



# Biopharma and Medtech Review 2022

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By Evaluate Vantage | FEBRUARY 2023



# Foreword

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## Welcome to *Evaluate Vantage's 2022* review.

This report provides a roundup of our end-of-year data stories, which dig into the trends driving business development decisions and financing deals across the pharmaceutical, biotechnology and medtech sectors.

Last year was a tough one for many developers, with public markets continuing their declines and investors' flight to safety accelerating. Small companies always feel a harsh climate more acutely than larger ones, and 2022 was no different. Only a fifth of the small cap biotech stocks tracked by *Evaluate Vantage* ended up on the year, with many trading below cash.

If anything the picture in medtech was even worse. More companies saw their market value slide than rise, regardless of their size, and surprisingly US-listed stocks felt as much pain as those in Europe or Asia.

Poor equity market conditions had an inevitable impact on IPOs, with both biopharma and medtech sectors experiencing a slump on 2021's activity. The drug development space notched up 19 flotations over the year while the medtech field only managed five. Those that did get away were mostly small offerings.

The closing of the IPO window also hit the biotech venture world, with sums deployed markedly lower than in 2021. True, these private investors mostly remain well stocked after a couple of bumper years. However, ongoing economic uncertainty and geopolitical concerns means that few expect much of recovery in 2023, in either private or public financings.

The device sector, by contrast, made a fairly decent showing on the total amount raised in 2022. But the number of deals fell, and a sharp drop in the final quarter of the year might augur poorly for the year ahead.

What might pick up this year is M&A, as the protracted slump in valuations is forcing sellers to the table. The biopharma space saw a flurry of activity in the final quarter of 2022. The medtech space was quiet, with one major exception as Johnson & Johnson bought Abiomed. Before parting with big sums in 2023, buyers will have to overcome concerns about economic growth, however.

Another potential worry is the regulatory environment, with the FDA taking its foot off the gas on both drug and device approvals last year. A clampdown on the accelerated approval pathway threatens to limit green lights for the therapeutic world further in 2023.

*Evaluate Vantage* will be monitoring these trends and others in the coming months. For a closer look at what 2023 might bring, [our Preview is available to download here](#).

The original articles that make up this Review of 2022 report can be found on [the insights section of our website](#).



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# Biopharma Review 2022

## Big caps bounce back for biopharma

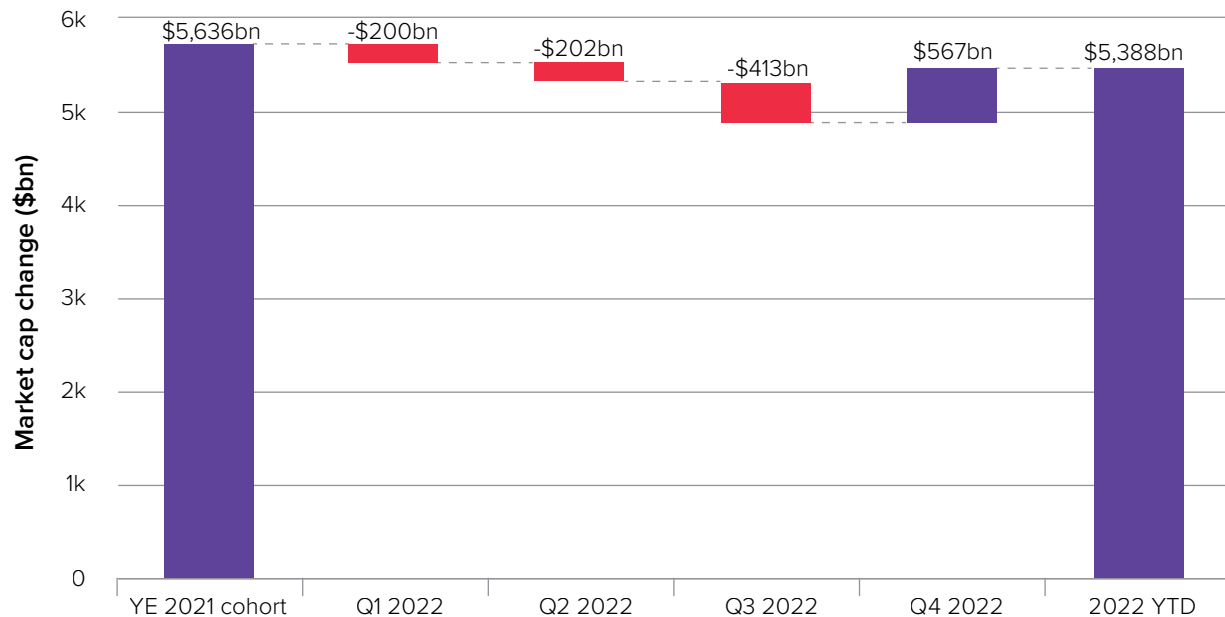
A big-cap recovery in the final quarter rescued 2022 biopharma valuations from disaster. The sector still ended down over the year but, considering the deepening declines seen over the first nine months, the situation could have been a lot worse.

