Producer Price Index (PPI). Both elicited much more dramatic responses.

Still, below the top-line figures we see at the top of the market, there's always stories in the stock market. Even today, a quiet Friday, there are stocks making big moves. In fact, many of today's biggest movers come from the solar, biotech, and health insurance business.

Pharma stocks jump

Small-caps might be down, but pharma and biotech stocks are up today... again!

For the unacquainted, the SPDR S&P Biotech ETF (XBI) and the iShares Biotechnology ETF (IBB) are up 6.2% and 5.2% this week respectively (mind you, those are intraday figures.) That's a kind premium on these battered-down stocks, especially when you compare it to the Russell's 3% return over the same period.

So who's leading the leaders today? Arrowhead Pharmaceuticals (+7%), Moderna (+7%), and Sarepta Therapeutics (+6.3%). Ironically, all firms that have faced their fair share of trial and tribulation recently.

Sarepta has faced FDA scrutiny over its gene therapy for Duchenne muscular dystrophy, forcing it to sell shares of Arrowhead, in which it was a sizable investor, to shore up its cash position.

And Moderna? Well, in case you didn't know, this administration isn't terribly enthused about mRNA vaccines for any number of reasons. Still, the company has an incredibly robust portfolio which might make the U.S. pay for, in every sense of the definition, turning their nose up at them.

Let the largest holdings in the XBI speak for themselves: Alnylam (ALNY) (+91% year-to-date), Insmed (INSM) (+80%), Halozyme (HALO) (+39%). Impressive might be an understatement.

Source: https://finance.yahoo.com/news/solar-biotech-health-insurance-stocks-210101357.html

Biopharma Funds Deliver Rare Monthly Gains

Stephen Taub, *Institutional Investor*, Aug 14, 2025 (excerpt)

Most biopharma and life sciences hedge funds finally posted strong results in July. Even so, many remain deep in the red for the year thanks in part to the Trump administration's opposition to vaccines, which has hurt many biopharma stocks this year.

However, when it comes to biopharma investments in fledgling companies, sometimes all it takes is for one investment to report strong clinical trial results to send a stock soaring. This was the case with several hedge funds last month — in fact, all year.

Take Nantahala Capital Partners Limited Partnership's LT Class, which stands out starkly within the group in 2025. It surged 16.1 percent in July alone, boosting its year-to-date gain to 39.8 percent, an investor says. This is far better than any other biopharma or life sciences fund.

RTW Investments, meanwhile, climbed 9.2 percent in July and is up 10.3 percent for the year. Shares of No. 2 long Argenx, a Dutch pharmaceuticals company focusing on antibody-based therapies for autoimmune diseases, jumped 22 percent last month.

RA Capital Management posted a strong 7.5 percent gain and is now up 70 basis points, or 0.7 percent, in 2025. The hedge fund firm was driven by No. 3 U.S. long Rhythm Pharmaceuticals.

The stock surged about 35 percent in July after announcing positive results from its Phase 2 trial for an oral receptor for patients with acquired hypothalamic obesity. It was the hedge fund's third-largest long at the end of the first quarter.

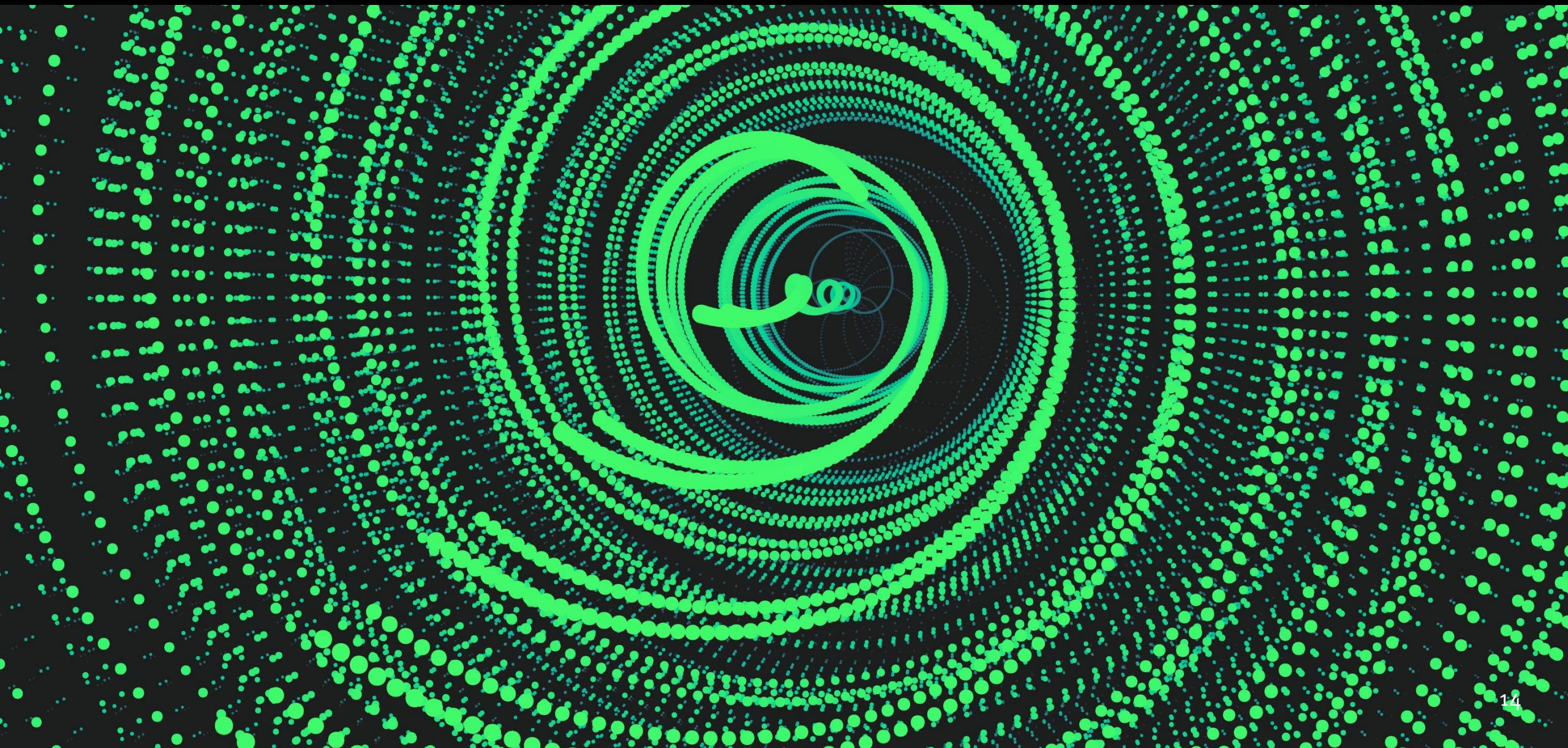
Other funds were able to move close to breakeven thanks to strong July results.

Soleus Capital Management posted an increase of more than 11 percent for the month, cutting its loss for the year to just 1.8 percent. The firm has never suffered an annual loss. It was helped in part by No. 3 common stock long Krystal Biotech, which rose more than 11 percent in July.

It focuses on developing redosable gene therapies. However, the stock dropped 10 percent on August 4 after reporting quarterly results that apparently dismayed investors.

Source: https://www.institutionalinvestor.com/article/premium/biopharma-funds-deliver-rare-monthly-gains

Biopharma Market Update



The XBI Closed at 90.7 Last Friday (Aug 15), Up 6.2% for the Week

The Stifel Global Biotech Value Tracker rose by 6.7% last week, more than the XBI but less than the BBC. Treasury yields are starting to improve. The XBI is up but barely for the year while the Stifel Global Biotech Value Tracker is up 39% for the year. The Stifel tracker is global and thus includes China biotech which has performed quite well in 2025.

Biotech Stocks Up Last Week

Return: Aug 9 to Aug 15, 2025

Nasdaq Biotech Index: +5.0%
Arca XBI ETF: +6.2%
Virtus LifeSci Biotech ETF (BBC): +9.2%
Stifel Global Biotech EV (adjusted): +6.7%*
S&P 500: +1.0%

Return: Dec 31, 2024 to Aug 15, 2025 (YTD)

Nasdaq Biotech Index: +9.1%
Arca XBI ETF: +0.7%
Virtus LifeSci Biotech ETF (BBC): -4.1%
Stifel Global Biotech EV (adjusted): +39%*
S&P 500: +9.7%

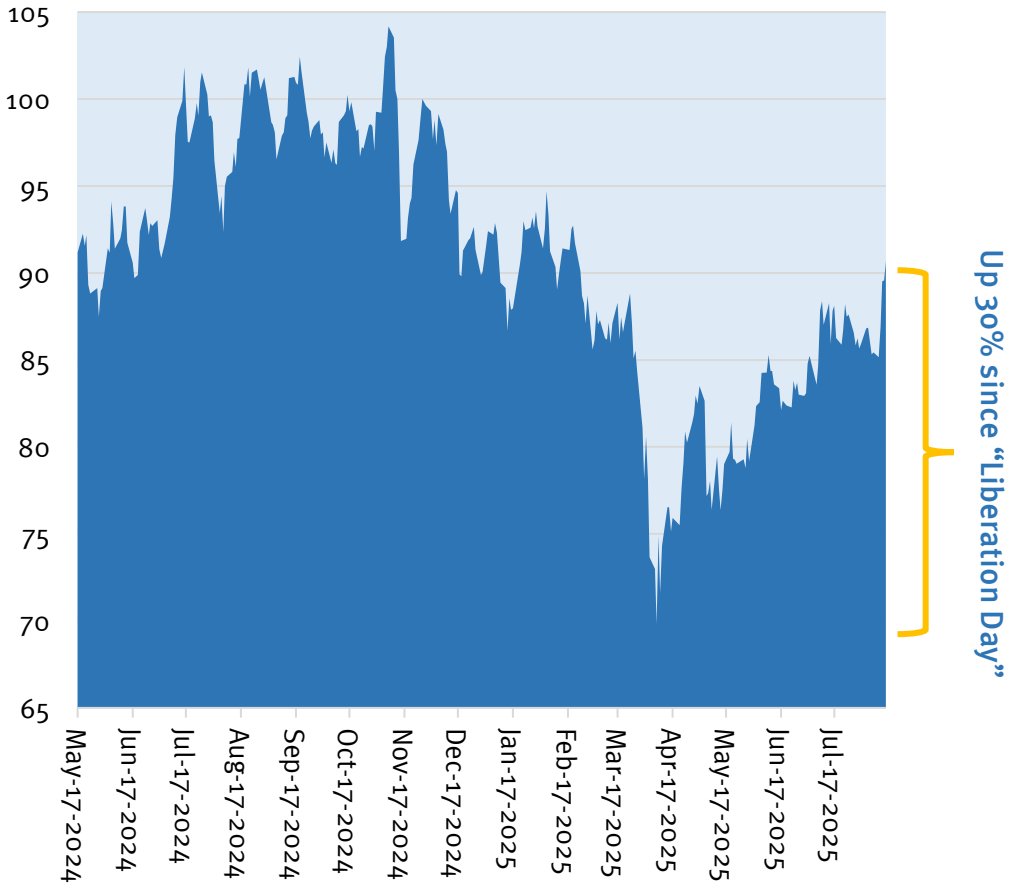
VIX Down

Aug 2, 2024: 23.4%
Dec 13, 2024: 13.8%
Mar 28, 2025: 21.7%
Apr 11, 2025: 37.6%
May 16, 2025: 18.4%
Jun 20, 2025: 20.4%
Jul 12, 2025: 16.4%
Aug 15, 2025: 15.1%

10-Year Treasury Yield Down

Aug 2, 2024: 3.80%
Dec 13, 2024: 4.4%
Mar 28, 2025: 4.27%
Apr 11, 2025: 4.48%
May 16, 2025: 4.43%
Jun 20, 2025: 4.3%
Jul 12, 2025: 4.43%
Aug 15, 2025: 4.3%

XBI, May 16, 2024 to Aug 15, 2025

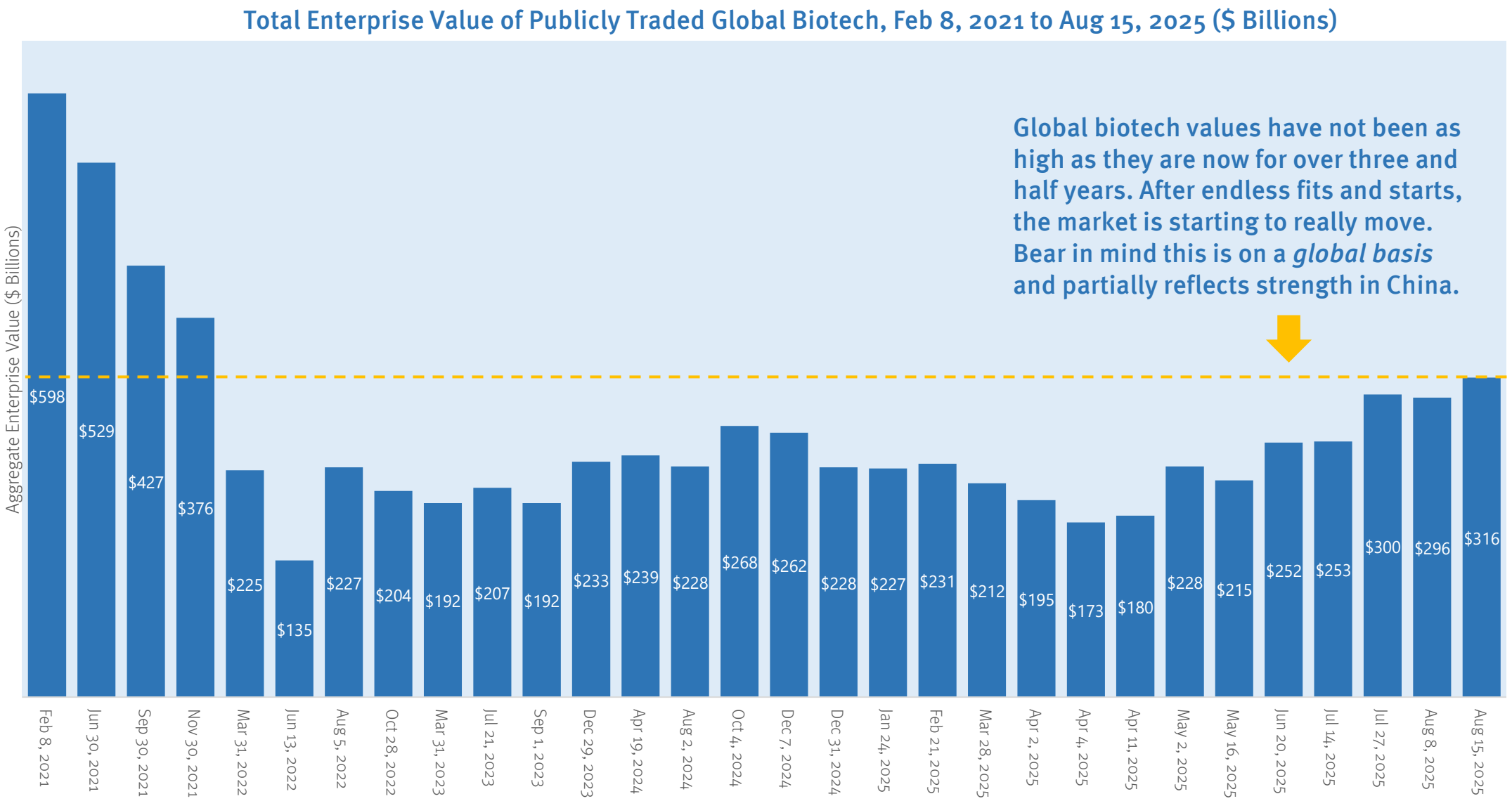


* Change by enterprise value. The adjusted number accounts for the effect of exits and additions via M&A, bankruptcies and IPOs. The annual change by market cap is even higher.

Source: S&P Capital IQ and Stifel analysis

Total Global Biotech Sector Rose 6.7% Last Week

Biotech stocks are up 83% since hitting a low point on Apr 8, 2025. Biotech stocks ended last week up 39% for the year.

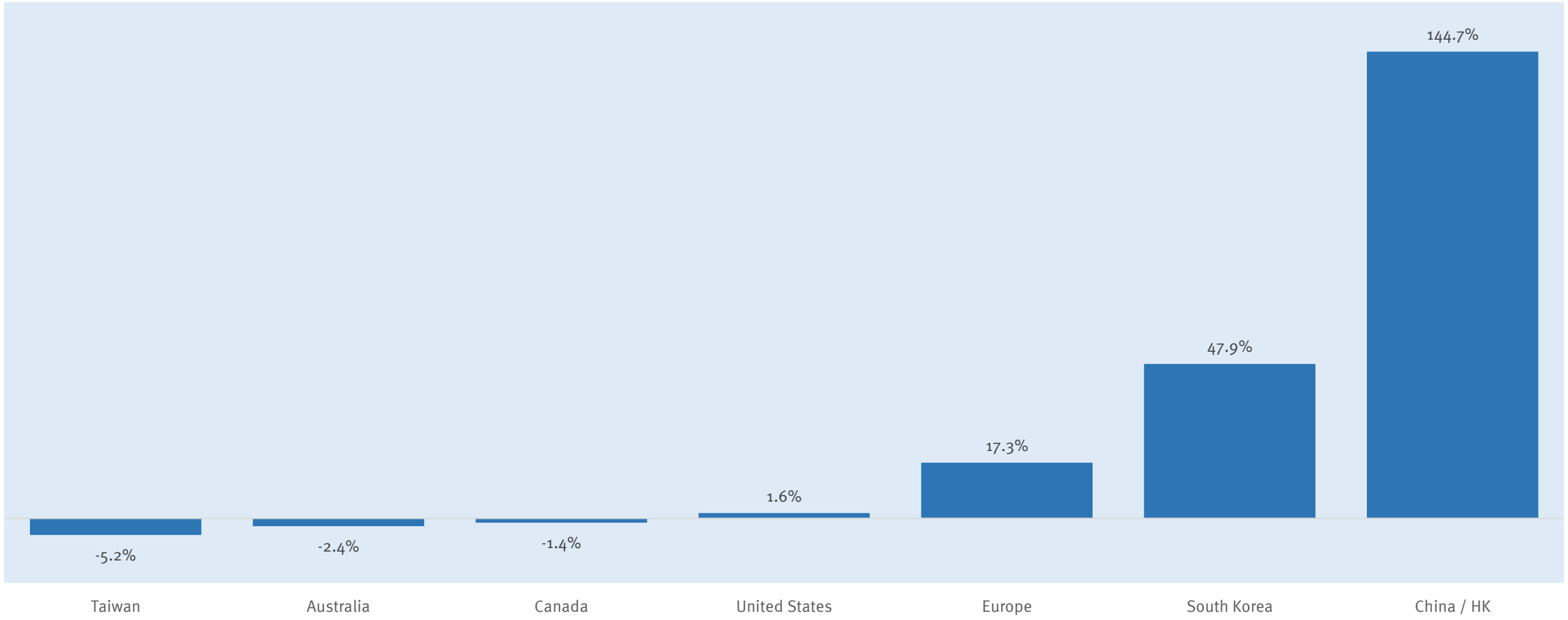


Source: CapitalIQ. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange.

China Biotech Has Done Extremely Well This Year

China biotech is up 145% this year. South Korea and Europe are up while the U.S. remains flat. However, it's important to recall that the U.S. biotech sector was down more than 30% just four months ago.

Percent Change in Total Market Cap of Public Biotech by Country/Region, Dec 31, 2024 to Aug 15, 2025

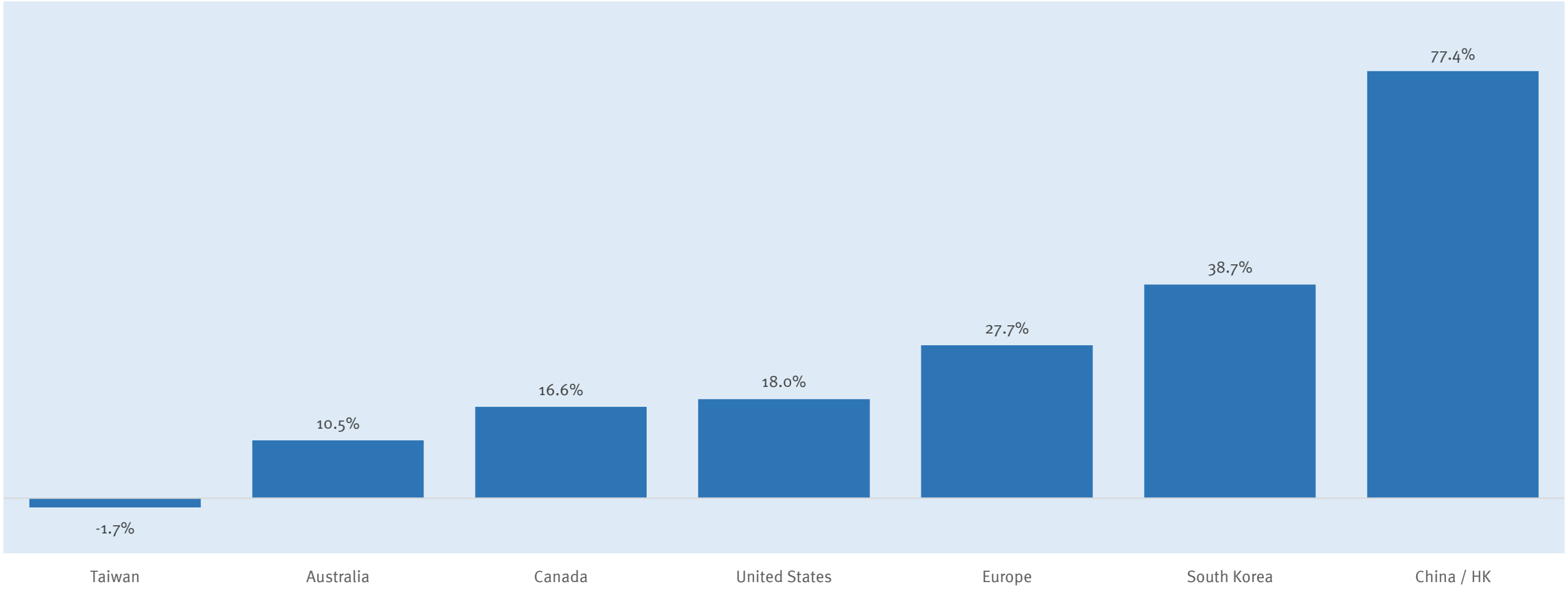


Source: CapitalIQ and Stifel analysis. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange. Europe biotech includes companies from all major EU countries.

China Biotech Has Done Best Since “Liberation Day”

The China biotech sector has had stellar performance since early April. U.S. biotech has recovered from sharp losses and is now up 18% since that time. Europe is up 28% and South Korea is up 39%.

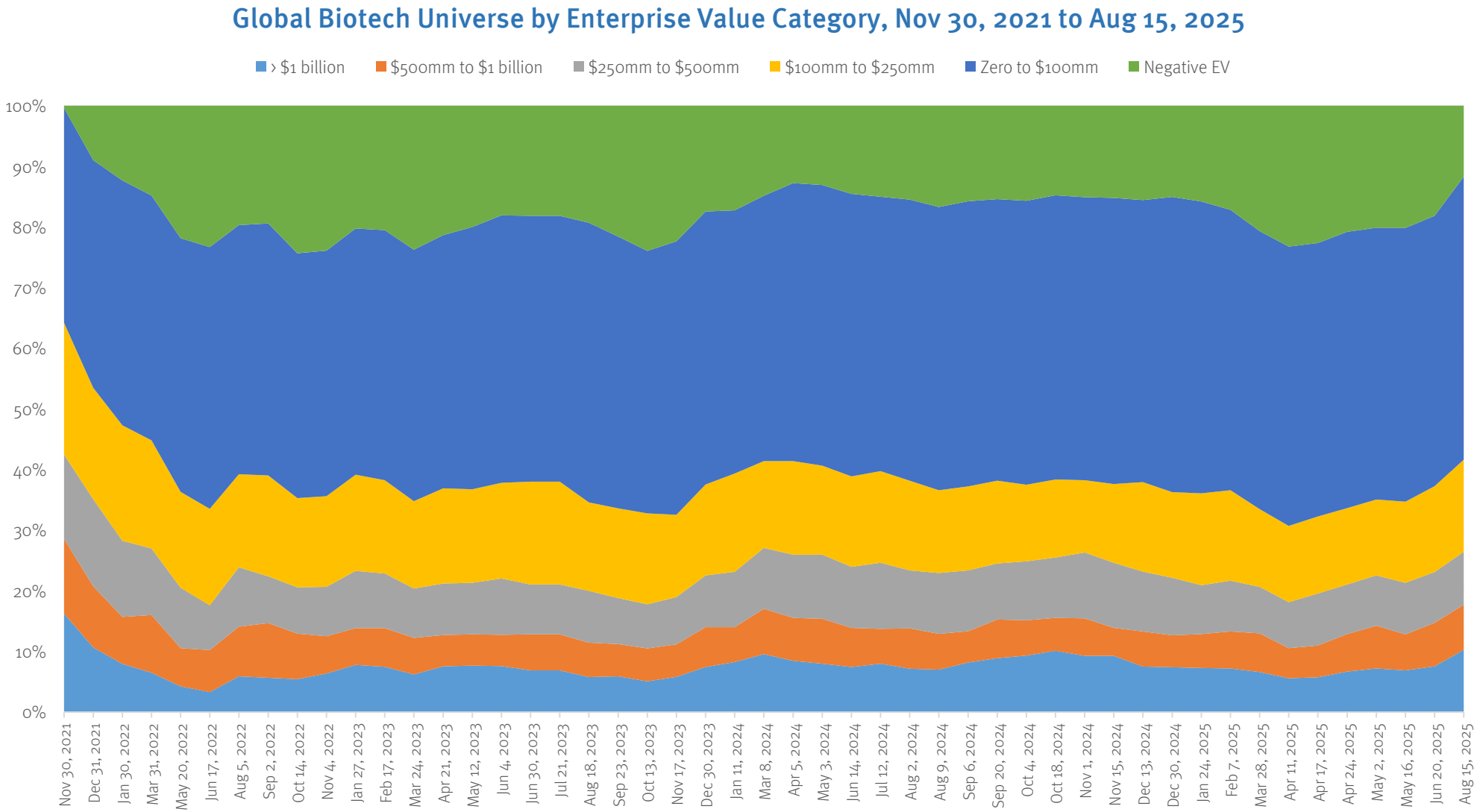
Percent Change in Total Market Cap of Public Biotech by Country/Region, Apr 3, 2024 to Aug 15, 2025



Source: CapitalIQ and Stifel analysis. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange. Europe biotech includes companies from all major EU countries.

The “Good Neighborhood” in Biotech is Growing Fast

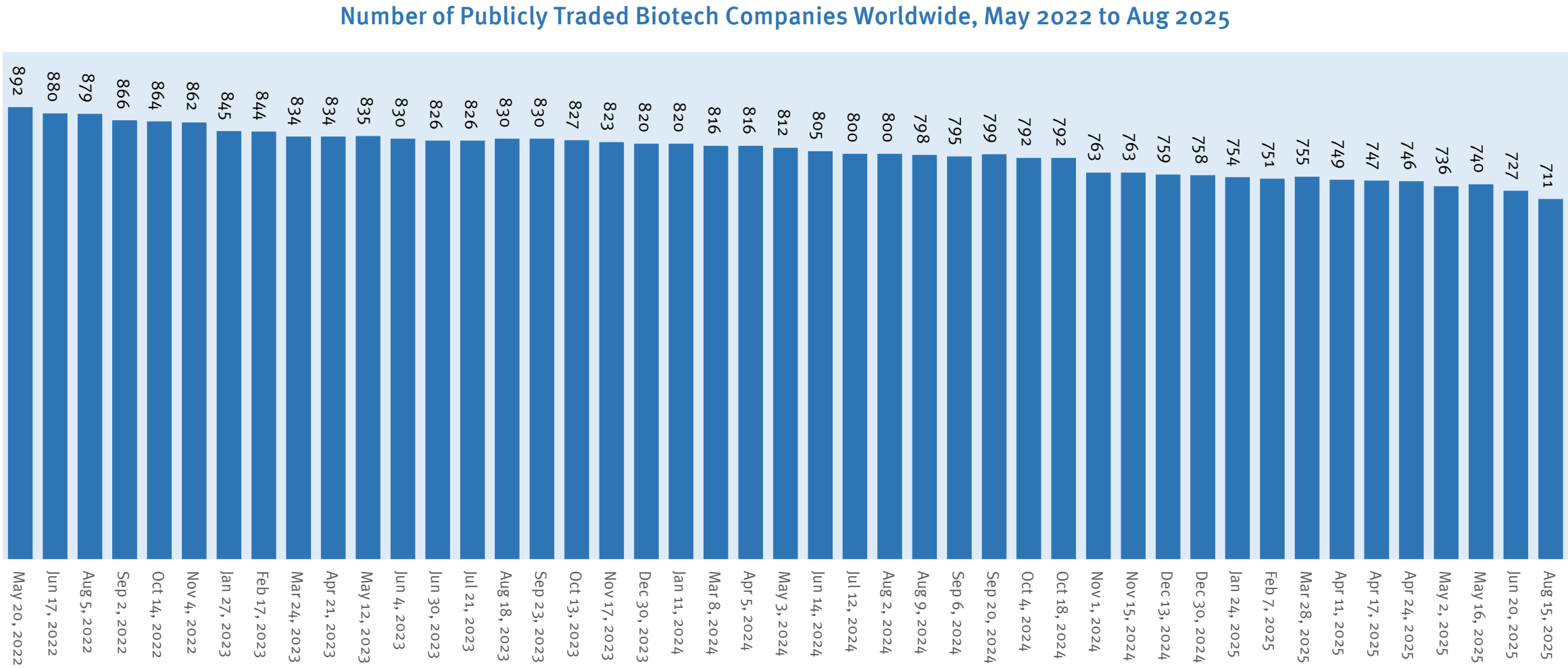
We have seen huge shrinkage in the negative EV population in the last month.



As of last Friday, 41% of biotechs had an EV over $100mm. Compare this to 31% in April.

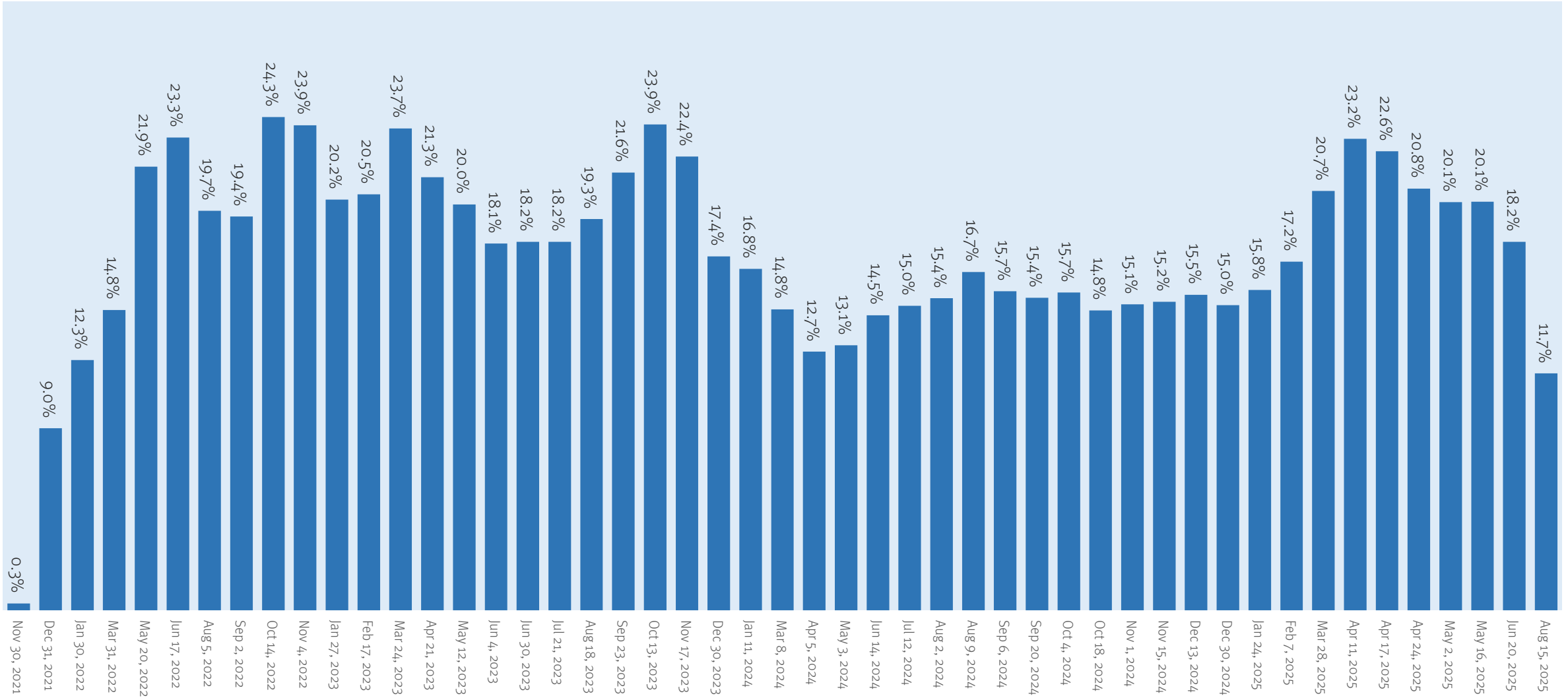
Source: CapitalIQ and Stifel analysis. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange.

Public Biotech Population Has Dropped Over 20% In Last 40 Months



Negative EV Biotech Population is Plummeting

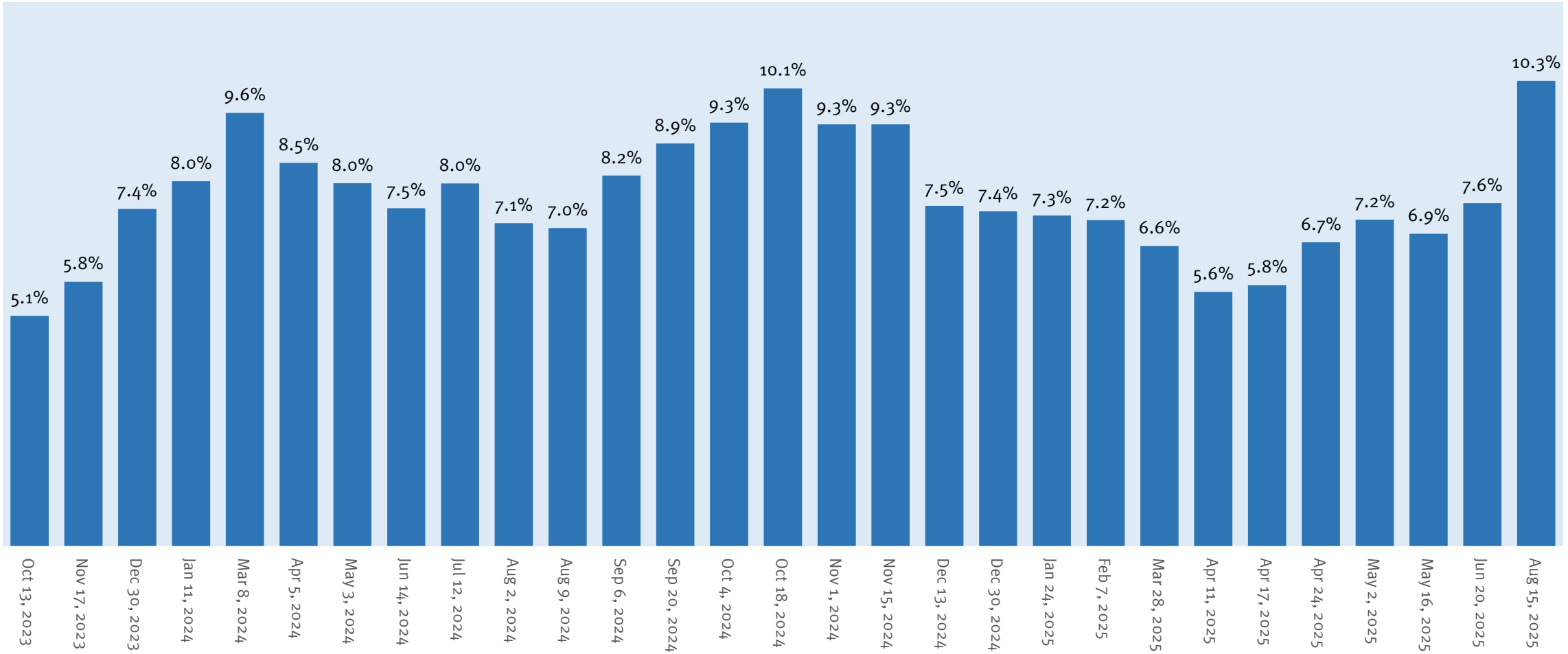
Percent of Global Biotechs with Negative Enterprise Value, Nov 2021 to Aug 2025



Source: CapitalIQ. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange.

Billion Dollar Biotech Population Has Jumped Big

Percent of Biotechs with an Enterprise Value of $1bn or More



Source: CapitalIQ. Biotechs are defined as any therapeutics company without an approved product on any global stock exchange.

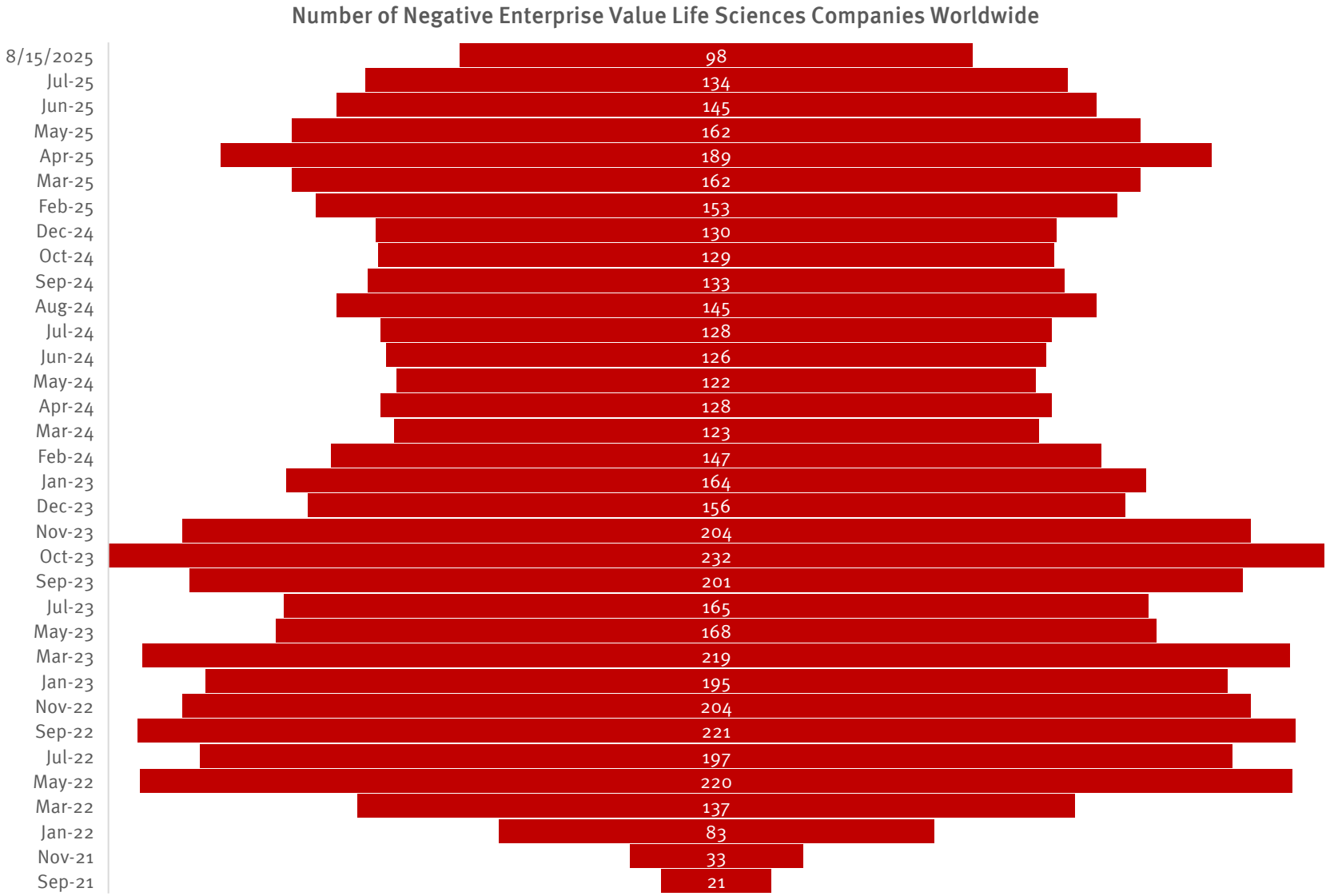
Life Sciences Sector Up Big Last Week

The life sciences sector is worth $9.8 trillion and jumped in value by 3.5% last week. The commercial pharma sector was a huge dollar gainer. Other high performing subsectors included biotech, HCIT, pharma services and life science tools.

Sector	Firm Count	Enterprise Value (Aug 15, 2025, $millions)	Change in Last Week (percent)	Change in Last Month (percent)	Change in Last Year (percent)
API	79	$99,510	2.2%	-0.2%	15.4%
Biotech	691	$313,778	6.7%	10.1%	-5.1%
CDMO	36	$164,470	2.0%	0.3%	16.5%
Diagnostics	74	$280,305	2.6%	6.5%	8.7%
OTC	29	$23,537	0.3%	-3.0%	-12.1%
Commercial Pharma	687	$6,312,909	4.0%	2.3%	-7.2%
Pharma Services	38	$192,239	4.8%	17.5%	6.5%
Life Science Tools	48	$590,738	4.8%	8.9%	-17.8%
Devices	170	$1,819,642	1.3%	1.7%	6.1%
HCIT	7	$26,674	6.6%	7.6%	40.0%
Total	**1859**	**$9,823,801**	**3.5%**	**3.1%**	**-3.6%**

Source: CapitalIQ and Stifel analysis

Number of Negative Enterprise Value Life Sciences Companies Fell Big in the Last Month



The count of negative EV life sciences companies worldwide fell from 134 a month ago to 98 last Friday.