A number of factors drove the remarkable bounce back in large caps, including the fading of Zantac litigation risk, Amgen's buyout of Horizon and growing expectations about the obesity market opportunity. Even mid and small caps managed a small uplift in the final quarter. Is it time to call the bottom?

Almost 700 globally listed biopharma stocks tracked by *Evaluate Pharma* form the basis of this analysis; only pure-play developers, and only those that started 2022 with a market cap of at least \$250m, are considered.

The \$567bn surge in combined market cap in the fourth quarter for this universe added back almost six months' worth of losses. It is too early to call this a recovery, but hopes that a floor has been hit might not be misplaced.

### The shifting valuation of global drugmakers



Source: Evaluate.



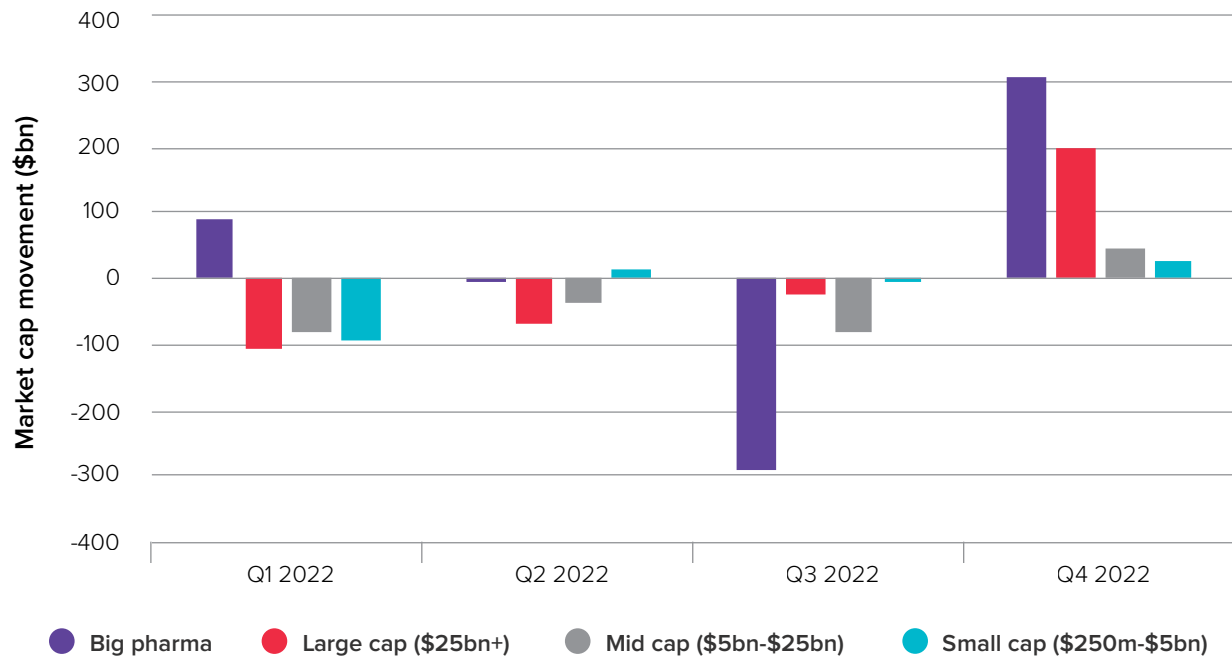
Evaluate Vantage has been tracking the performance of these companies over the year; the following graphs concern four market cap brackets, into which developers were sorted at the beginning of 2022.

Almost across-the-board gains drove the 11-strong big pharma group higher in the fourth quarter, while recoveries at a number of flagging big developers, including Moderna, Gilead and Beigene, boosted the large-cap segment.

Somewhat remarkably, Novo Nordisk put on the most market cap of this group in the final months of the year, with investors apparently unalarmed by the growing threat of Lilly's impressive diabetes and obesity drug Mounjaro.

Perhaps investors are becoming more appreciative of big biopharma's defensive nature, as uncertain economic times persist.

### Absolute market cap gains and losses, by size bracket



Source: Evaluate.