This is similar to the level in February 2022.

While negative EV companies are not yet an endangered species, they are becoming far less common in the life sciences sector. The combination of better results, dissolutions, continued takeouts of these companies by the likes of Concentra and Xoma, and crypto conversions has helped to cut the population of negative EV companies by 45% in just four months.

It's been quite a long time but the evidence that the biotech sector is normalizing is growing ever stronger.

Source: CapitalIQ

The Biotech Crypto Pivot

The “Crypto Pivot” Gains Traction as Biotechs Head for Exits

As we looked at exits from the public biotech population, we noted this month that a number of companies are pivoting in part or in whole to cryptocurrency strategies.

This move reflects the financial pressures facing biotechs and the apparent market opportunity in cryptocurrency investing.

By adopting a crypto treasury model—whether through direct Bitcoin holdings, Ethereum staking, or token-based reserves—biotechs position themselves as publicly listed vehicles for investors seeking exposure to digital assets.

In doing so, they tap into new pools of capital, attract speculative trading interest, and, in some cases, attempt to replicate the MicroStrategy model of using a public listing to provide crypto access without requiring shareholders to directly hold tokens.

The benefits of this approach are tied to diversification, investor appeal and potential financial upside. Companies can hedge against inflation or fiat depreciation by holding Bitcoin or other major tokens, while staking models (Ethereum, Solana) generate recurring yield. For struggling firms, a crypto pivot can dramatically boost liquidity and share price by capturing retail and institutional investor enthusiasm for digital assets.

However, the risks are equally significant: crypto volatility can erode balance sheets, regulatory scrutiny remains high, and companies risk diluting their original strategic identity. In industries like biotech, this can lead to a loss of credibility with scientific stakeholders, potential operational underfunding, and the perception of abandoning core innovation in favor of financial speculation.

BIOTECH & PHARMA PIVOTING INTO CRYPTO

EYENOVIA — Investing $50M of PIPE proceeds in cryptocurrency HYPE tokens

LIXTE — Allowing up to 25% of treasury to be allocated to cryptocurrencies

silo PHARMA — Implementing crypto treasury strategy, plans to purchase BTC, ETH, SOL

atai — Allocating $5M to Bitcoin as part of treasury reserves

Case Study: Eyenovia Pivots into Buying a Cryptocurrency Called HYPE

EYENOVIA ANNOUNCES $50 MILLION INVESTMENT TO LAUNCH A HYPERLIQUID (HYPE TOKEN) CRYPTOCURRENCY TREASURY RESERVE STRATEGY

Announces private placement
EYEN to become first U.S.-based publicly listed company to hold HYPE in its treasury
Hyunsu Jung appointed Chief Investment Officer and Board Member

LAGUNA HILLS, Calif., June 17, 2025 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN) ("Eyenovia" or the "Company") today announced that it has entered into a securities purchase agreement (the "SPA") for a $50 million private placement in public equity (the "PIPE Financing") with institutional accredited investors. The Company will use the funds to build a reserve of a token called HYPE, which is native to the decentralized digital asset exchange and Layer-1 blockchain, Hyperliquid. The Company expects to receive aggregate gross proceeds of approximately $50 million, before deducting offering expenses. In connection with the transaction, the Company is also announcing today that it has appointed Hyunsu Jung as its Chief Investment Officer and as a Board member.
Pursuant to the terms and conditions of the SPA, the Company will issue non-voting convertible preferred stock convertible into approximately 15.4 million shares of the Company's common stock at a conversion price of $3.25 per share, and warrants to purchase approximately 30.8 million shares of the Company's common stock, at an exercise price of $3.25 per share. The conversion of the preferred stock and the exercise of the warrants are subject to beneficial ownership limitations set by the investors. The transaction is expected to generate aggregate gross proceeds of approximately $150 million if the warrants are exercised in full, as to which no assurance can be given.

"We are pleased to join the growing number of companies who have adopted similar strategies for the diversification, liquidity and long-term capital appreciation potential that cryptocurrency represents," stated Michael Rowe, Chief Executive Officer of Eyenovia. "Following a thorough review of all available alternatives, the Board and I have concluded that this transaction is in the best interests of our shareholders."

Source: https://ir.eyenovia.com/news-releases/news-release-details/eyenovia-announces-50-million-investment-launch-hyperliquid-hype

Eyenovia Renames Itself

EYENOVIA ANNOUNCES REBRANDING AND CORPORATE NAME CHANGE TO HYPERION DEFI, INC.

Company to commence trading on Nasdaq under the symbol "HYPD" effective July 3rd
Also announces official launch of the Kinetiq x Hyperion validator

LAGUNA HILLS, Calif., July 02, 2025 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN) ("Eyenovia" or the "Company"), a pioneer in ophthalmic technologies and the first publicly-listed U.S. company to build a strategic treasury of HYPE, the native token of the Hyperliquid protocol, today announced that it is rebranding and changing its corporate name to Hyperion DeFi, Inc. Concurrent with the name change, the Company's shares will begin trading under the new ticker symbol "HYPD" on the Nasdaq Capital Market at the start of trading on July 3, 2025.

The name change reflects the Company's recent launch of its cryptocurrency treasury reserve strategy focused on the HYPE token, which is native to the decentralized digital asset exchange and Layer-1 blockchain, Hyperliquid.

"Our corporate name change to Hyperion DeFi, Inc. reflects our new vision for the company and represents the next important step in the evolution of our cryptocurrency treasury reserve strategy," stated Michael Rowe, Chief Executive Officer of Eyenovia/Hyperion DeFi, Inc. "Notably, 'Hyperion' refers to the tallest known living tree – a California Redwood – which reflects our belief that Hyperion DeFi has the potential to grow into the largest holder of the HYPE token globally and the largest cryptocurrency-based treasury overall. At the same time, 'DeFi' refers to the exploration of new technologies, which is applicable not only to this new treasury reserve strategy but to our continued development of the Optejet dispenser as well."

"As reflected in the Keats poem of the same name which chronicles the defeat of the Titans at the hands of the Olympians, 'Hyperion' evokes themes of changing order," added Hyunsu Jung, Chief Investment Officer. "In this case, the emergence of blockchain technology challenges not only existing financial infrastructure but also centralized cryptocurrency exchanges. We believe that we are uniquely positioned to be a pioneer in the growing acceptance of digital currencies as a treasury asset, and I look forward to making that vision of Hyperion DeFi a reality."

Source: https://ir.eyenovia.com/news-releases/news-release-details/eyenovia-announces-rebranding-and-corporate-name-change-hyperion

180 Life Sciences Shifts to Crypto

180 Life Sciences Announce an Upsized $425 Million Private Placement to Establish an Ether Treasury Reserve Led by Consortium of Digital Asset Leaders to Launch ETHZilla

PALO ALTO, Calif., July 29, 2025 /PRNewswire/ -- 180 Life Sciences Corp. (Nasdaq: ATNF) (the "Company" or "180 Life Sciences") today announced that it plans to adopt a treasury policy under which the principal holding in its treasury reserve will be Ether ("ETH"), the native digital asset of Ethereum. Following the closing of the transaction, the Company intends to rebrand to ETHZilla Corporation.

The offering consists of an approximately $425 million private investment in public equity transaction ("PIPE") for the purchase and sale of common stock (and pre-funded warrants, if applicable) at a purchase price of $2.65 per share. The investors will be granted registration rights as part of the transaction. The PIPE transaction is expected to close on or around August 1, 2025, subject to the satisfaction of customary closing conditions. In addition, the Company has approval to sell an aggregate amount of up to $150 million in debt securities and expects to announce an offering following the closing of the PIPE. The consummation of any subsequent offering is subject to the satisfaction and completion of definitive documentation.

Upon closing, the Company intends to use the net proceeds from the offering primarily for the purchase of ETH, as well as general corporate purposes and transaction expenses. The Company's current management team and a majority of the Company's directors will remain in place.

Over 60 institutional and crypto-native investors in the PIPE transaction including Harbour Island, Electric Capital, Polychain Capital, GSR, Omicron Technologies, Konstantin Lomashuk (Co-Founder Lido and p2p.org), Sreeram Kannan (Founder, Eigenlayer), Mike Silagadze (Founder, Ether.fi), Danny Ryan (Co-Founder, Etherealize), Vivek Raman (Co-Founder, Etherealize), Sam Kazemanian (Co-Founder, Frax), Grant Hummer (Co-Founder of Etherealize), Robert Leshner (Founder, Compound and Superstate), Tarun Chitra (Founder, Gauntlet) and several other prominent Ethereum ecosystem founders and leaders.

Source: https://ir.180lifesciences.com/news-events/press-releases/detail/108/180-life-sciences-announce-an-upsized-425-million-private

180 Life Sciences Takes Off After Announcing it Holds $350 million of Ethereum

Brian Swint, *Barrons*, Aug 13, 2025 (excerpt)

A small-cap biotech start-up has skyrocketed in value this week, and it isn't because of a breakthrough in dietary supplements and food ingredients. Rather, it's a shift to cryptocurrencies that's driving the rally.

180 Life Sciences Corp., which is backed by venture capitalist Peter Thiel, surged 44% to $14.78 when the market opened Wednesday. That comes on top of a 207% gain on Tuesday, more than a tripling in value. It's up 432% for the week.

The company announced yesterday that it now holds almost $350 million in Ethereum, the second-biggest cryptocurrency after Bitcoin, and another $240 million in cash. It will rebrand itself as ETHZilla, a play on Ethereum's stock market ticker of ETH. It says on its website that digital token will become key for the global financial system, and the company will aim to increase its Ethereum holdings per share over time by strategically deploying its holdings.

Source: https://www.barrons.com/articles/crypto-stock-ethereum-180-life-sciences-thiel-dbd04049

Summary of Cryptocurrency Strategies Undertaken by Selected Biotech Companies

Strategy	#1 Full Pivot to be a Crypto Investment Company	#2 Invest Some of the Cash in Crypto (and raise more cash to invest)	#3 Say You are Evaluating a Crypto Strategy	#4 Reverse Merge into a crypto company
Core Activity	Direct acquisition and holding of Bitcoin as a treasury asset	Acquire and stake Bitcoin, XRP, Solana or Ethereum to earn yield	Tell investors you are thinking of buying some cryptocurrency.	Merge with private crypto-focused company
Primary Goal	Provide investors public BTC exposure while hedging against inflation	Generate staking rewards; potential price appreciation; public vehicle for other holdings of crypto	Change business plan to enjoy upside of crypto investment.	Provide crypto firms public access; expand market cap and shareholder value
Value Generation Approach	Bitcoin price appreciation; hedging via options/futures	Yield from price appreciation	Yield from price appreciation	Potential returns from merged company's operations
Impact to Existing Business	Legacy business operations phased out as company shifts to a crypto focus	Legacy operations remain	Legacy operations remain while company explores its ability to finance a crypto strategy	Operating business often phased out; new strategy dominates
Post-Deal Resources Required	Crypto purchasing & custody partner; optional expert consultants	Network expert consultants or FTEs; technical expertise for staking required	Network expert consultants or FTEs; technical expertise for staking required	Integration depends on merger target
Risk Factors	Price volatility of Bitcoin/Ethereum/XRP; regulatory uncertainty	Price volatility; slashing/lock-up risks; network security	Price volatility; slashing/lock-up risks; network security	Risks depend on merged entity success; potential dilution
Companies that Have Done This (not biotech)	DeFi Development, Metaplanet	Know Labs, Semler Scientific, Sharplink Gaming, Upexi, Vivo Power	Know Labs, Semler Scientific, Sharplink Gaming, Upexi, Vivo Power	Nakamoto/KindlyMD (Nasdaq: KDLY)
Biotechs that Have Done This	180 Life Sciences, EyeNovia	Atai Life Sciences	Liminatus Pharma, Processa Pharmaceuticals	Strive Asset Management (Ticker: ASST)

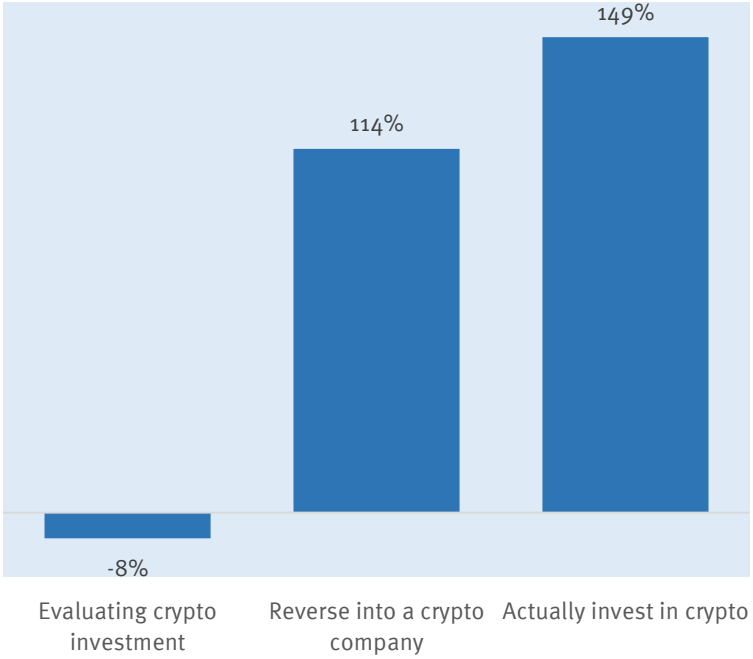
Various Crypto Strategies Are Having Radically Different Value Consequences

These data show that investors are impressed when companies actually shift from biotech into crypto. Returns are quite high (at least for now) when companies make this transition. In contrast, saying that you are *thinking about it is* associated with negative returns. In this market, talk is cheap.

	Announcement Date	Ticker	Firm	Stock Return (one day before announcement to Aug 15)	Strategy
Evaluation	7/25/2025	LIMN	Liminatus Pharma	-64%	Evaluating a crypto treasury strategy
	8/7/2025	PCSA	Processa Pharma	-5%	Evaluating a crypto treasury strategy
	8/5/2025	SILO	Silo Pharma	-8%	Evaluating a crypto treasury strategy
Invest	7/29/2025	ATNF	180 Life Sciences	149%	Raises $425mm to rebrand as ETHzilla
	3/20/2025	ATAI	ATAI Life Sciences	179%	To invest $5mm into crypto
	6/17/2025	EYEN	Eyenovia	142%	Raises $50 to invest in crypto
Merge	4/25/2025	COEP	Coeptis	114%	Reversing into a crypto company

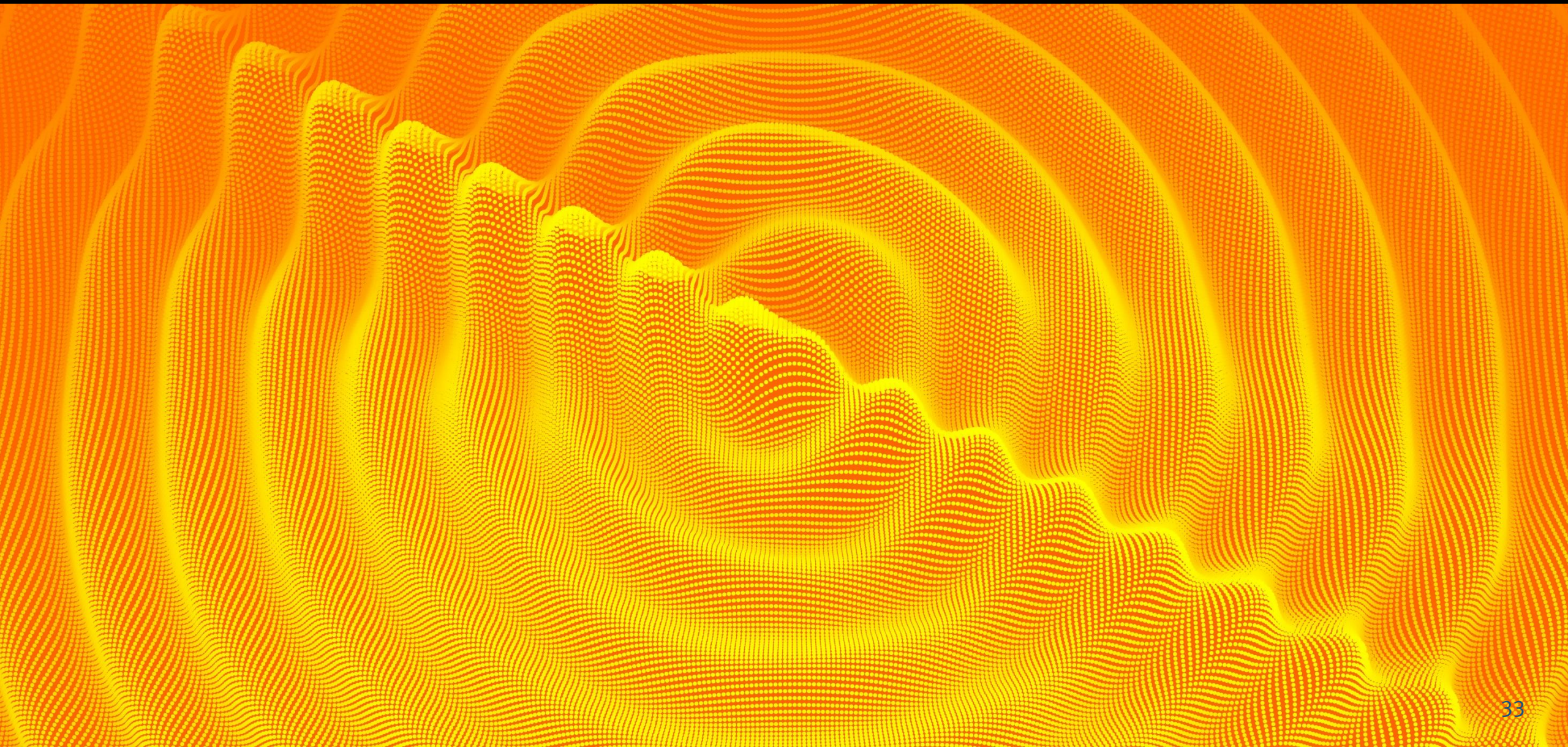
Median Return Associated with Various Biotech Crypto Strategies

(Day Before Announcement to Aug 15, 2025)

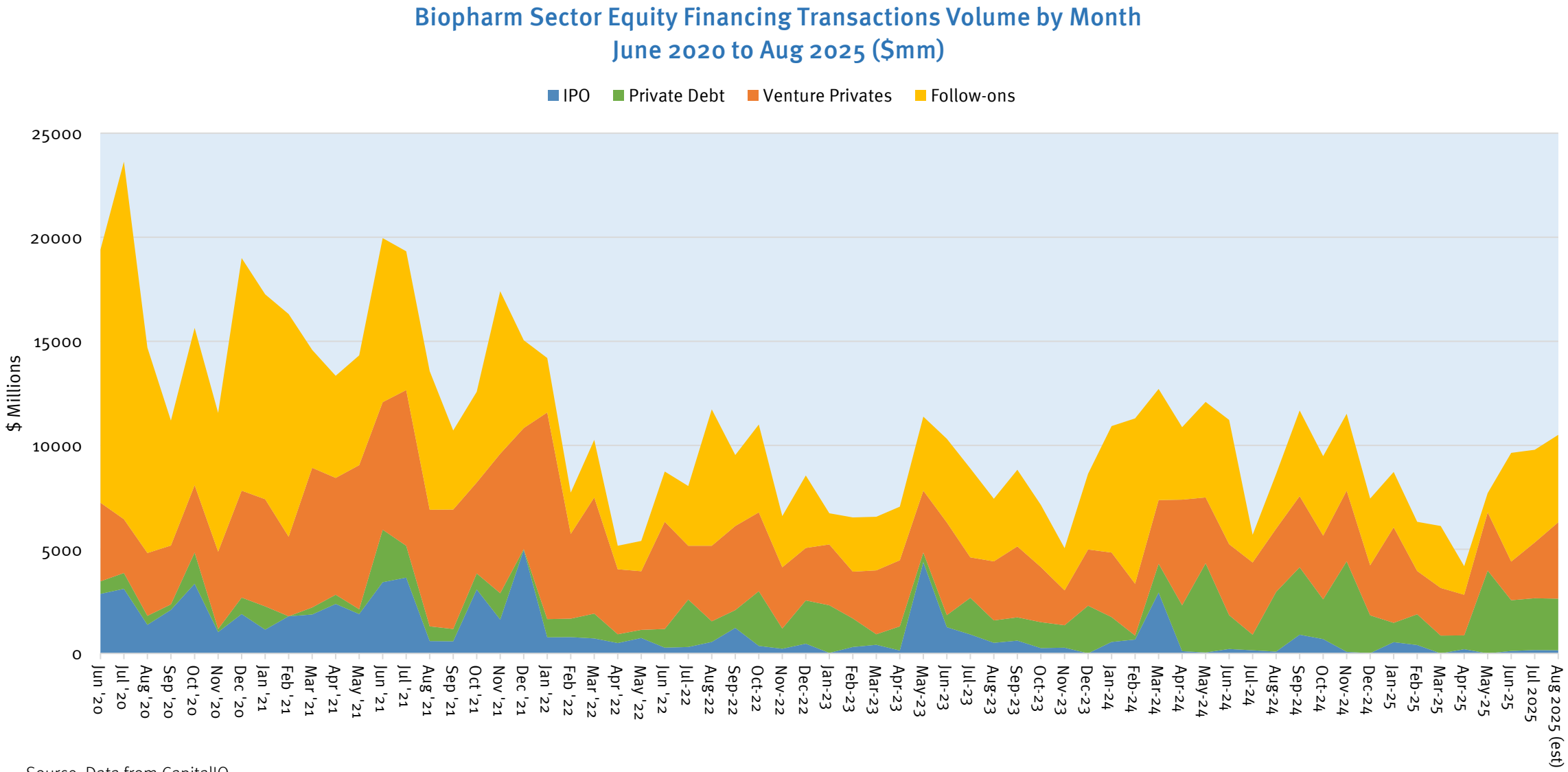


Source: CapitalIQ and Stifel analysis.