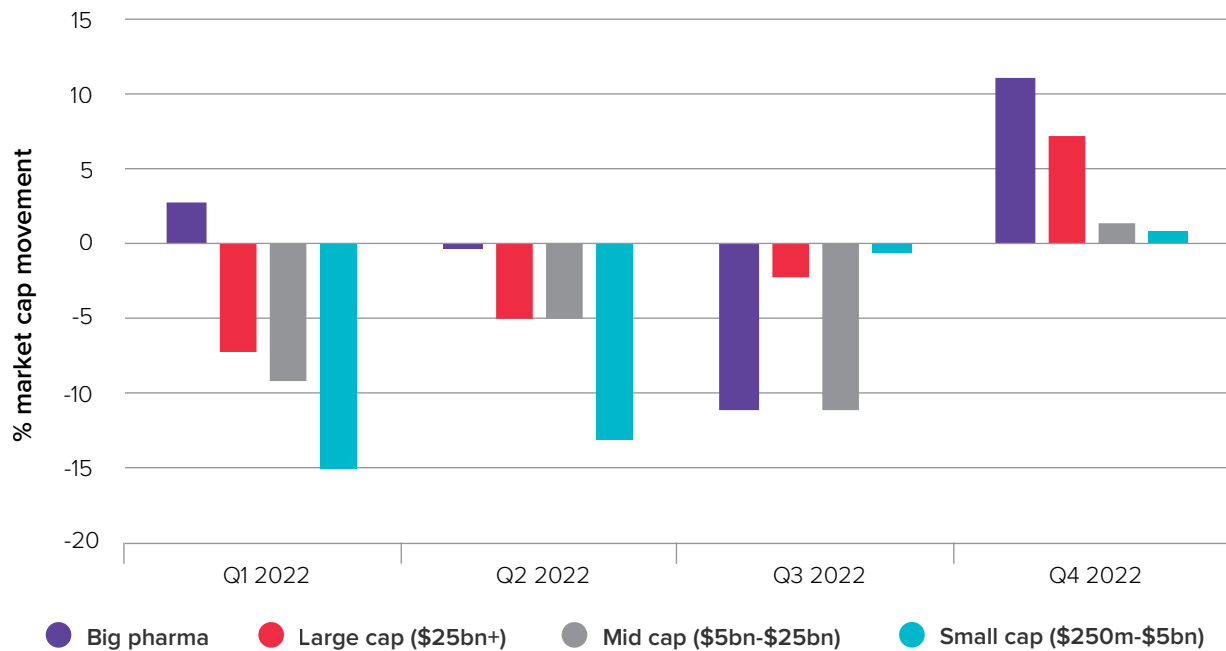


The smaller end of the sector was less buoyant, though overall the fourth quarter saw the strongest performances of the year. The mid-cap group benefited from Horizon adding \$11.6bn in market cap as a result of Amgen's approach; this stock is still included in the analysis because the deal has yet to close.

A handful of notable clinical wins just about managed to outweigh the disaster stories found among the small caps, though the situation at this end of the sector is of course much more precarious. Cash is running out for many of these groups, and the prospect of raising any more is poor.

Over the whole of the year, only a fifth of the 532 small-cap stocks ended up in positive territory. The large caps might have regained their mojo, but outside this group 2023 promises to be tough – floor or no floor.

### Percentage market cap gains and losses, by size bracket



Note: The 11 big pharma groups in this analysis are: J&J, Lilly, Pfizer, Abbvie, Merck & Co, Roche, AstraZeneca, Novartis, Bristol Myers Squibb, Sanofi, GSK.

Source: Evaluate.



## Biopharma's stock market winners of 2022 revealed

In a tough year for biopharma, clear pipeline success was required to end the year on the stock market leaders' board. Hats off then to the likes of Daiichi Sankyo, Orion, Verona and Madrigal, all of which won substantial share price gains in 2022.

On the flip side, the pandemic players came back to earth after [reaching eye-watering highs in 2021](#). These developers, including Biontech, Moderna and Novavax, dominate the list of stock market losers, with good old-fashioned clinical setbacks claiming a few other names.

Amid a broad end-of-year boost for big caps Merck & Co shot to the top spot; considering the main theme around this name is concern about the Keytruda patent cliff this was a surprising finding. With data on a subcutaneous formulation of the drug due in the coming weeks, perhaps investors are betting that this huge oncology franchise will last longer than assumed.

Drivers are more obvious for the likes of Lilly, Abbvie and Daiichi, all of which are in the process of establishing drugs with huge expectations attached. Takeda and Vertex are recovery stories – both developers have started to overcome growth worries.

Among the mid caps, Sarepta was boosted by solid progress with its gene therapy for Duchenne muscular dystrophy; the FDA's accelerated approval decision, due in May, will be one of the mostly closely watched of the year.

Halozyme, meanwhile, is crucial to the franchise extension of several blockbuster cancer antibodies, [providing the technology behind various subcutaneous formulations](#) – although not Merck's Keytruda.

Finland's Orion is riding high on a mid-stage [prostate cancer candidate that Merck paid handsomely to license](#). And among the small caps [Verona climbed on COPD data, Madrigal achieved a rare win](#) in Nash, and Rhythm gained over the year on US and European approvals for Imcrivee, for the rare genetic condition Bardet-Biedl syndrome.



## Biopharma's biggest stock market winners of 2022

Company	12-mth share price chg	12-mth market cap chg (\$bn)	Market cap at Dec 30, 2022 (\$bn)
<b>Big pharma</b>			
Merck & Co	45%	87.7	281
Lilly	32%	83.4	348
Abbvie	19%	46.4	286
<b>Large cap (\$25bn+ market cap)</b>			
Daiichi Sankyo	45%	15.5	65.5
Vertex	32%	18.3	74.1
Takeda	31%	7.95	51.5
<b>Mid cap (\$5-25bn market cap)</b>			
Sarepta	44%	3.53	11.4
Halozyme	42%	2.03	7.69
Orion	42%	1.93	7.81
<b>Small cap (\$250m-5bn market cap)</b>			
Verona Pharma	289%	1.57	1.98
Madrigal	243%	3.52	4.96
Rhythm	192%	1.14	1.64

Source: Evaluate Pharma. Companies are assigned these groups based on year-end 2021 market caps, and remain in the same group for the rest of the year.

The fourth-quarter big cap rebound means that only three big pharma groups lost value over the whole year. Roche was a poor performer throughout 2022, a year that ended badly for the Swiss major with [a big Alzheimer's disappointment](#), a failure that will likely prompt difficult questions for the group's executive team in the coming months.

GSK is having [well documented pipeline problems of its own](#), and even the [lifting of Zantac litigation concerns](#) could not rescue the UK group from a down year.

Most of the other fallers went out with the Covid tide. Alongside the vaccine developers Moderna and Biontech, the wannabes Novavax and Curevac continued their declines alongside the vaccine manufacturers Lonza and South Korea's Enzychem.

And where would biopharma be without its blow ups? One of the most spectacular last year was that of Fate, [the NK cell-based researcher that was once worth \\$10bn](#), before its pipeline imploded. Elsewhere among the small caps, [Tricida reached the end of the road for veverimer in metabolic acidosis](#), while any lingering hopes around Rubius's red blood cell platform were [erased by a disappointing update at AACR](#).





## Biopharma's biggest stock market losers in 2022

Company	12-mth share price chg	12-mth market cap chg (\$bn)	Market cap at Dec 30, 2022 (\$bn)
<b>Big pharma</b>			
Roche	-23%	-104	256
Pfizer	-13%	-43.8	288
GSK	-11%	-33	76.1
<b>Large cap (\$25bn+ market cap)</b>			
Biontech	-42%	-26.1	36.5
Lonza	-41%	-26	35.6
Moderna	-29%	-34	69
<b>Mid cap (\$5-25bn market cap)</b>			
Novavax	-93%	-10	0.81
Fate Therapeutics	-83%	-4.61	0.98
Curevac	-82%	-5.27	1.15
<b>Small cap (\$250m-5bn market cap)</b>			
Rubius	-98%	-0.85	0.02
Tricida	-98%	-0.47	0.01
Enzychem Lifesciences	-97%	-0.37	0.11

Source: Evaluate Pharma. Companies are assigned these groups based on year-end 2021 market caps, and remain in the same group for the rest of the year.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of sector share prices.](#)