Capital Markets Update



Monthly Financing Volumes Continue to Pick Up



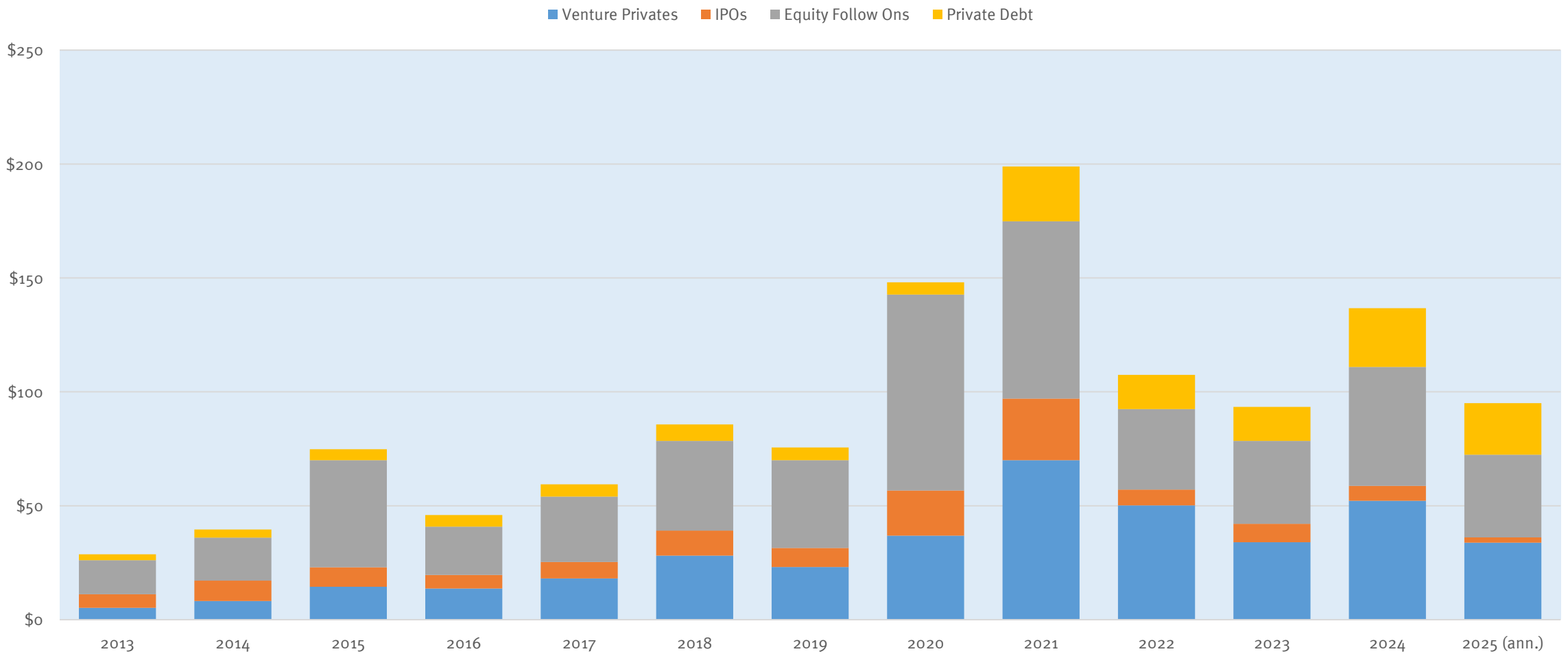
Source: Data from CapitalIQ.

Capital Raising Pace in 2025 Now Ahead of 2023

The rapid pace of financings of the last six weeks has pushed up our estimates of total financing volume for 2025 to be above the levels of 2023.

Equity Raised, Private Debt Raised in the Biopharma Sector, 2013 - 2025

(Extrapolated Total for 2025, $ Billions, Worldwide)



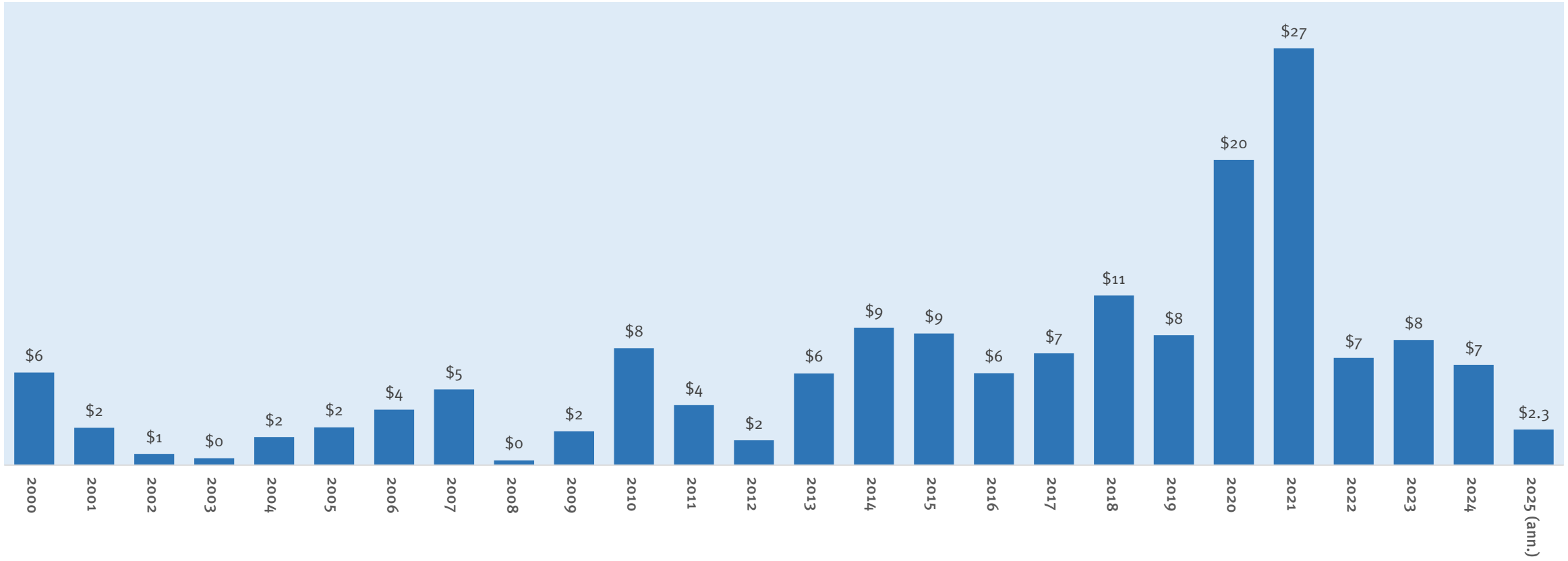
Source: Data from CapitalIQ.

IPO Market Has Remained Quiet Through 2025

The last biotech company to go public on the NASDAQ was Aardvark which priced its deal on Feb 12th (more than six months ago). Since then fourteen biotech companies have gone public in other countries (mainly HK). We do think this changes in the rest of 2025 as we are starting to see the IPO calendar fill back in.

IPO Volume in the Biopharma Sector, 2000 - 2025 (annualized)

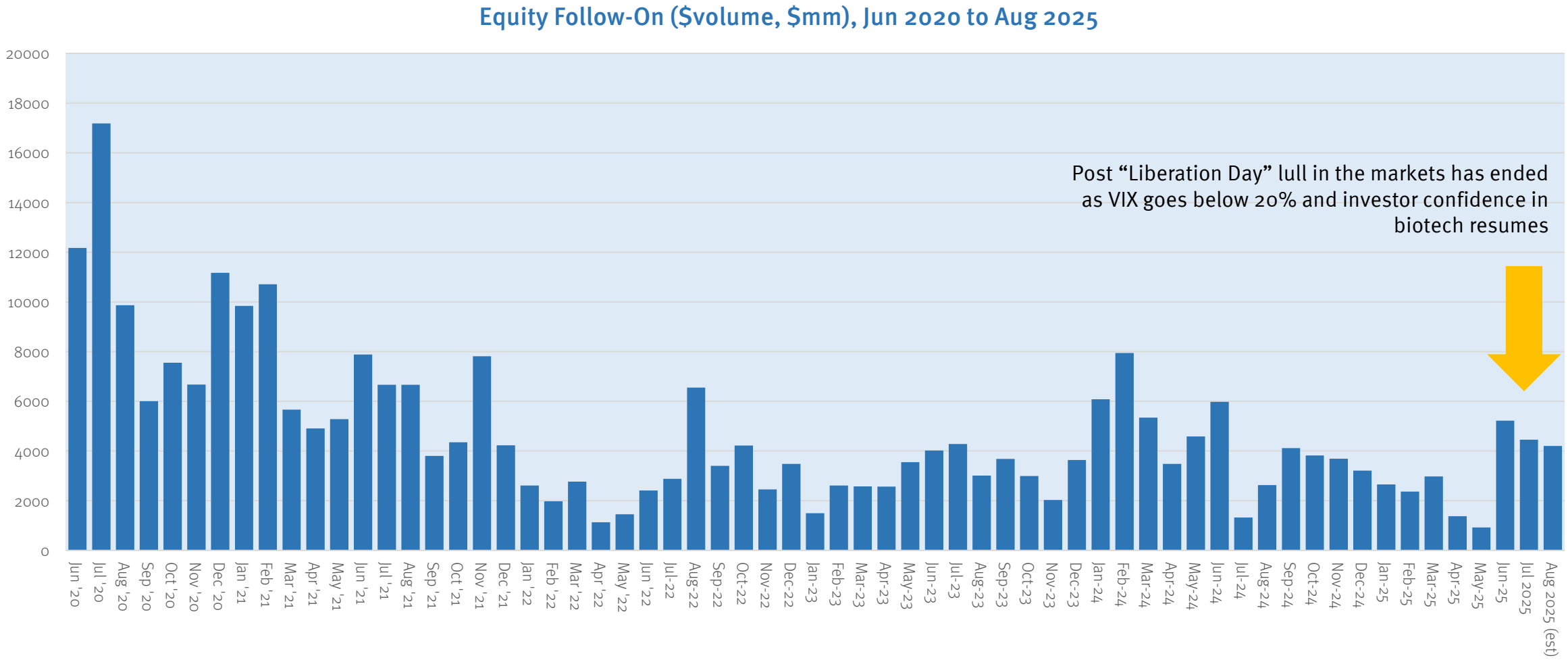
($ Billions, Worldwide)



Source: Data from CapitalIQ.

Global Follow-On Market Has Picked Up in the Last Six Weeks

The follow-on market has shown a substantial pickup in activity as the XBI has begun to rise and normalization has spread throughout the markets.

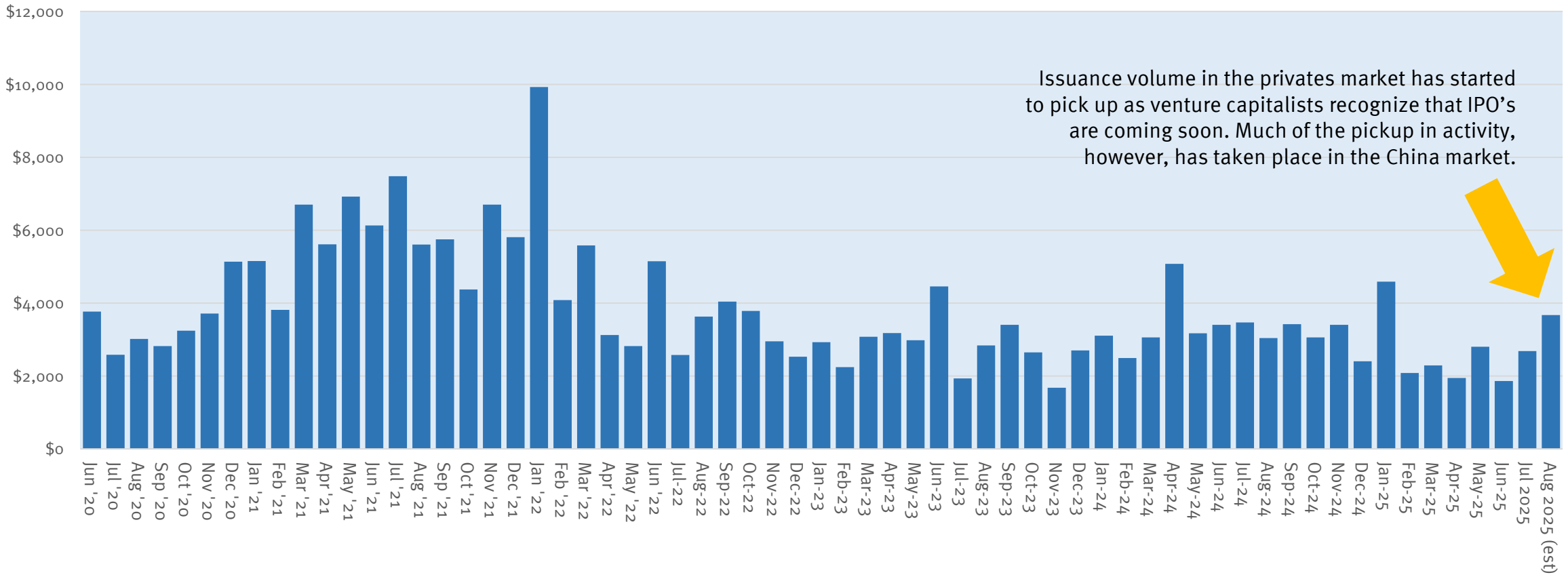


Source: Data from CapitalIQ, Crunchbase. Data for July 2025 is extrapolated based on results through July 11th.

Venture Equity Private Deal Pace Picking Up Nicely

The market for venture privates has picked up quite a bit this month despite the Summer holidays.

Monthly Private Equity Placement ($volume, $mm), Jun 2020 to August 2025



Source: Data from CapitalIQ, Crunchbase. Data for Aug 2025 is extrapolated based on results through August 15th.

Swedish Biotech Gets $46M to Run Early TCR Cell Therapy Clinical Trial

Lei Lei Wu, *Endpoints News*, August 18, 2025 (excerpt)

Anocca announced Monday that it secured a fresh SEK 440 million — or roughly $46 million — to run an early-stage trial of a cell therapy for KRAS mutant pancreatic cancer.

The Swedish biotech started enrolling its first clinical trial for a T cell receptor-based T cell therapy targeting KRAS mutations, which are known to drive cancer growth. More than 90% of pancreatic cancer cases have KRAS mutations.

Anocca CEO and co-founder Reagan Jarvis told *Endpoints News* that the new raise will keep the company operating through the end of next year, when it expects to complete the Phase 1 study. It is being conducted at sites in Sweden, Denmark, Germany and the Netherlands.

The first TCR-based cell therapy — Adaptimmune's Tecelra — was approved last year, marking one of the few approvals of a cell therapy to treat a solid tumor cancer. However, the company recently sold the therapy in a bid to save itself. Like Tecelra, which treats a rare soft tissue cancer, Anocca's cell therapy can only be used by patients if they have an HLA match, which refers to certain immune proteins that help the body determine what's foreign and what's not.

When asked about the financial struggles of the cell therapy sector, Jarvis acknowledged that it's been a tough market for a number of years. He said that Anocca primarily raised money this round from existing investors — which he described as "a very Nordic investor base" — though there were some new investors. Jarvis also said that he believed the data for T cell therapies were solid, but companies have to figure out how to make them at scale.

Source: https://endpoints.news/anocca-gets-46m-to-run-early-tcr-cell-therapy-clinical-trial/

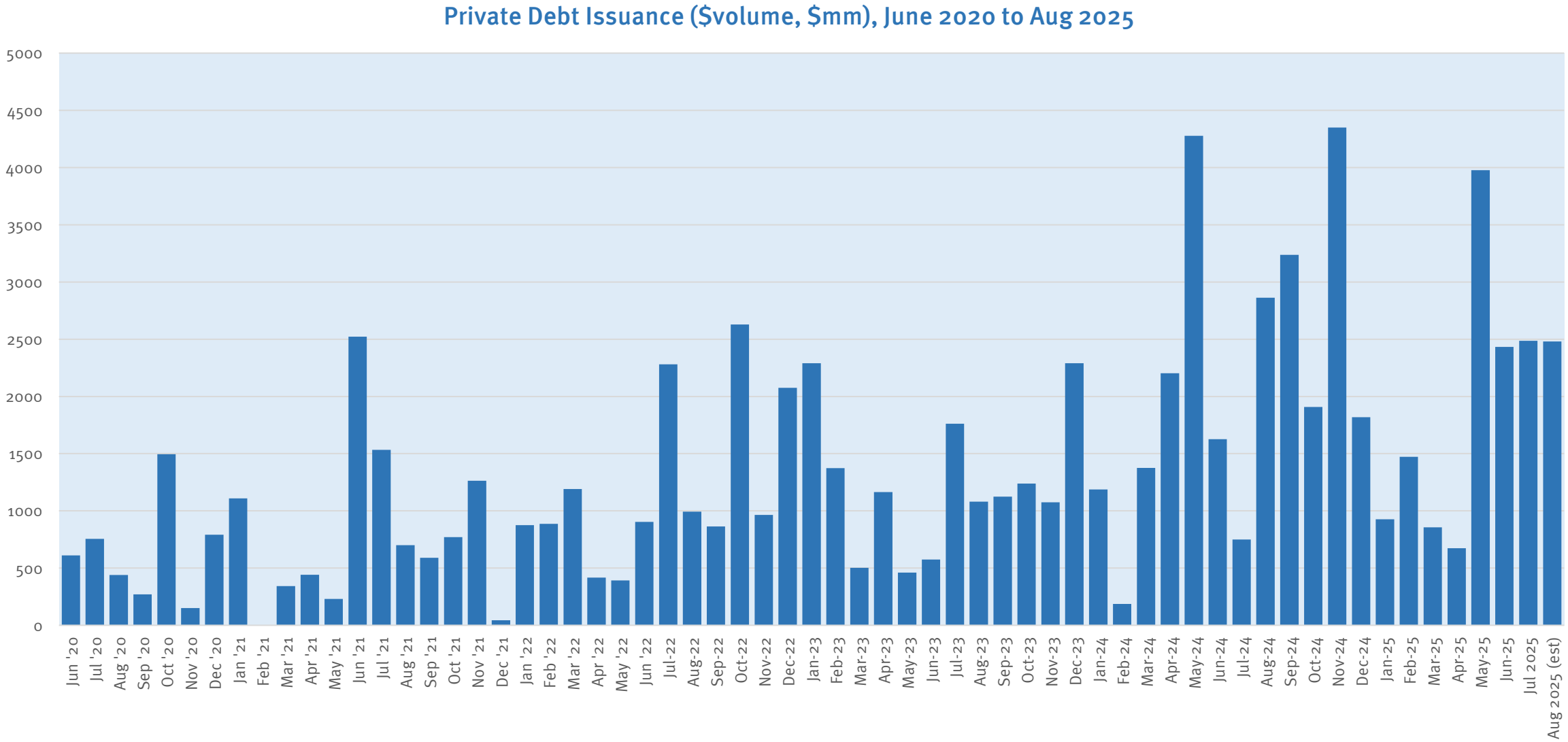
Reagan Jarvis
CEO
Anocca

Largest Private Venture Raises of the Last Five Weeks

Announcement Date	Issuer	Amount Raised ($ Millions)
07/24/2025	TCG Labs Soleil	$400.0
07/18/2025	MapLight Therapeutics, Inc.	$372.5
07/31/2025	Kriya Therapeutics, Inc.	$313.3
07/23/2025	Dispatch Bio	$216.0
08/03/2025	Strand Therapeutics	$153.0
07/29/2025	ArtBio GmbH	$132.0
08/07/2025	Minghui Pharmaceutical	$131.0
07/21/2025	Tongxin Medical Equipment	$100.0
07/22/2025	Avalyn Pharma	$100.0
07/30/2025	Chai Discovery, Inc.	$70.0
08/08/2025	Haichang Biotech	$69.6
08/05/2025	ARMR Sciences Inc.	$63.8
07/24/2025	Abiochem Biotechnology(Group) Co., Ltd.	$62.9
07/28/2025	Shanghai VelaVigo Pharamaceutical Co., Ltd.	$60.0
08/04/2025	Jitai Technology (Beijing) Co., Ltd.	$55.7
08/04/2025	METiS Pharmaceuticals	$55.7
08/05/2025	Baoling Bio	$52.9
07/16/2025	Quetzal Therapeutics	$50.0