# Flotations fail to bounce back

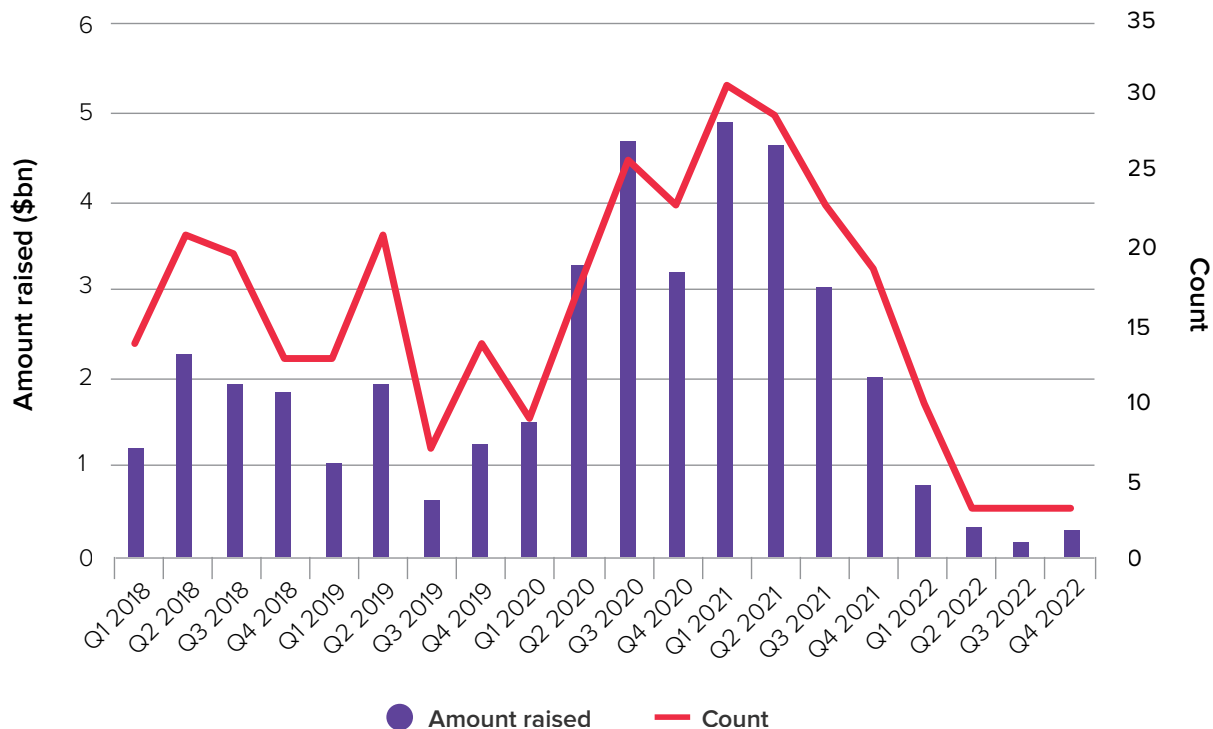
A torrid year for biopharma on the stock markets all but wiped out the prospect of going public. The IPO numbers for the full year show just how dire the situation is, with just three groups managing to get away in the fourth quarter – taking the 2022 total to 19.

This makes last year the worst for drug developer flotations since 2012, which saw 16 groups go public. And, in a further blow to the sector, one of the [IPO success stories of last year, Third Harmonic](#), is already looking in danger of becoming a zombie after the December discontinuation of its lead candidate, THB001, [on liver toxicity fears](#).

That some very early-stage players are still managing to float, and bank substantial sums, raises questions about whether investors have learnt much from the recent period of IPO excess. Prime Medicine, for example, which raised \$175m in October, 2022's fourth-largest flotation in *Evaluate Vantage's* analysis.

This analysis, of data collected by *Evaluate Pharma*, concerns IPOs of pure-play drug developers only; secondary listings are not included.

## Biotech IPOs by quarter on Western exchanges



Source: Evaluate.



Prime is some way from human trials, but perhaps its backers could not resist the lure of the next big thing in gene editing, prime editing. Prime promises to address the drawbacks of gene therapy and other gene-editing methods such as Crispr/Cas9 and base editing.

Meanwhile, Acrivon, which is [developing an asset originated by Array and Icos](#), raised \$99m in November, a respectable sum. Unlike Prime it priced well below its initially-proposed range.

The following chart shows that this scenario is now the reality for many groups going public.

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### Average Nasdaq float price premium/discount to IPO price range



Source: Evaluate Pharma.

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At least these companies managed to get away. IPOs from the likes of Alopexx and Intensity Therapeutics, slated for the fourth quarter, were postponed.

The question now is whether the bottom has been reached. A lot will depend on market sentiment, and things here do not look encouraging, with worries about war and inflation continuing to bite, alongside new fears about a Covid resurgence in China and the possibility of the emergence of new variants.

For biopharma in particular, the US Inflation Reduction Act looms large, with some respondents to a recent *Evaluate Vantage* survey contending that the [sector was “uninvestable” unless these laws changed](#).

Encouragingly for the IPO market, Astrazeneca bought one of last year’s largest new issues, Cincor, at a 63% premium to its flotation price in the opening days of 2023. This suggests that desirable assets are still reaching the equity markets.

However, it will take a lot more than this to prise the IPO window back open.

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### Biggest biopharma IPOs of 2022

Company (month of float)	Primary focus	Amount raised (\$m)	Premium/(discount); float price to initial offer	Share price change, float to end-Q4
HilleVax (April)	Norovirus vaccine	200	0%	-2%
CinCor (January)*	Resistant hypertension	194	0%	-23%
Amylyx (January)	Neurodegenerative diseases	190	0%	94%
Prime Medicine (October)	Gene editing	175	0%	9%
Arcellx (February)	T-cell therapies	142	-6%	107%

\*Acquired by Astrazeneca for \$1.3bn up front in January 2023.

Source: Evaluate Pharma.

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[See our website for further analyses of these data and Evaluate Vantage’s wider coverage of sector IPOs.](#)

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## Biopharma's venture year ends with another dip

Venture capital investment is back to 2019 levels. This much is apparent from the latest cut of the data, which shows the smallest quarter for drug developers for three years in the final three months of 2022.

Investors insist that venture funds remain well stocked, which is true for now. But the closing of the IPO window and a wider shift in risk appetite is forcing firms to circle the wagons and protect existing portfolio companies. Until these factors change, investments are unlikely to tick higher.

The big question is how low these numbers might fall. 2021 was an outlier, and saw levels of cash deployment that could never be sustained; despite the recent retrenchment investment levels remain historically very strong. Venture firms report healthy interest in life sciences from their own investors – but a protracted global downturn will be felt eventually.

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### Annual biopharma venture investments

Year	Investment (\$bn)	Financing count	Avg per financing (\$m)	No of rounds ≥\$50m	No of rounds ≥\$100m
2022	21.7	381	58.9	149	65
2021	28.5	514	55.6	216	93
2020	22.6	543	42.4	173	63
2019	15.7	483	33.6	125	37
2018	18.2	548	34.8	127	36

Source: Evaluate Pharma.

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For now, the annual numbers show that 2022 was still a strong year. It is worth remembering, however, that the \$3bn raised by the anti-aging researcher Altos Labs gave the top line a big boost. Remove that deal, which would be an outlier in any year, and the average round size drops to \$51m.

This analysis, of data collected by *Evaluate Pharma*, concerns venture financings of pure-play developers only; sectors like medtech and digital health are excluded.



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## 2022's biggest biotech venture rounds

Company	Country	Investment (\$m)	Financing round
Altos Labs	US	3,000	Undisclosed
Areteia Therapeutics	US	350	Series A
Acelyrin	US	300	Series C
Emalex Biosciences	US	250	Series D
Kallyope	US	236	Series D

Source: Evaluate Pharma.

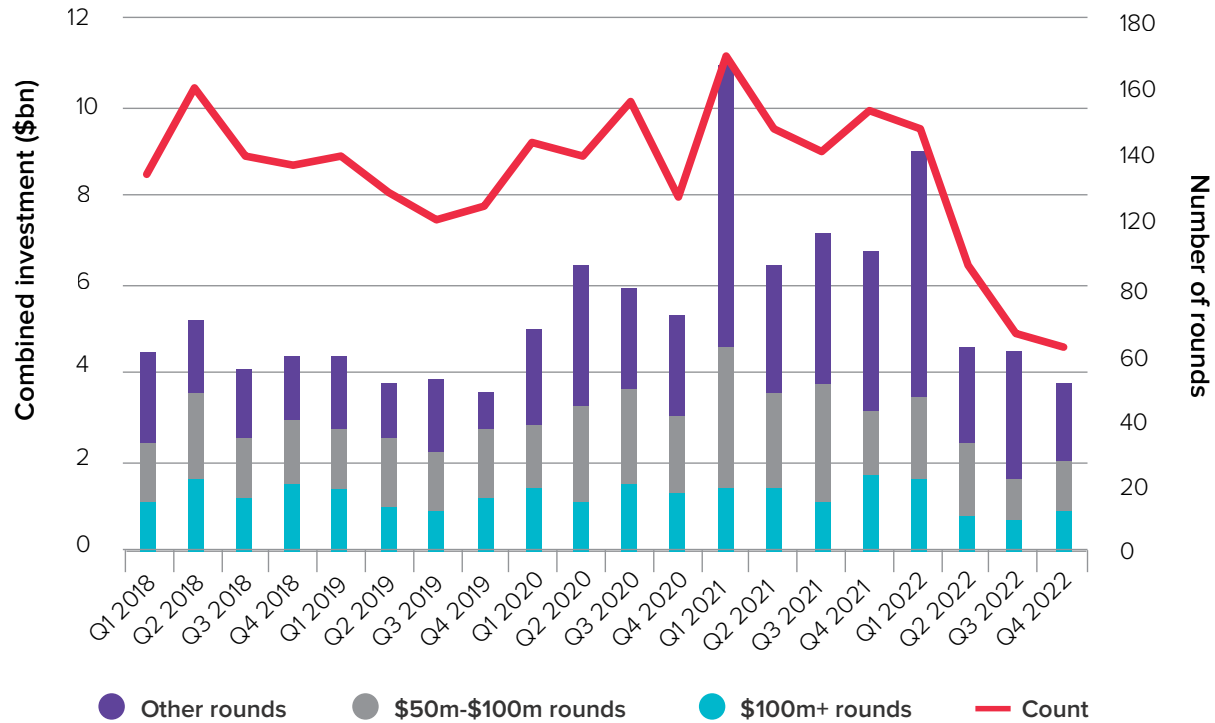
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The number of large rounds is falling largely because of the exit of crossover investors, who supported the large, pre-IPO rounds that have vanished. The total financing count also dropped substantially last year, in another sign of venture firms pulling the purse strings tighter.