Source: CapitalIQ, Crunchbase

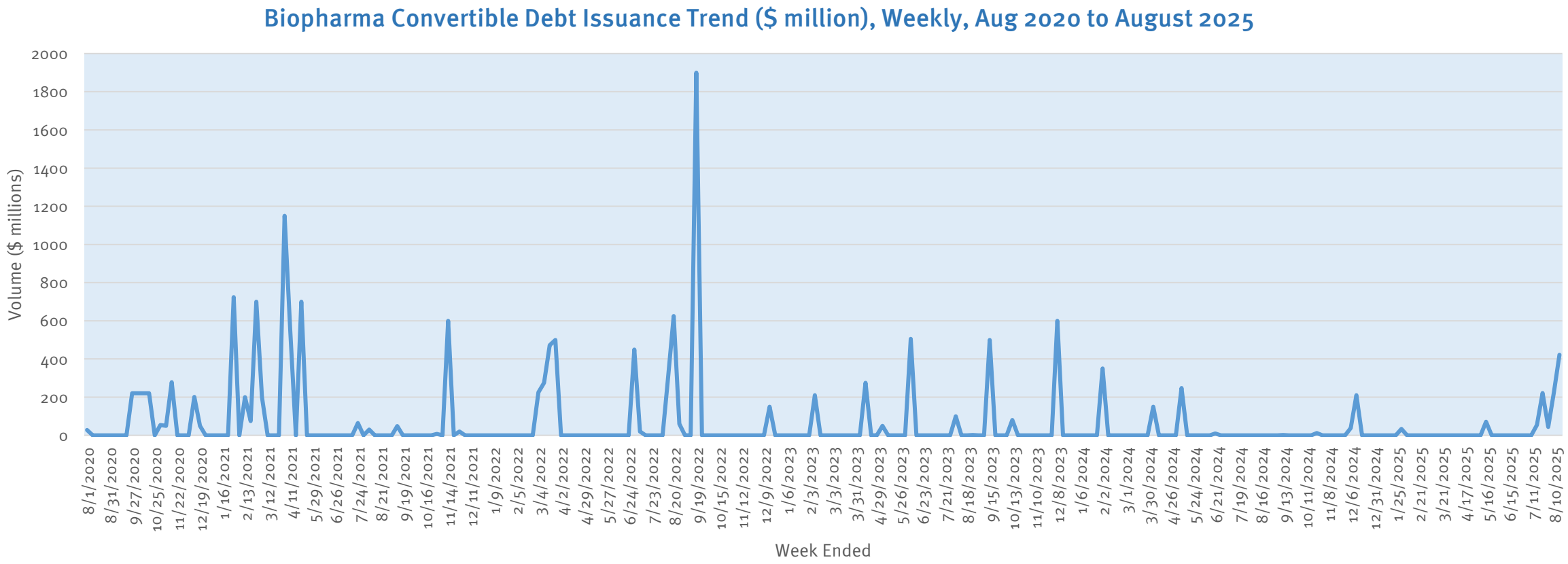
Biopharma Private Debt Placement Volume Continues to Surge



Source: Data from CapitalIQ, Crunchbase. Data for Aug 2025 is extrapolated based on results through Aug 15th.

Convertible Bond Issuance is Up Substantially

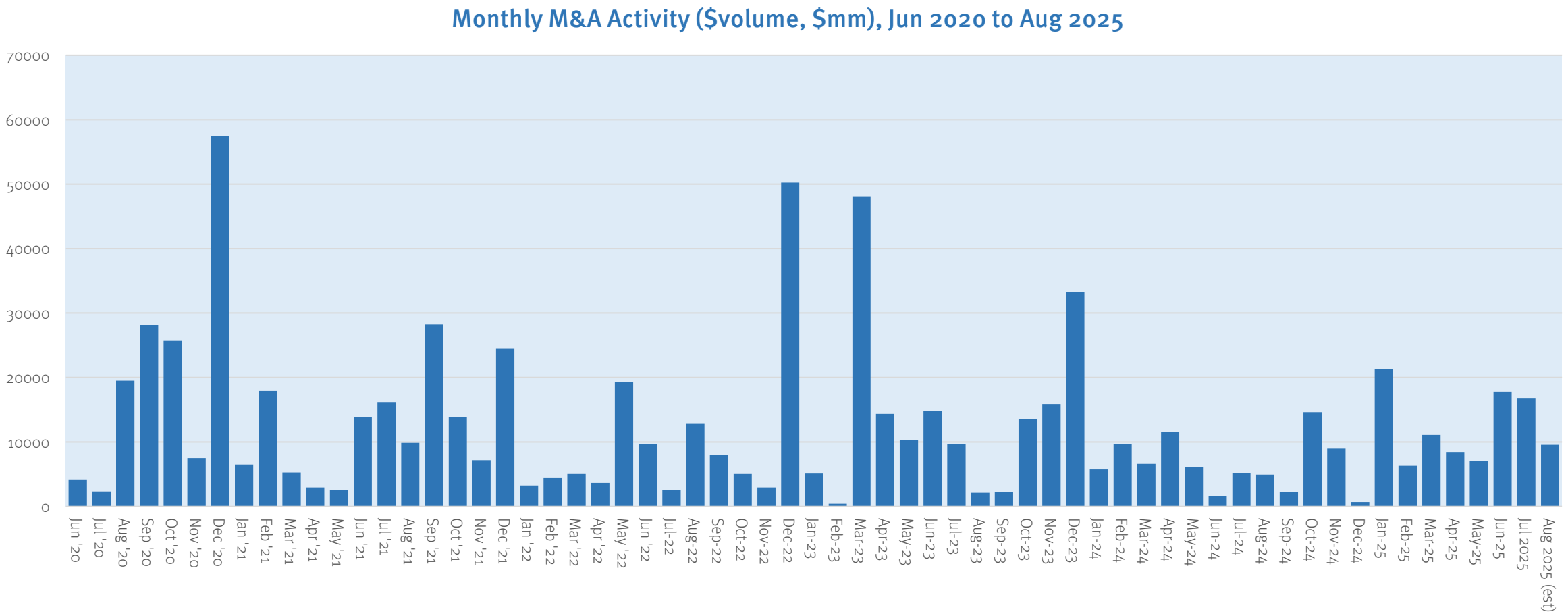
The first 28 weeks of this year saw $105 million of convertible bond issuance by biopharma companies. In contrast, we have seen $1bn in issuance in the last five weeks. Over 80% of this volume has been in the United States. Convertible bonds have become particularly attractive amid the current financing environment. With elevated interest rates making traditional debt expensive, issuers are turning to convertibles, which typically come with lower interest costs—often 3–4% compared to 7–9% for high-yield bonds. We are seeing heightened investor demand for these instruments in today's uncertain environment as well.



Source: Data from CapitalIQ, Crunchbase.

M&A Market Has Quieted Down in August

August has seen the biopharma M&A market take a bit of a breather after a very busy June and July. The largest deals this month have involved the takeouts of Y-Mabs by SERB ($401 million); the Cormedix acquisition of Melinta ($325 million, Aug 7); and the Xoma acquisition of Hillevax ($121.3 million, Aug 4). We continue to see considerably heightened M&A activity at mid-level and small sizes across the market. Most of the activity we are seeing remains late-stage or commercial-stage.



Source: S&P, CapitalIQ

Life-Sciences Investor Hatteras Venture Partners Raises Over $200 Million

Clay Thorp
General Partner
Hatteras Venture Partners

Brian Gormley, *Wall Street Journal*, August 13, 2025 (excerpt)

Hatteras Venture Partners has secured more than $200 million to finance healthcare startups, joining other experienced medical venture firms in closing new investment pools even as the fundraising market slows.

Durham, N.C.-based Hatteras raised $177 million for its seventh venture-capital fund and about $30 million for its first opportunity fund, which targets maturing companies across its portfolio of biotechnology, medical-technology and healthcare-technology companies.

Hatteras began fundraising in 2022 and closed the opportunity fund in 2024 and the venture fund in June, co-founder and General Partner Clay Thorp said. The new venture pool fell short of its $200 million goal but is the largest in Hatteras's 25-year history and tops the $137 million raised for the firm's sixth fund.

"In this environment, we feel fantastic about how we're positioned," Thorp said.

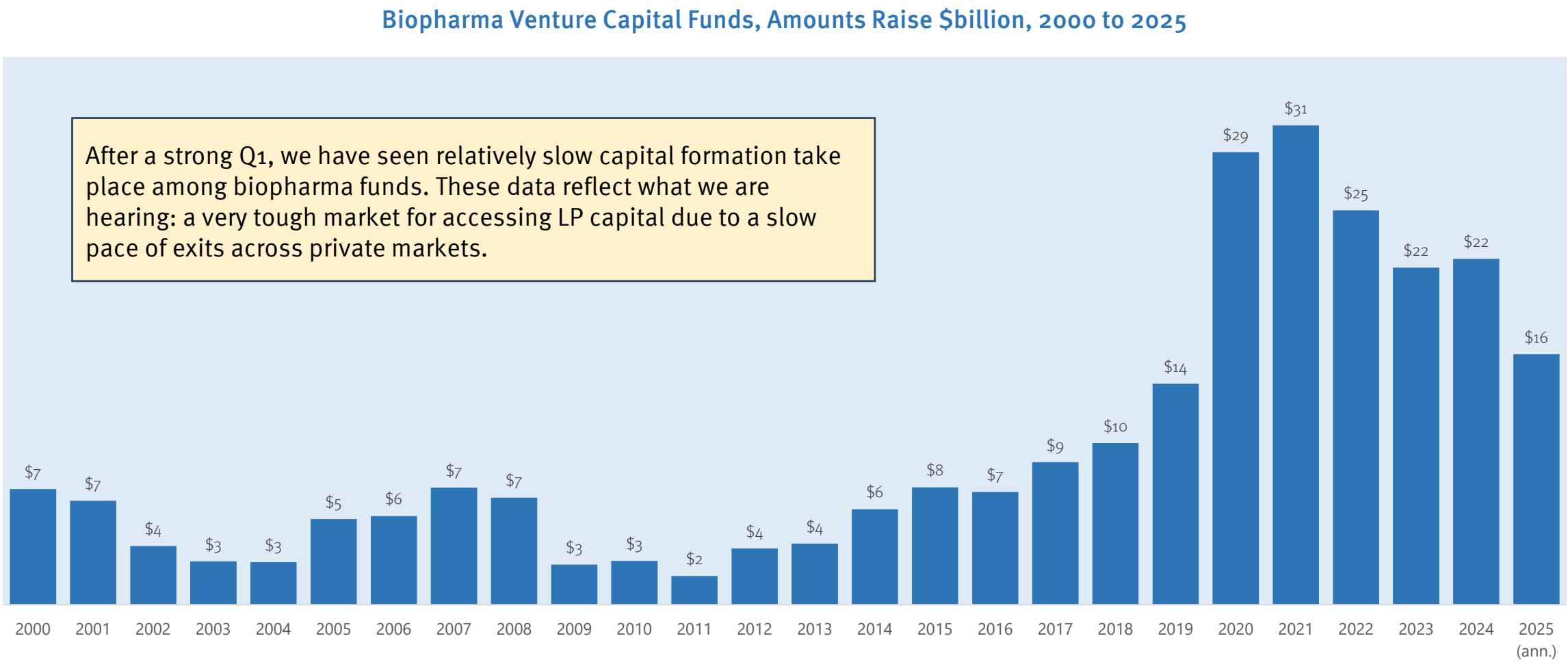
Biotech initial public offerings have stalled and many drugmakers that went public during the pandemic have sputtered. Some signs point up: top drug companies are buying and collaborating with small biotechs and some maturing healthtech and medtech companies have gone public recently.

Still, limited partners are favoring firms with long histories of success. In addition to Hatteras, other established firms closing funds recently include Frazier Life Sciences, Omega Funds and Catalio Capital Management.

Hatteras in 2009 co-led the Series A financing for HistoSonics, whose focused ultrasound therapy has since received regulatory clearance to treat liver tumors and shows potential in several other diseases. Hatteras sold a portion of its HistoSonics shares recently when an investor group acquired a majority stake, Thorp said. The deal valued HistoSonics at $2.25 billion.

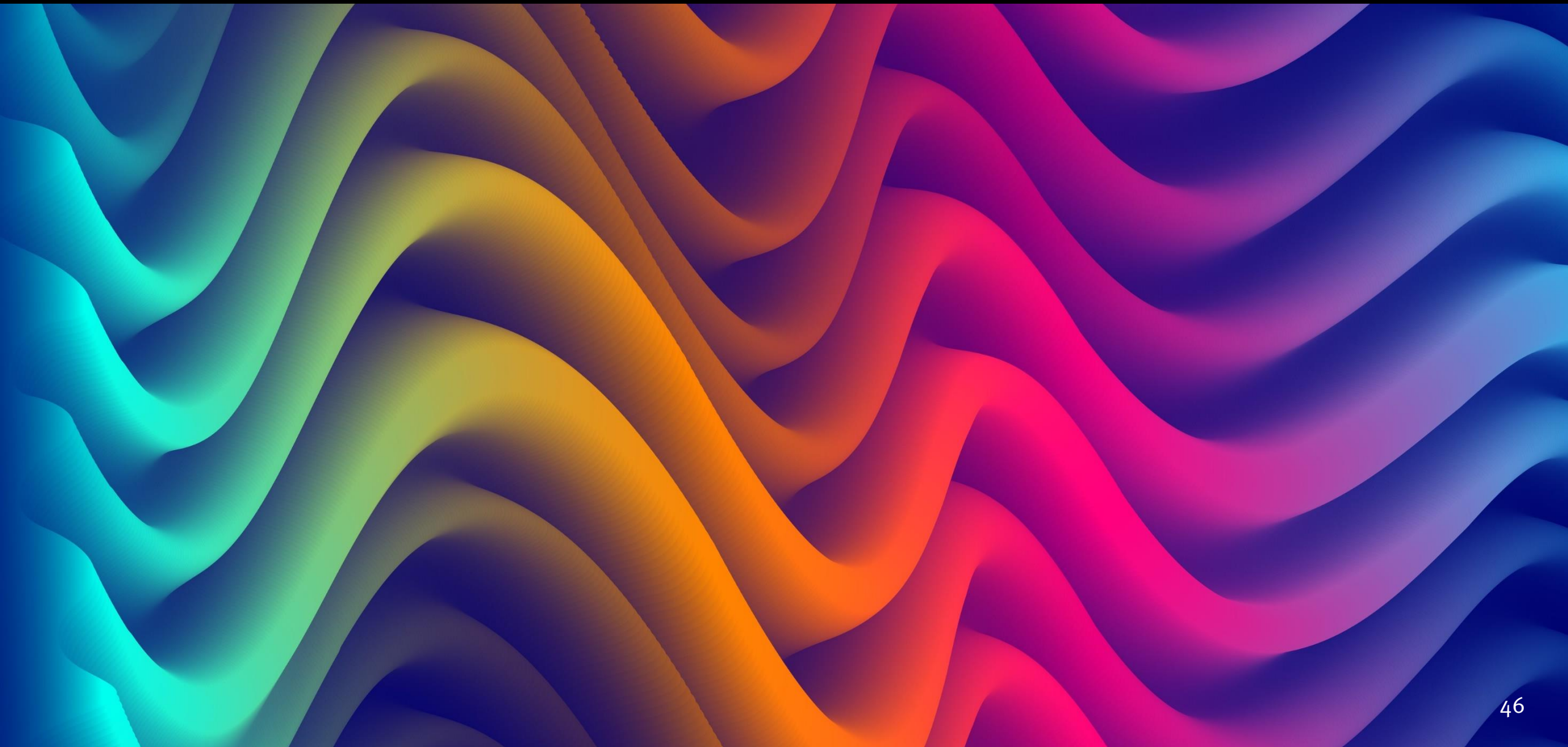
Source: https://www.wsj.com/articles/life-sciences-investor-hatteras-venture-partners-raises-over-200-million-746f4f03

Venture Fund Capital Formation Has Slowed in 2025



Source: Stifel database of venture capital raises in the life sciecnces.

The Evolving Cardiovascular Drug Field



The Pace of New Cardiovascular Drug Introductions is Accelerating

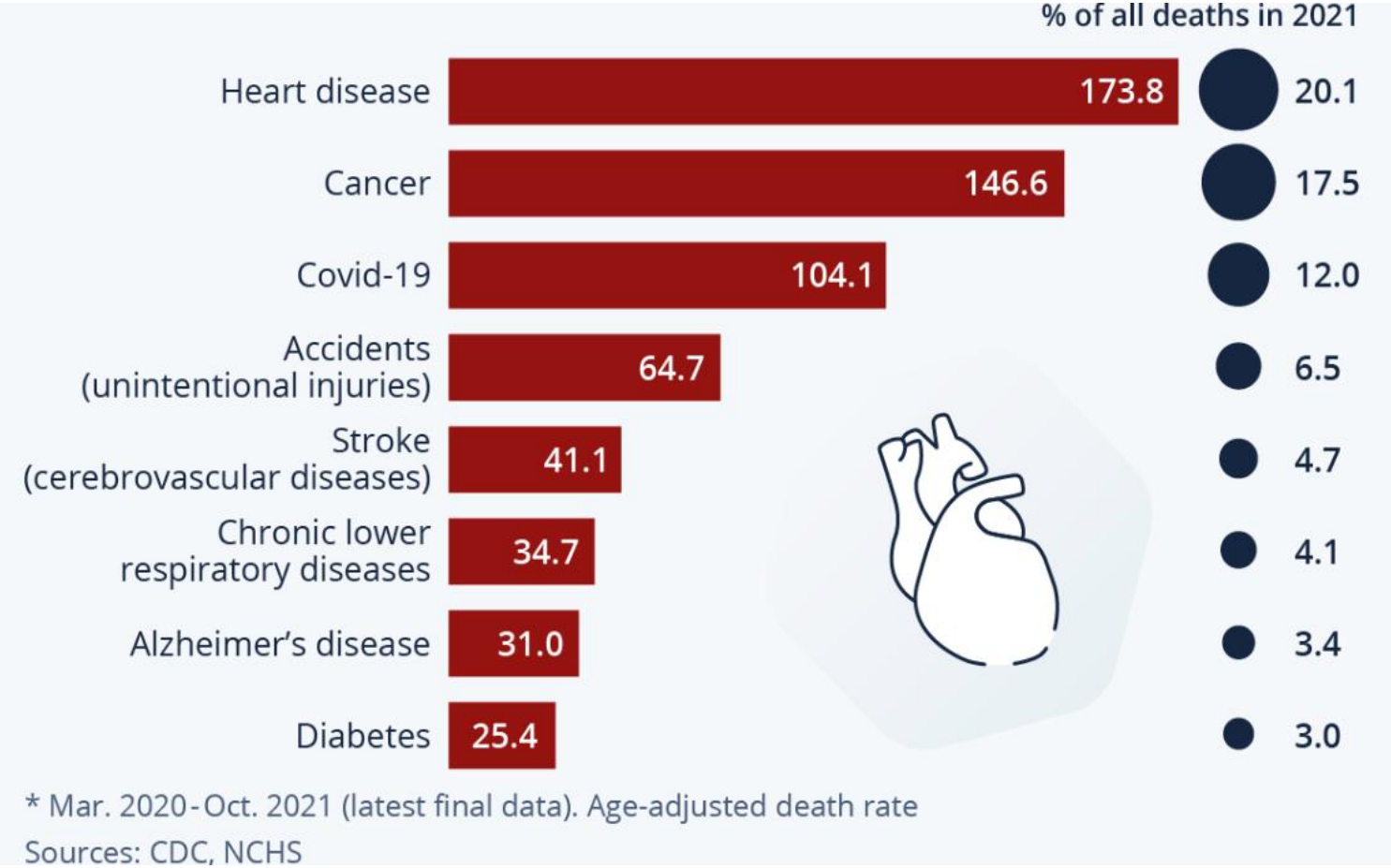
Key New Cardiovascular Drug Launches in the U.S. Market, 1980 to 2025