The following quarterly numbers illustrate this increasingly prudent stance, with the volume of financings dropping quarter on quarter. Capital is being concentrated into ever fewer bets. Few will rue the end of more profligate times, but concern about missed opportunities must be growing.



### Quarterly biopharma venture capital investments



Source: Evaluate.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of venture financing.](#)



## Amgen saves biopharma's buyout year

Beaten-down biopharma received a well-needed boost in the closing weeks of 2022, when [Amgen won the bidding for Horizon Therapeutics](#). The \$28bn deal also rescued the sector's M&A stats, taking the total capital committed to just over \$90bn.

Remarkably, transactions struck by just two companies – Pfizer and Amgen – account for more than half of that figure. The former is spending its Covid cash while the latter is trying to replace fading blockbusters, a motivation expected to drive deal making at other large developers in the coming months.

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### Annual biopharma M&A activity

Year	Total deal value (\$bn)	Deal count	Median deal value, excl- \$30bn+ deals (\$bn)
2018	148.4	183	195
2019	239.2	176	438
2020	131.0	176	279
2021	90.8	165	363
2022	90.5	171	247

Source: Evaluate Pharma.

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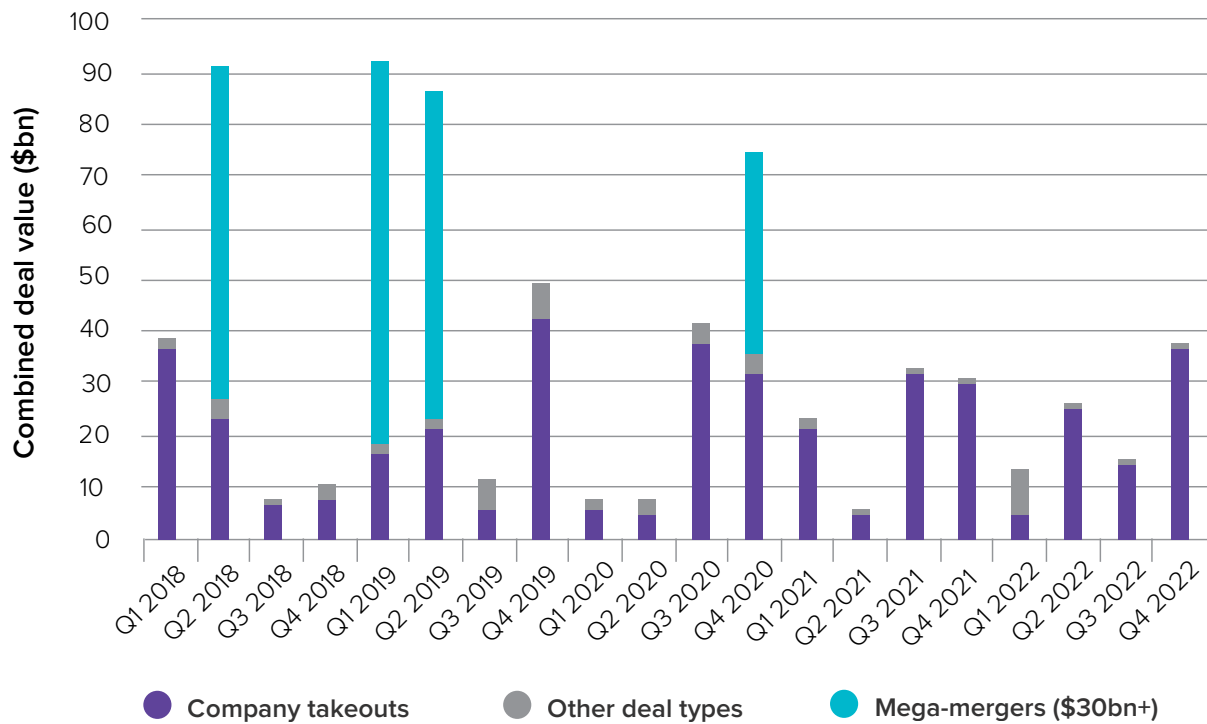
With biotech valuations still depressed acquirers have the power to dictate terms, and this power play was on show in 2022. Companies as diverse as [Epizyme](#), [Radius](#) and [F-Star](#) finally accepted the new reality and sold out at depressed valuations.