1980's	1990's	2000's	2010 to 2014	2015 to 2019	2020 to 2025
1981 - Vasotec	1991 - Zocor	2001 – Tracleer	2010 - Pradaxa	2015 - Repatha	2020 - Nexletol
1981 - Capoten	1991 - Pravachol	2001 – Diovan	2011 - Brilinta	2015 - Procoralan	2021 - Mounjaro
1981 - Tenormin	1994 - ReoPro	2001 - Arixtra	2011 - Edarbi	2015 - Praxbind	2021 - Verquvo
1982 - Cardizem	1995 - Coreg	2002 – Inspra	2011 - Xarelto	2015 - Veltassa	2021 - Leqvio
1985 - Isoptin SR	1995 - Cozaar	2002 - Benicar	2012 - Juxtapid	2015 - Savaysa	2021 - Evkeeza
1987 - Mevacor	1996 - Lipitor	2002 - Zetia	2012 - Eliquis	2015 - Uptravi	2021 - Arcalyst
1989 - Ticlid	1997 - Plavix	2003 - Crestor	2012 - Vascepa	2015 - Kengreal	2022 - Camzyos
1989 - Adalat ER	1998 - Prinivil	2006 - Toprol XL	2013 - Adempas	2015 - Entresto	2023 - Inpefa
	1998 - Integrillin	2006 - Ranexa	2013 - Opsumit	2015 - Praluent	2024 - Winrevair
	1998 - Aggrastat	2007 - Bystolic	2013 - Kynamro	2017 - Bevyxxa	2025 - Attruby
			2014 - Farxiga	2017 - Giapreza	2025 - Amvuttra
			2014 - Jardiance	2018 - Lokelma	
			2014 - Zontivity	2018 - Ozempic	
				2019 - Vyndaqel	

Source: Stifel Research

New Cardiovascular Drug Introductions Driven by High Unmet Need

Deaths in the U.S., Per 100,000 People, 2021

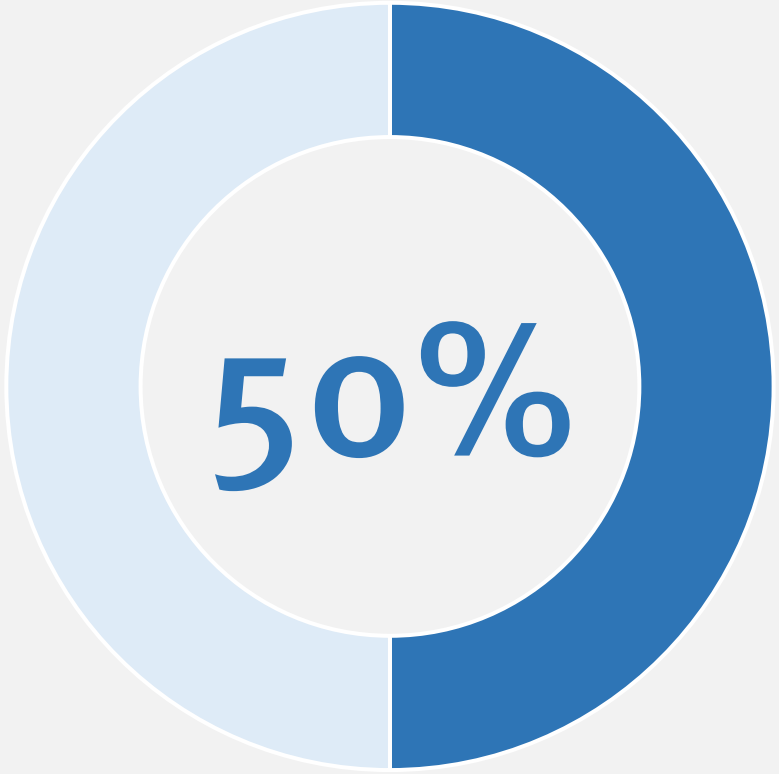


Heart disease, stroke and diabetes are by far the biggest killers in the U.S. population.

Cardiovascular disease (CVD) remains the leading cause of death worldwide, responsible for approximately 18 million deaths annually, per WHO estimates. Despite significant historical progress with statins, antihypertensives, and antithrombotics, residual risk remains high, especially in a growing population of aging, obese, and diabetic patients. This clinical unmet need—across heart failure, ASCVD, stroke prevention, and metabolic-cardiac syndromes—offers a vast, durable commercial opportunity.

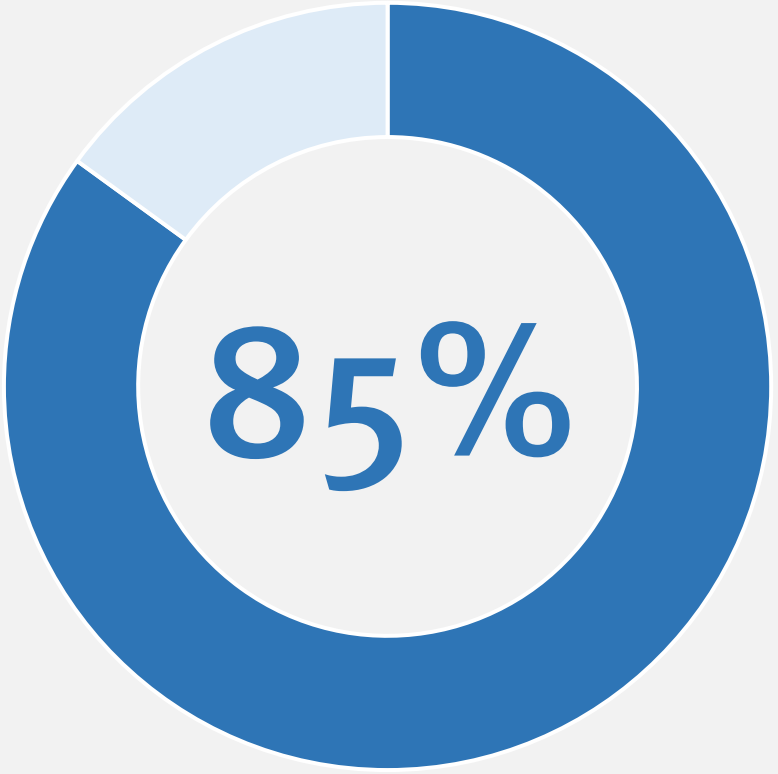
Major Unmet Needs Remain

5 Year Mortality with Heart Failure



Prognosis is similar to some cancers. Worse with reduced ejection fraction (HFrEF), advanced NYHA class, or recurrent hospitalizations.

Percent of CV Deaths from Atherosclerosis



Despite presence of statins and PCSK9 drugs, atherosclerosis remains a major killer.

Scientific Advances Driving Expansion of Cardiovascular Drug Development

Emerging **mechanistic insights** into inflammation, lipid metabolism, myocardial energetics, and fibrosis have opened up **new targets and therapeutic classes**. For instance:

- **PCSK9 inhibitors** and **siRNA-based therapies** (e.g., inclisiran) offer potent LDL-lowering with durable effects.
- **SGLT2 inhibitors**, originally for diabetes, have shown **broad CV benefit** across heart failure and CKD.
- **Lp(a) and APOC3** targeting agents are in development, addressing previously "undruggable" risk factors.
- **Gene editing**, RNA therapeutics, and precision cardiology (e.g., RNAi or CRISPR for rare lipid disorders) have brought **new modalities** to bear on CV risk.

Key Factors Influencing Investment Decisions in CV Drugs

Chronic Lifelong Indications

CV drugs often offer:

- **Lifelong dosing** potential
- **Broad primary and secondary prevention** applicability
- High **persistency and adherence** if tolerability is good

This creates the kind of **high-volume, high-margin opportunity** that contrasts with the finite duration and segmentation of many oncology or rare disease assets.

Changing Attitude on CVOTs

Cardiovascular outcomes trials (CVOTs) have long been a regulatory staple, but **recent flexibility** from the FDA and global regulators has accelerated programs with validated biomarkers (e.g., LDL-C, Lp(a)) and facilitated **faster approval pathways** (e.g., for orphan lipid disorders or HF subtypes).

Payors, meanwhile, are recognizing the **cost savings of preventing CV events**, improving access and pricing dynamics.

Shift to Specialty Drug Pricing

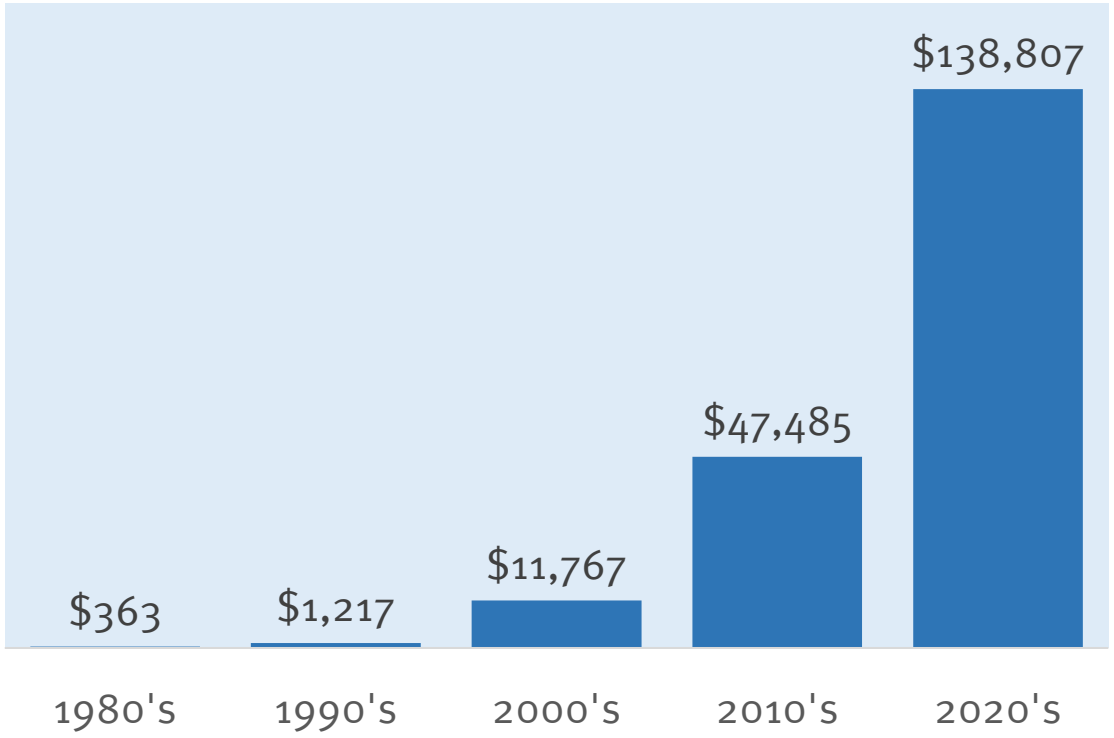
Over the past 50 years, the **pricing** of CV drugs has **increased significantly**, especially for therapies targeting specialty or high-risk populations.

In the 1980s and 1990s, blockbuster CV drugs such as ACE inhibitors, statins, and beta-blockers were priced **modestly** and aimed at broad primary care markets.

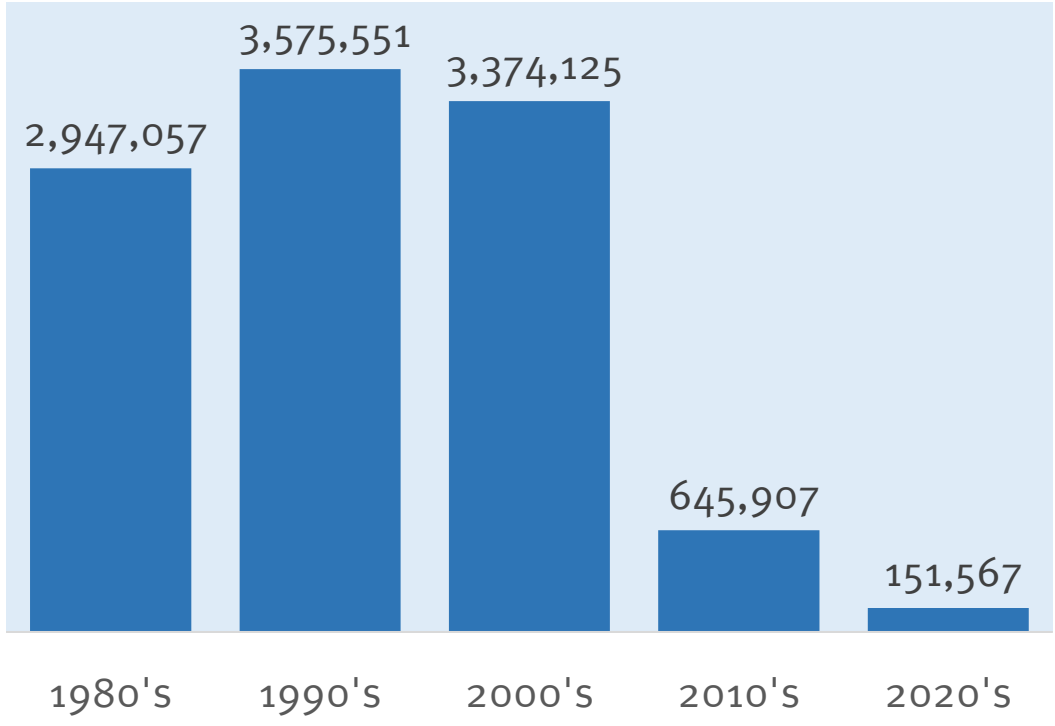
However, recent decades have seen a shift toward specialty therapies developed for **narrower populations**—such as PCSK9 inhibitors for familial hypercholesterolemia, SGLT2 inhibitors and ARNIs for heart failure.

Change in CV Drug Pricing Has Come With a Focus on High Unmet Needs in Narrower Populations

Average Per Annum Price for U.S. Market at Launch (53 cardiovascular drug approvals), 1980 to 2025



Average Number of Patients in Indication at Launch (53 cardiovascular drug approvals), 1980 to 2025



Source: Stifel Research

New CV Entrants are Focusing on Narrower Indications

Historically, companies like Merck, Pfizer, and AstraZeneca dominated CV.

But as **older blockbusters lost exclusivity** and R&D shifted toward oncology and rare diseases in the 2010s, CV innovation slowed.

Now, companies like **Novartis, Amgen, Novo Nordisk, Eli Lilly**, and even **biotech entrants (e.g., Alnylam, Verve, Ionis)** are **reclaiming the field** with a focus on **first-in-class and best-in-class assets**.

amvuttra (vutrisiran) injection 25 mg/0.5 mL

LEQVIO® (inclisiran) injection 284 mg/1.5 mL

Some Illustrative Key Drugs in the Cardiovascular Pipeline

Company	Product	Mechanism of Action	Lead Indication	WW Peak Sales ($mm)
89bio	Pegozafermin	Fibroblast growth factor 21 (FGF21) stimulant	NASH	4,724
Cytokinetics	CK-586	Cardiac myosin inhibitor	Chronic heart failure (CHF)	3,974
NewAmsterdam Pharma	Obicetrapib	Cholesteryl ester transfer protein (CETP) inhibitor	Hyperlipidaemia	3,556
Cytokinetics	Aficamten	Cardiac myosin inhibitor	Hypertrophic cardiomyopathy	3,397
SILENCE THERAPEUTICS	Zerlasiran	Apolipoprotein A (ApoA) RNAi therapeutic	Hyperlipidemia	2,650
TENAYA THERAPEUTICS	TN-301	Histone deacetylase 6 (HDAC6) inhibitor	Chronic heart failure (CHF)	2,500
genemabio	seralutinib	Platelet-derived growth factor receptor (PDGFR) inhibitor	Pulmonary hypertension	2,244
VIKING THERAPEUTICS	VK2809	Thyroid hormone receptor agonist	Hyperlipidemia	1,874
AMGEN	Olpasiran	Apolipoprotein A (ApoA) RNAi therapeutic	Hyperlipidemia	1,624
TENAYA THERAPEUTICS	TN-201	Cardiac myosin inhibitor	Hypertrophic cardiomyopathy	1,500
NOVARTIS	Pelacarsen	Apolipoprotein A (ApoA) antisense	Atherosclerosis	1,221
MERCK	MK-0616	Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor	Hyperlipidemia	1,105
MINERALYS	Lorundrostat	Aldosterone synthase inhibitor	Hypertension (HTN)	1,080
Milestone PHARMACEUTICALS	Cardamyst	Calcium channel blocker	Arrhythmia, supraventricular	1,000

Source: Evaluate Pharma

Transformative Trends in CV Medicine For 2025

American College of Cardiology, Jan 6, 2025

Trend #1: Anti-Obesity Drugs: Cardiovascular Benefit Beyond Weight Loss. Undoubtedly, the most talked-about trend in cardiovascular medicine today is the latest generation of anti-obesity medications. The two most popular of these increasingly popular drugs – semaglutide and tirzepatide – demonstrate remarkable cardiovascular benefits that extend beyond weight management.

Trend #2: The AI Revolution: Precision Diagnostics and Predictive Care. From drug discovery to coronary plaque analysis, artificial intelligence (AI) is rapidly emerging as a game-changer in cardiovascular medicine, offering unprecedented capabilities in diagnostics, risk assessment and personalized treatment planning. Machine-learning algorithms are now demonstrating remarkable accuracy in interpreting complex medical imaging, detecting subtle cardiac abnormalities at speed. Particularly promising are neural networks that can analyze electrocardiograms (ECGs) and echocardiograms with high-level expertise.

Trend #3: Inflammation: The Hidden Cardiovascular Threat. In a silo-breaking multidisciplinary effort published in the European Journal of Clinical Investigation in July, investigators led by Peter Libby, MD, FACC (Brigham and Women's Hospital, Boston) and Robert S. Rosenson, MD, FACC (Mount Sinai Hospital, New York) make the case that common inflammatory pathways participate in the pathogenesis of multiple acute and chronic diseases and urge researchers towards greater collaboration and cross fertilization to speed the development and application of therapies with interdisciplinary benefit

Trend #4: CRISPR: Genetic Editing's Promise in CV Medicine. The potential of CRISPR gene-editing in cardiovascular medicine is nothing short of revolutionary. CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats and is a technology used to selectively modify the DNA of living organisms. Hereditary conditions like familial hypercholesterolemia are prime targets for CRISPR interventions.

Trend #5: Amyloidosis: A New Frontier in Cardiac Care. The CRISPR trial is just one of the recent advances in the treatment of cardiac amyloidosis. Once considered rare, the condition is experiencing a renaissance in diagnostic and treatment approaches, with advanced imaging techniques and genetic screening enabling earlier detection. Emerging therapies offer new hope for patients.

Source: https://www.acc.org/latest-in-cardiology/articles/2025/01/01/42/cover-story-transformative-trends-in-cv-medicine-for-2025

KOL Conversations

In recent months we have spoken to a number of leading players in cardiovascular disease research. This is what we are hearing about the future.

KOL #1: There is huge potential for drugs that control CV risk via inflammation control. Likes the approach of Novo Nordisk's IL-6 antibody with the ZEUS trials. Thinks NLRP3's are going to have an important role as well in cardiovascular disease.

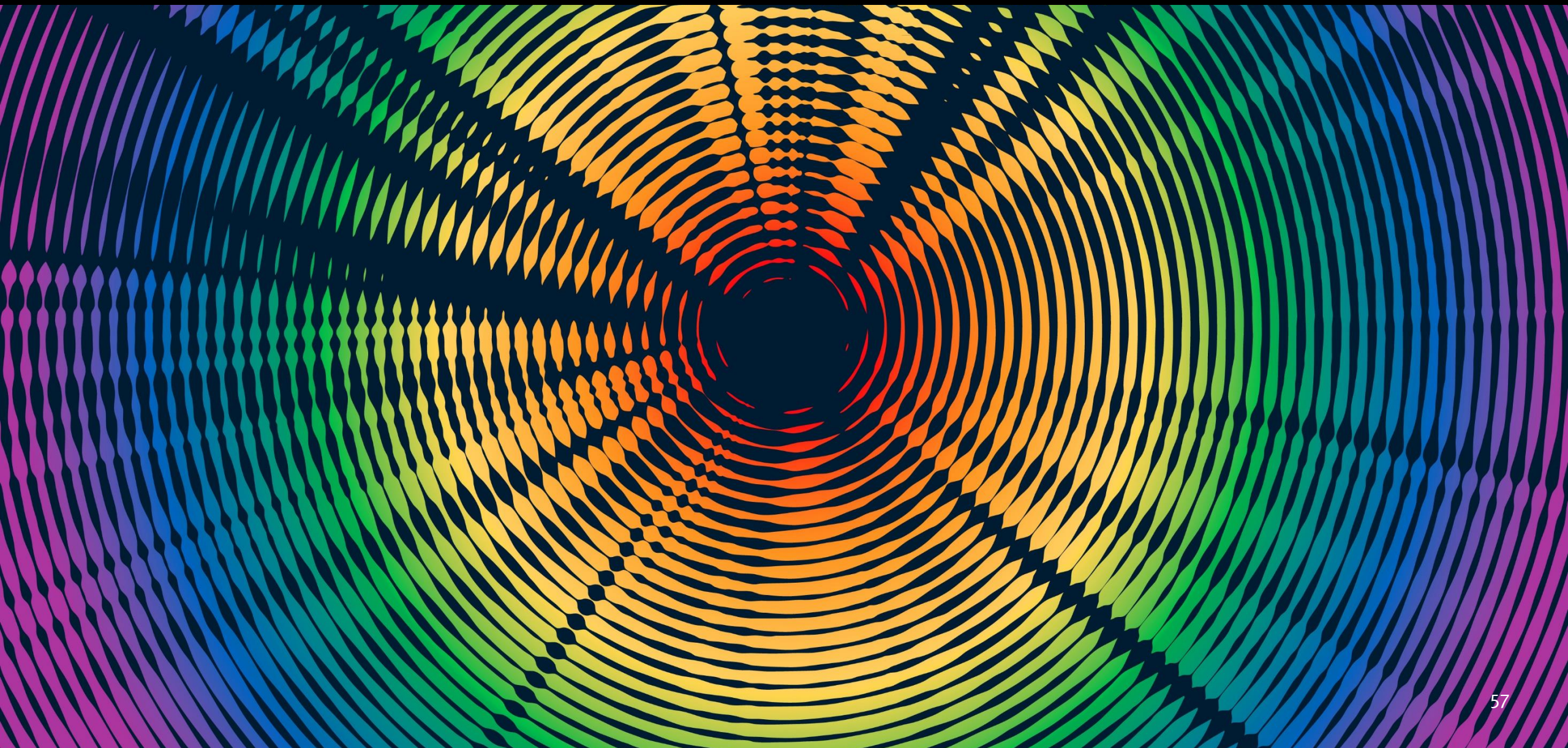
KOL #1: Huge opportunity for the various specific forms of heart failure and cardiomyopathies. In general, while we are doing better with heart failure this remains one of the biggest unmet needs. Sees arrhythmias as doing better with devices. Thinks Lp(a) drugs will disappoint. Not that many patients.

KOL #1: Biggest opportunities are drugs that target underlying causes of biological aging and CV disease at the same time. We are just starting to understand the interaction between cell senescence and cardiometabolic disease. It's big and it's controllable with drugs. He is working on a new target.

KOL #2: New drugs targeting HF are needed. He is a fan of IL-14 as a target and is working on a number of new approaches to HF. Agrees with KOL #1 on the potential for various niche CM's, including arrhythmogenic cardiomyopathy. Acute decompensated heart failure is a major unmet need in his clinic.

KOL #3: We are missing a huge opportunity in atherosclerosis and heart failure: leaky vessels. We know how to drug this problem and could shut down one of the most important causes of residual risk with novel pharmacology.

Industry Update



A Big Week for FDA Approvals

The FDA was on a tear last week with drug approvals. FDA skeptics got some evidence to consider here.

US FDA approves Tonix Pharma's drug to manage pain related to chronic condition

By **Siddhi Mahatole** and **Sriparna Roy**

August 15, 2025 5:26 PM EDT · Updated August 15, 2025

Reuters

Wegovy® approved by FDA for the treatment of adults with noncirrhotic MASH with moderate to advanced liver fibrosis

novo nordisk®

Aug 15, 2025

Precigen scores FDA nod for first-ever treatment for HPV-related disorder

By **Kevin Dunleavy** · Aug 15, 2025 8:55am

FiercePharma

Exclusive: US Pharma Tariffs Likely Weeks Away as Trump Plans for Alaska

Maggie Fick, Andrea Shalal and Dave Graham, *Reuters*, August 13, 2025 (excerpt)

The announcement by President Donald Trump's administration of the results of a probe into pharmaceutical imports and new sector-specific U.S. tariffs likely remains weeks away, four official and industry sources said, later than initially promised as he focuses on other matters.

Commerce Secretary Howard Lutnick had said in April when the review of whether reliance on foreign drug production threatens U.S. national security was launched that he anticipated that it would conclude between mid-May and mid-June. Global pharmaceutical companies are bracing for the outcome of the investigation, which will usher in sector-specific tariffs that Trump has said could start small and eventually rise to 250%.

The Republican president said as recently as last week that his plan relies on phased-in tariffs, giving drugmakers time to increase manufacturing in the United States as he pushes to alter what he says are global trade distortions in many industries.

One government official in Europe and a source with knowledge of the White House process, as well as two sources at European drug firms familiar with the process, told Reuters that the report and tariffs announcement was not imminent and likely weeks away. These sources spoke on condition of anonymity.

A White House spokesperson, asked about media reporting indicating that the results of the probe could be several weeks away, cautioned that such reports were pure speculation unless confirmed by the White House. The spokesperson declined to give further details about the timing of the pharma probe or one involving semiconductors.

That source and one other source said that they expect the Trump administration to announce the results of its national security investigation into semiconductors first, followed by the pharma announcement, putting it a few weeks away.

Source: https://www.reuters.com/business/healthcare-pharmaceuticals/us-pharma-tariffs-likely-weeks-away-trump-plans-alaska-sources-say-2025-08-13/

Lilly Says it Will Raise Drug Prices in Europe, Responding to Trump Threats

Jonathan Gardner, *Biopharma Dive*, August 14, 2025 (excerpt)

Eli Lilly on Thursday responded to a Trump administration plan to lower U.S. drug costs by issuing a statement claiming it will raise prices in European countries to "align" them with the costs paid "across developed countries."

The statement, which wasn't attributed to any specific Lilly executive, said the effort includes an agreement with the U.K. government to hike the price of the company's blockbuster diabetes medicine Mounjaro "while maintaining access" for people with the disease.

Lilly didn't commit to cutting U.S. prices. But it did say that for prices to be reduced in the U.S., the amounts "paid by governments and health systems need to increase in other developed markets like Europe." The company is working with other, unspecified governments and expects to make "any necessary pricing adjustments" by Sept. 1.

Lilly didn't specify how it will raise prices in those countries — many of which have nationalized healthcare systems that negotiate drug costs for their entire population — without affecting access. It also didn't reveal whether the planned hikes would be tied to a drug's list price or the confidential rebate deals cut between drugmakers and national customers. The statement also pointed out the difficulty of lowering prices in the U.S. because of the healthcare system's structure.

"The U.S. system is complex and opaque, with multiple cross subsidies, abuse of government programs like 340B, and insurance cost-sharing burdens for patients," Lilly said.

Through an executive order signed in May, President Donald Trump aims to link the price paid for drugs in the U.S. to the lowest price paid in other high-income countries. This "most favored nation" policy is also meant to spur price negotiations between the federal government and companies, as well as to push drugmakers to establish new ways to distribute medicines to patients at a reduced cost.

Source: https://www.biopharmadive.com/news/lilly-drug-prices-europe-most-favored-nation-uk-mounjaro/757704/

Trump Pharma Tariffs Would Raise Drug Prices for Americans

Alex Durante, *Tax Foundation*, Aug 14, 2025 (excerpt)

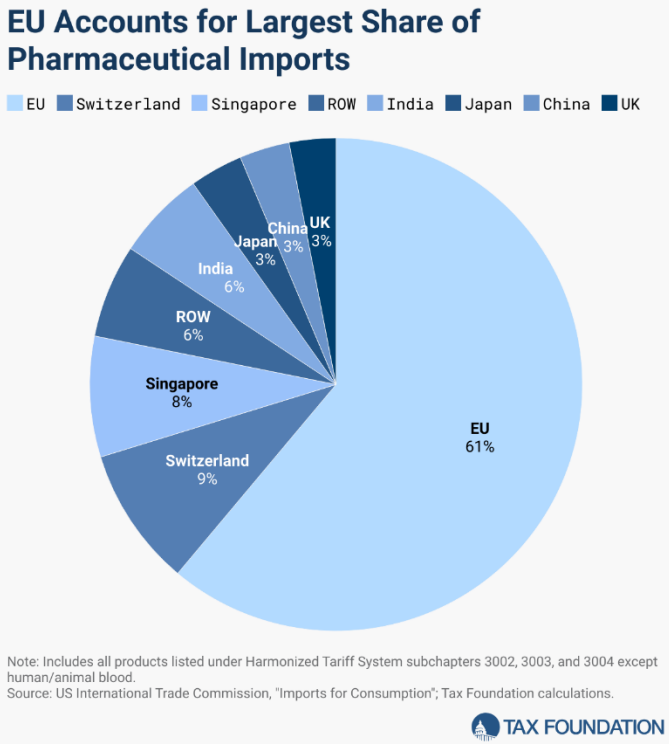
President Trump has recently floated the idea of imposing tariffs of up to 250 percent on pharmaceuticals, with the intention of shifting pharmaceutical production to the US. These tariffs would not only drive drug prices higher but could also lead to shortages and reduce long-run drug innovation. The US pharmaceutical market consists of two types of drugs: branded and non-branded (generics). The Food and Drug Administration (FDA) estimates that about 90 percent of all prescriptions filled every year are generics, a large share of which are manufactured in India, where about 35 percent of the world's active pharmaceutical ingredients (APIs) for generics are produced. Branded drugs, by contrast, come in large part from the EU, where about 43 percent of branded APIs are produced. While branded drugs only represent a small share of prescriptions, they account for nearly 90 percent of US drug spending, as those producers can charge elevated prices while their drugs are under patent.

Tariffs could impact both drug markets, though somewhat differently. Firms that manufacture generics face thinner margins on their products due to competition in the generic market. They will be less able to absorb the tariffs and will likely pass their cost increases onto consumers, which could be reflected in higher insurance premiums. Drugmakers that earn high profits from branded drugs will have a greater ability to absorb those tariff increases, and may be more inclined to do so to preserve their market share.

Yet even this would not be a desirable outcome, because those profits are often reinvested in new drug development, which is costly, and it is the prospect of profits that incentivizes drug innovation in the first place. One estimate posits that the research and development costs to bring a new drug to market can exceed $3 billion, largely due to an expensive regulatory process. Increased costs could potentially slow drug development, especially for orphan drugs, which are used to treat rare diseases.

Firms could restructure their supply chains to reduce tariff exposure by increasing domestic production. However, this would be a costly and time-consuming endeavor and could lead to drug shortages in the short run. In quarter one of 2024 alone, more than 300 drugs were in shortage, 70 percent of which were generics. Consumers would more than likely end up switching to more expensive branded drugs as an alternative. Whether consumers purchase drugs abroad or domestically, the result would ultimately be higher prices and an elevated risk of shortages.

Source: https://taxfoundation.org/blog/trump-tariffs-pharma-drug-prices/



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The Consequences of Pharmaceutical Tariffs in the United States

Sean D Sullivan, Jens Grueger, Aidan P Sullivan, and Scott D Ramsey, *J Manag Care Spec Pharm. 2025 Jun;31(6):533–536.* (excerpt)

The Trump Administration has threatened to impose tariffs on imported branded, generic, and biosimilar pharmaceutical products. Although specific details regarding the exact rates and implementation timeline remain unclear, the administration has indicated that these tariffs will be substantial.

Tariffs will impact both intermediate goods (eg, ingredients and packaging materials) for domestic manufacturing and finished products. Although specific details regarding the exact rates and implementation timeline remain unclear, the administration has indicated that these tariffs will be substantial and sector specific. In response, Eli Lilly, Johnson & Johnson, Merck, Roche, and Novartis have made public statements announcing significant new investments in US manufacturing facilities. The construction and certification of new manufacturing capacity in the United States will take years.

A central question is the net impact of tariffs: the balance of harms and benefits to the economy. In The Wealth of Nations, the economist Adam Smith argued that tariffs distort markets, reduce efficiency and productivity, harm consumers, and favor special interests at the expense of public welfare. Tariffs imposed on branded, generic, and biosimilar finished products will have wide-ranging implications for health care, product availability, and consumers in the United States. The Budget Lab at Yale University projected that a 25% ad valorem tariff would increase medication costs by an “average of around $600 per year per household in the United States.” Tariffs can also create supply chain disruptions, increase costs and limit patient access to essential medications, and negatively impact research and innovation. We explore these consequences for the health care system and patients.

Imposing tariffs will likely disrupt the movement of essential raw materials, active pharmaceutical ingredients, and finished medications. In the near term, disruptions will likely increase costs, delay access to treatments, and trigger shortages, especially for critical generic medicines with already tenuous supply, such as antibiotics, intravenous fluids, sterile injectables (e.g., epinephrine, heparin), and infused cancer therapies. A recent article in the Washington Post highlighted for heparin the complicated chain of events that lead from raw material to patient care.

Smaller pharmaceutical companies and startups, which play a critical role in innovation and drug discovery, are particularly vulnerable to capital market fluctuations and increased operational costs from tariffs. These organizations may lack the resources to effectively absorb increased expenses or restructure supply chains.

Source: https://pmc.ncbi.nlm.nih.gov/articles/PMC12123191/

Merck KGaA Ventures into New Territory in the US

Alexandra Pecci, *Biopharma Dive,* Aug 15, 2025 (excerpt)

Merck KGaA has been making moves to propel itself into becoming what CEO Belén Garijo described as a "globally diversified science and technology powerhouse."

Most recently, the company closed a $3.4 billion acquisition of Pfizer spinout SpringWorks Therapeutics, which will help it stake a claim in the rare oncology market.

More broadly, Merck KGaA's strategy it's all about "doubling down" on R&D and building the company's U.S. footprint, said Miguel Fernández Alcalde, president of EMD Serono, the company's healthcare business in the U.S. and Canada.

Germany-based Merck KGaA has undergone a number of transformations throughout its history. In 2022, the company restructured into three distinct business units, including one focused on the life sciences sector and manufacturing services. But with the contract manufacturing blitz of the COVID-19 pandemic era fading, the company is refocusing again.

EMD Serono relocated its U.S. headquarters to Boston's Seaport district to place itself squarely in the thick of the region's most innovative "biotechs, startups, academia and scientists," Fernández Alcalde said.

Merck KGaA also elevated its global head of R&D and chief medical officer of its healthcare business, Danny Bar-Zohar, to healthcare CEO.

"That tells you that the company's moving along in the direction of doubling down on R&D," Fernández Alcalde said.

Fernández Alcalde's appointment to president of EMD Serono in December is also part of the company's overall quest to build its U.S. footprint and bolster R&D through external deals.

"I want to make sure we are bringing the U.S. [business] to the next level in terms of contributions to the whole organization," he said. "We have lots of opportunities in the U.S. ecosystem and U.S. market. My job and my vision and ambition is to really untap all those things."

Source: https://www.biopharmadive.com/news/merck-kgaa-emd-serono-us-drug-innovation/757771/

Refocused, Deal-Hungry Drugmaker BioMarin Pushes Toward $4 Billion Revenue

Ron Leuty, *San Francisco Business Times*, Aug 12, 2025 (excerpt)

Call it a coming-out party for the new BioMarin Pharmaceutical Inc.

The San Rafael-based rare-disease drug developer (Nasdaq: BMRN) last week showcased year-over-year revenue growth of 15%, expanded profitability and its first acquisition in a decade. It has its sights set on 2027 revenue of $4 billion.

For a company that had seen disappointing commercial uptake of its hemophilia A gene therapy and cut close to 400 jobs, last week's second-quarter growth figures signaled headway for a strategy put in place by CEO Alexander Hardy after he joined BioMarin in late 2023 from Genentech Inc. BioMarin's stock price jumped more than 10% to $63.97 within a day of announcing those second-quarter numbers.

"The big decisions and changes last year are really coming to fruition," Hardy said in an interview. But along with opportunities, there are concerns as BioMarin comes to grips with short-term issues and long-term goals. Its top-earning drug, Voxzogo for children with achondroplasia, the leading genetic cause of dwarfism, could face competition by the end of the year. The company also dropped work last quarter on a preclinical drug for the genetic disorder phenylketonuria, or PKU, in which the body can't break down an amino acid in protein.

By yesterday's close — a week after its stock-price jump offered a measure of validation — BioMarin's shares traded at $56.80.

BioMarin largely shaped the rare-disease drug space, zeroing in mostly on drugs that provide long-term replacements for diseases in which a mutated gene causes production of a key enzyme to be thrown out of whack. Those drugs tend to carry six-figure price tags and get covered by insurers, making the 3,000-person company one of a handful of Bay Area biotechs to be profitable. The company has put eight products on the market over 28 years. It projects revenue this year of $3.125 billion to $3.2 billion, including $900 million to $935 million from Voxzogo alone.

Hardy's restructuring of BioMarin along three product lines — its legacy enzyme-replacement therapies, skeletal conditions like bone growth and the Roctavian gene therapy — is designed to give the company better focus as it decides which drugs and deals to pursue, he said.

BioMarin's new emphasis is also on getting more out of the drugs it already has in its portfolio. It's a new muscle for BioMarin to build, Hardy said, after years of concentrating on single drugs for a single disorder.

Voxzogo, for example, is being studied in five skeletal conditions beyond achondroplasia, including a late-stage clinical trial that will read out topline data in the first half of next year in hypochondroplasia. That is a milder form of achondroplasia marked by short limbs, a large head and broad feet. If all goes well, BioMarin could launch the drug in hypochondroplasia in 2027.

It helps, too, that BioMarin, which has long faced speculation that it is a Big Pharma buyout target, has more than $1.9 billion in cash, equivalents and investments. That now makes it a hunter in an environment where generalist investors have put biotech companies on ice for close to four years, leading hundreds of companies to cut jobs, shed programs, close up shop or sell to deep-pocketed companies.

"We're in an enviable situation. Biotech IPOs are not happening, we're profitable and growing, we're producing cashflow and we can find and execute deals right now," Hardy said. "It's a buyers' market and BioMarin is really well positioned as a buyer."

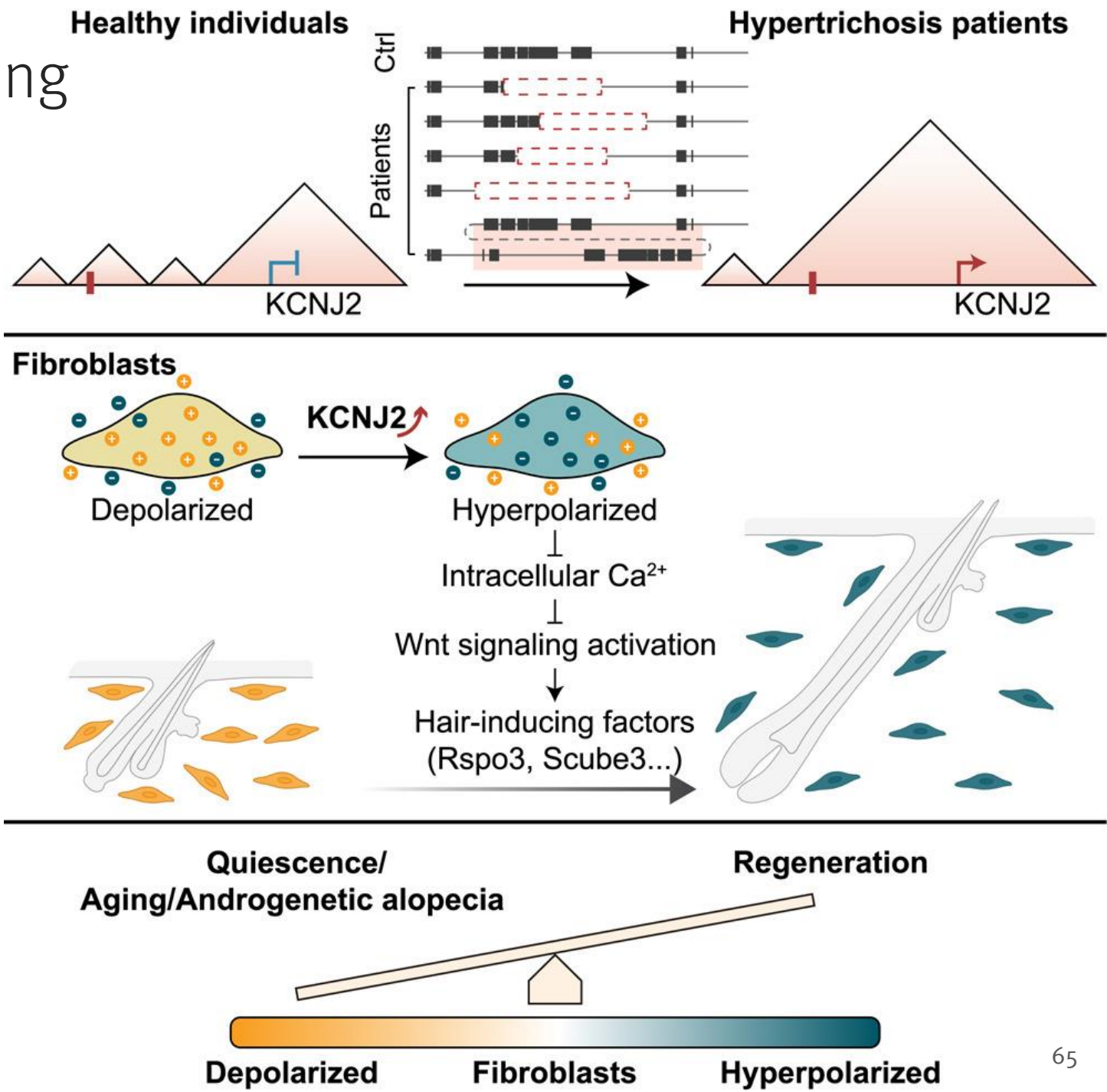
Source: https://www.bizjournals.com/sanfrancisco/news/2025/08/12/rare-disease-biomarin-pharmaceutical-revenue-bmrn.html

Fibroblast Bioelectric Signaling Drives Hair Growth

Chen et. al., *Cell*, Aug 15, 2025 (excerpt)

Hair loss affects millions globally, significantly impacting quality of life and psychological well-being. Despite its prevalence, effective strategies for promoting human hair growth remain elusive. By investigating congenital generalized hypertrichosis terminalis (CGHT), a rare genetic disorder characterized by excessive hair growth, we discover that chromatin deletions or an inverted duplication disrupt the topologically associating domain (TAD), leading to the upregulation of the potassium channel KCNJ2 in dermal fibroblasts. Mouse genetics demonstrate that KCNJ2-mediated membrane hyperpolarization in dermal fibroblasts promotes hair growth by enhancing fibroblasts Wnt signaling responses, involving a reduction in intracellular calcium levels.

Notably, fibroblast membrane potential oscillates during the normal hair cycle, with hyperpolarization specifically associated with the growth phase. Inducing fibroblast membrane depolarization delays the growth phase, while KCNJ2-mediated hyperpolarization rescues hair loss in aging and androgenetic alopecia models. These results uncover a previously unrecognized role of fibroblast bioelectricity in tissue regeneration, offering novel therapeutic avenues for hair loss treatment.



Source: https://www.cell.com/cell/abstract/S0092-8674(25)00857-8

Brain Editing Now ‘Closer to Reality’: the Gene-Altering Tools Tackling Deadly Disorders

Heidi Ledford, *Nature*, Aug 14, 2025 (excerpt)

Scientists are closing in on the ability to apply genome editing to a formidable new target: the human brain.

In the past two years, a spate of technological advances and promising results in mice have been laying the groundwork for treating devastating brain disorders using techniques derived from CRISPR–Cas9 gene editing. Researchers hope that human trials are just a few years away.

“The data have never looked so good,” says Monica Coenraads, founder and chief executive of the Rett Syndrome Research Trust in Trumbull, Connecticut. “This is less and less science fiction, and closer to reality.”

Daunting challenge: Researchers have already developed gene-editing therapies to treat diseases of the blood, liver and eyes. In May, researchers reported a stunning success using a bespoke gene-editing therapy to treat a baby boy named KJ with a deadly liver disease.

But the brain poses special challenges. The molecular components needed to treat KJ were inserted into fatty particles that naturally accumulate in the liver. Researchers are searching for similar particles that can selectively target the brain, which is surrounded by a defensive barrier that can prevent many substances from entering.

Snip and stitch: Studies in mice suggest that gene-editing technology, which can rewrite small snippets of a cell’s genome, is ready to correct some of these mutations. In July, researchers reported that they had repaired mutations that, in humans, cause a disease called alternating hemiplegia of childhood (AHC). The condition, which typically starts causing symptoms before a child reaches 18 months old, causes seizures, learning disabilities and episodes of partial paralysis. “It’s a horrible disease,” says David Liu, a chemical biologist at the Broad Institute of MIT and Harvard in Cambridge, Massachusetts.

Liu and his colleagues deployed a gene-editing offshoot of CRISPR called prime editing in mice with a mutation that causes AHC. The technique corrected the mutation in about half of the brain’s cortex, a region that controls learning and memory. The mice also showed improvements in a variety of measures: their seizure-like episodes became less severe, cognition and motor control improved and lifespans lengthened. “The mouse results were dramatic,” says Liu. “We were amazed.”

Source: https://www.nature.com/articles/d41586-025-02578-8

Editorials on Current Policy Issues

Editorial: America Is Abandoning One of the Greatest Medical Breakthroughs

Rick Bright, Former Head of BARDA, *New York Times*, Aug 18, 2025 (excerpts)

In early 2020, when the first genetic sequence of the new coronavirus was posted online, scientists were ready. Within hours, they began designing a vaccine. Within weeks, clinical trials were underway. That unprecedented speed, which saved millions of lives, was possible only because years earlier, the United States had invested in a vaccine technology called mRNA. Today, that work is being sidelined, and with it, our best chance to quickly respond when the next threat emerges.

The Department of Health and Human Services recently announced it would wind down 22 mRNA vaccine development projects under the Biomedical Advanced Research and Development Authority, or BARDA, halting nearly $500 million in investments. This decision undercuts one of the most significant medical advances in decades, technology that could protect millions more from the threats ahead.

I know the stakes because I was BARDA's director when the United States made the decision to invest heavily in mRNA. That investment did not begin with Covid-19. It began in 2016, when we faced the Zika virus outbreak. We needed a way to design a vaccine in days, not years, to protect pregnant women and their babies from devastating birth defects. Older vaccine approaches were too slow. The solution was mRNA: a flexible, rapid-response technology that could be reprogrammed for any pathogen once its genetic sequence was known. That early investment laid the groundwork for the lightning-fast Covid-19 response four years later. During the pandemic, mRNA vaccines went from the genetic sequence of the virus to human trials in under 70 days. They were evaluated in large, rigorous trials, meeting the same safety and effectiveness standards as other vaccines. By the end of 2021, they had saved an estimated 20 million lives globally, including more than one million in the United States

If the United States abandons mRNA, it will not simply be forfeiting a public health advantage. It will be ceding a strategic asset. In national security terms, mRNA is the equivalent of a missile defense system for biology. The ability to rapidly design, produce and deploy medical countermeasures is as vital to our defense as any military capability. Adversaries who invest in this technology will be able to respond faster to outbreaks, protecting their populations sooner than we can. Right now, the United States has a decisive advantage in mRNA science, manufacturing capacity and regulatory expertise. But in an era where biological threats can be engineered, losing this competitive edge would leave the United States vulnerable and dependent on others for lifesaving tools.

The consequences of canceling mRNA contracts will affect more nations than just the United States. Many countries have been building regional mRNA manufacturing capacity. For a leader like the United States to pull back now undermines that effort and weakens our collective ability to respond to the next outbreak. It means choosing to face the next biological threat with fewer defenses and slower tools while others build speed and strength.

There is a better path forward. The department of Health and Human Services can work with scientists, public health experts and security leaders to refine and improve mRNA technology while preserving critical programs and production capacity. By recalibrating rather than severing support, we can keep this powerful tool ready for the time it is needed most. The next crisis will not wait for us to rebuild what we have thrown away.

Source: https://www.nytimes.com/2025/08/18/opinion/mrna-vaccines.html

Editorial: America Can't Afford to Abandon mRNA

Michelle Lynn Hall, AVP Genetic Medicines, Eli Lilly, Editorial, *Medium*, August 17, 2025 (excerpts)

On August 5, the Department of Health and Human Services (HHS) suddenly cut funding for 22 ongoing mRNA vaccine projects worth nearly $500 million. In doing so, it didn't just jeopardize our ability to handle the next pandemic. It also crippled one of the most vital medical platforms of our time — the future of medical treatments for cancer, rare diseases, and more — and gave a strategic edge to foreign competitors who will not hesitate to take advantage of it. The projects that were halted were not speculative moonshots; they were late-stage, pandemic-ready programs funded by the Biomedical Advanced Research and Development Authority (BARDA). Their foundations support the development of the next generation of curative therapies, offering hope where there was none.

What Was Cut

The projects affected were wide-ranging. Moderna's bird flu vaccine program was halted. Academic and biotech efforts at Emory, Tiba Biotech, Luminary Labs, ModeX, and Seqirus were defunded. Even collaborations with larger players, such as AstraZeneca's nucleic acid vaccine program, were rolled back. This wasn't an isolated belt-tightening. It was a systemic retreat from mRNA platforms at the precise moment they are most needed.

Flawed Rationale

The justifications offered for these cuts have shifted and, in some cases, outright contradicted one another.

False Claim #1: "mRNA vaccines are ineffective and dangerous."

In the HHS's Aug 5 press release, Robert F. Kennedy Jr. continues to allege that mRNA vaccines were both ineffective and dangerous, citing cherry-picked data on myocarditis and breakthrough infections. His framing suggested the platform itself posed unacceptable risks.

But the evidence points the other way. As STAT reported, "Kennedy is literally citing evidence that contradicts his position." Most of the studies he listed found infection-related harms, proof of why vaccines are needed. Yet, as the article concluded, "This isn't scientific disagreement. It's either staggering incompetence or willful misrepresentation." Meanwhile, the report omitted the most definitive studies, including a Danish analysis of nearly 1 million booster recipients that found no increased risk for 29 specified conditions. CDC data further show that during the Delta wave, unvaccinated Americans faced a 53-fold higher risk of death. The facts don't undermine mRNA vaccines; they scream for continued investment.

False Claim #2: "The public no longer trusts mRNA vaccines."

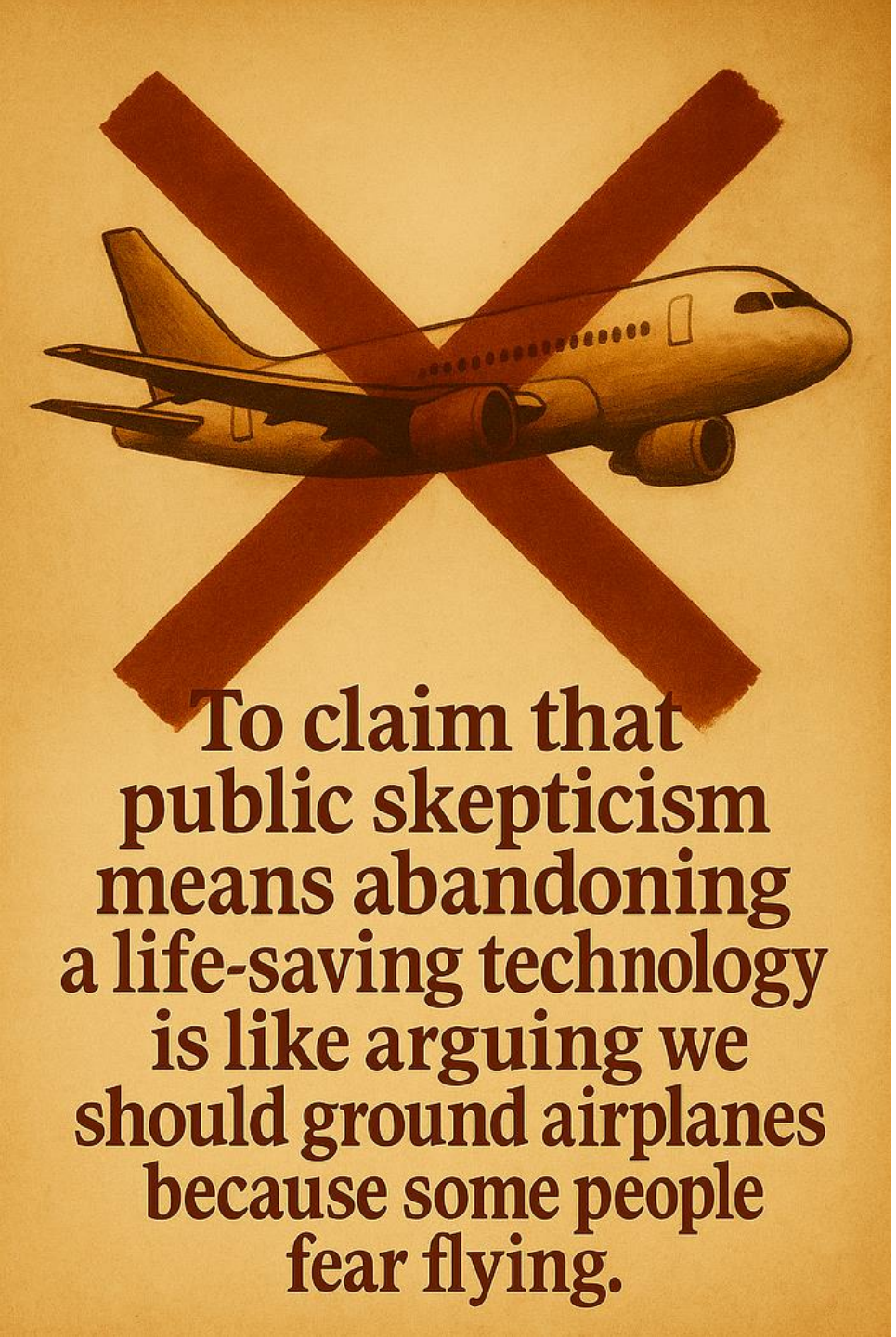
A week after RFK Jr's statement, NIH director Jay Bhattacharya offered a different excuse: public mistrust was supposedly rampant, so why fund the platform at all?

But this is fatalism dressed up as policy. According to the Kaiser Family Foundation, 56 percent of U.S. adults remain at least "somewhat confident" that COVID-19 vaccines are safe. Uptake among seniors, those most at risk, remains strong. To claim that public skepticism means abandoning a life-saving technology is like arguing we should ground airplanes because some people fear flying. Leadership should build trust, not surrender to doubt.

False Claim #3: "Cutting mRNA funding will save money."

Though never stated outright, cost-cutting could be another driver in this slash-and-burn DOGE-era approach to government spending. But cutting

Source: https://medium.com/@michelle.lynn.hall/america-cant-afford-to-abandon-mrna-4fb38556fdaa



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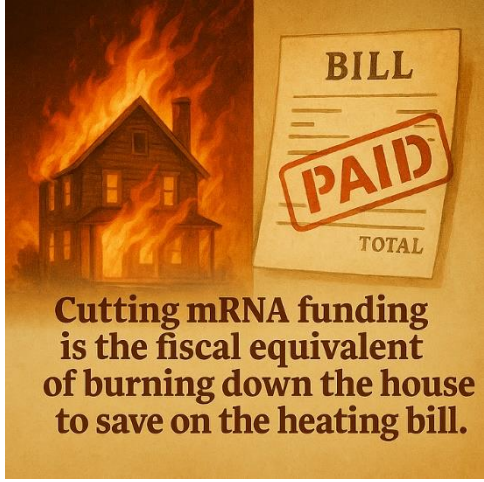

mRNA funding is penny-wise and pound-foolish. The 22 BARDA-funded projects eliminated totaled about $500 million, less than 0.01 percent of nearly $6 trillion in 2025 federal spending. By contrast, the COVID-19 vaccination program prevented an estimated 18 million hospitalizations and 3 million deaths, saving nearly $1 trillion in health care costs and economic losses. That's 2,300 times more saved than what's now being slashed. It's the fiscal equivalent of burning down the house to save on the heating bill.

The reality is simple.
mRNA vaccines were one of the most effective, life-saving, and cost-saving public health interventions in modern history. None of the stated reasons for their divestment stands up to scrutiny.

Conflict of Interest and Public Policy
So, if the motivation isn't safety, efficacy, public mistrust, or fiscal responsibility, what is the real motivation behind these moves by the HHS?

Revisiting Elisabeth Warren's exchange with RFK Jr during his confirmation hearing in January 2025 is illuminating. Warren highlighted that he has earned approximately $2.5 million in referral fees from Wisner Baum, a personal-injury law firm handling lawsuits against vaccine manufacturers. That includes a 10% contingency share in any successful case involving Gardasil or other vaccine-related claims (Warren Senate testimony).

Ethics disclosures further show that much of this compensation stems from cases poised directly against the pharmaceutical industry, including Merck. And while RFK Jr. initially agreed to stop accepting such fees during his time in office, he later backpedaled, allowing these payments to continue, potentially funneling them to his adult son.

The implications are stark: as HHS Secretary, he now oversees agencies and policies that directly influence the outcome of lawsuits from which he (or his family) are financially benefiting. During the hearing, Senator Warren laid it out plainly: "Kids might die, but Robert Kennedy will keep cashing in." And so he is.

Source: https://medium.com/@michelle.lynn.hall/america-cant-afford-to-abandon-mrna-4fb38556fdaa

mRNA Editorial Continued

Make no mistake — these HHS moves have nothing to do with mRNA vaccine safety, efficacy, public perception, or fiscal responsibility. This is entirely to put more money into RFK Jr's pocket. And the American people are footing the bill, sometimes at the expense of our own health.

Let's not forget where the SARS-CoV-2 virus originated — wildlife-to-human transmission, catalyzed by increasing human/wildlife interaction, globalization, and climate change. Zoonotic diseases like SARS-CoV-2 (i.e., infectious diseases that are transmissible from wildlife to humans) continue to be a key threat to human health. HIV preceded SARS-CoV-2 as the prime example, being transmitted originally from non-human primates to humans. Roughly 64% of zoonotic diseases are sensitive to temperature changes, making them more likely to spread in a warming world. And in today's interconnected economy, a novel pathogen can circle the globe at the pace of airplane travel.

Gutting Early Detection

At the same time that we're hampering our ability to respond to the next pandemic once it inevitably makes its way to US soil, we've also eliminated our ability to contain these novel viruses well before they ever reach us. Earlier this year, the United States Agency for International Development (USAID) was dissolved. USAID's PREDICT program identified 984 novel viruses between 2009 and 2019, more than doubling the number of known mammalian viruses.

Eliminating these programs is like ripping out our smoke detectors in the middle of wildfire season. By defunding both mRNA research and global surveillance networks, we are dismantling our ability to predict and respond — setting the stage for a perfect storm. The next pandemic will come sooner than we expect, hit harder than the last, and it will be our own doing.

1. **Beyond Pandemics:** mRNA as a Medical Game-Changer
2. Even for those who distrust mRNA vaccines, it's critical to understand that mRNA isn't just about infectious disease.
3. **Cancer immunotherapy:** Personalized mRNA vaccines (now rebranded as "individualized neoantigen therapies", at least partially for political reasons) are now in advanced clinical trials. These train the immune system to recognize tumor-specific mutations. This is a critical innovation for the ~ 40% of Americans who will be diagnosed with cancer at some point in their lives.
4. **Rare diseases:** mRNA can encode proteins or gene-editing tools to correct genetic defects. Earlier this year, an experimental mRNA therapy saved the life of "Baby KJ," born with a fatal metabolic disorder. Within days, his condition reversed — a glimpse of what's possible when we invest in this platform.

Disclosure

I am a former employee of Moderna and a current employee of Eli Lilly. I no longer hold any stock in Moderna, but do hold stock in Eli Lilly, which recently acquired Verve, whose assets rely on mRNA. All views expressed here are my own and do not necessarily reflect those of my employer.

Source: https://medium.com/@michelle.lynn.hall/america-cant-afford-to-abandon-mrna-4fb38556fdaa

Essay/Editorial: China's Biotech is Cheaper and Faster

Jacob Dryer, *New York Times*, August 17, 2025 (excerpts)

Just outside Shanghai, in the city of Wuxi, China is building its future of medicine — a booming biotechnology hub of factories and laboratories where global pharmaceutical companies can develop and manufacture drugs faster and cheaper than anywhere else.

Amid the Trump administration's tariffs on China, I figured manufacturing hubs like this one would be racked with anxiety. But when I visited Wuxi in April, government officials insisted that its research hub was flourishing. They were proud to tell me about their superstar labs and companies that are continuing to thrive. The fact that Chinese biotechnology stocks have surged over 60 percent since January seems to bolster this claim. The city's researchers certainly seemed positioned to be busy for decades.

In its quest to dethrone American dominance in biotech, China isn't necessarily trying to beat America at its own game. While the U.S. biotech industry is known for incubating cutting-edge treatments and cures, China's approach to innovation is mostly focused on speeding up manufacturing and slashing costs. The idea isn't to advance, say, breakthroughs in the gene-editing technology CRISPR; it's to make the country's research, development, testing and production of drugs and medical products hyperefficient and cheaper.

As a result, China's biotech sector can deliver drugs and other medical products to customers at much cheaper prices, including inexpensive generics. These may not be world-changing cures, but they are treatments that millions of people around the world rely on every day.

To American officials, these obstacles are essential to stymieing a Chinese ascendancy that not only threatens U.S. economic dominance but also presents the potential for Chinese technological innovation to eclipse America's.

But the pressure on the West to purchase cheaper drugs and treatments from China will only dial up. Consider Britain's National Health Service, perpetually short of money. If China offers countries like Britain a way to affordably take care of their aging populations, will they say no? Would any American really choose to forgo a cheap cancer vaccine that could save a dying mother in the name of national security?

The United States could follow the logic of national security hawks and ban Chinese medicines outright. Or it could seek to benefit from Chinese innovations, much as the Chinese have from America's.

But there's some irony here: In so many ways, the Chinese system of today has been built on replicating American best practices. Many of China's most impressive scientists were trained in the United States. If China's biotech products are good enough for its 1.4 billion citizens, they should be good enough to meet global standards — provided they pass transparent regulatory scrutiny. China is and always will be the biggest market for Chinese pharmaceuticals. Any medicines that we might use from Chinese companies are the best China can do for its own population.

Chinese success is still often perceived as America's loss, but it doesn't have to be. The U.S. health care system continues to be stressed by inequalities and inefficiencies, and the United States would do well to take inspiration from China's success in streamlining drug discovery and development to provide more affordable and accessible treatments to Americans. Both countries are racing to make people live longer and healthier lives. But if China finds ways to achieve this goal more quickly and cheaply, Americans shouldn't be left behind because of politics.

Source: https://www.nytimes.com/2025/08/17/opinion/china-biotech.html

Disclosure

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