Biopharma's top-line M&A stats reflect this trend. The table above shows that the number of transactions did not really dip last year, though the total sum committed hit a five-year low. The median deal value dropped to a four-year low.

This picture would look a lot sorer had Amgen not decided to pay up for Horizon. A big question is whether the sector is in for another long wait for the next big deal; the last transaction of comparable size was AstraZeneca's late-2020 takeout of Alexion, for \$39bn.

Valuations at the more established end of the sector have been mostly unaffected by the market rout – many large developers have benefitted from their so-called defensive qualities. This means that filling revenue gaps will be expensive, though the looming patent cliff at the end of this decade will eventually force hands.

### Quarterly biopharma M&A spend



Source: Evaluate.



For this analysis, which is based on data collected by *Evaluate Pharma*, *Evaluate Vantage* includes only M&A deals struck by pure-play drug developers, with sectors like medtech or diagnostics excluded. Other deal types refers to majority and minority stake purchases and business unit buys; licensing deals are not counted.

## 2022's biggest biopharma company acquisitions

Acquirer	Target	Deal value
Amgen	Horizon Therapeutics	\$27.8bn
Pfizer	Biohaven	\$11.6bn
Pfizer	Global Blood Therapeutics	\$5.4bn
Bristol Myers Squibb	Turning Point	\$4.1bn
Amgen	Chemocentryx	\$3.7bn

Note: Horizon deal not closed.

Source: Evaluate Pharma



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of sector M&A activity.](#)



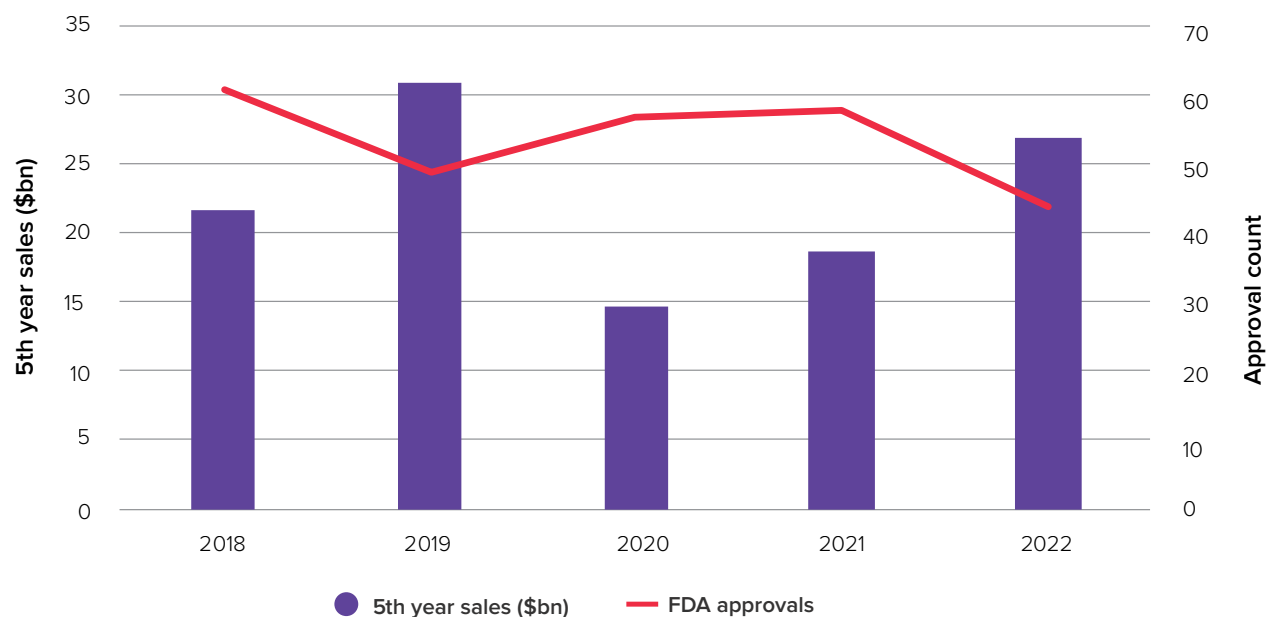
## A year of two halves for US approvals

A slow start to US approvals translated into an only slightly disappointing 2022, as the pace of FDA green lights picked up in the second half and the year ended with 42 new drugs registered.

True, this was down on the 10-year average of 48, and on the remarkable 58 drugs the FDA had approved, despite the Covid pandemic, in 2021. But delays pushed decisions on at least six new projects into 2023. And on at least one metric last year did not disappoint: combined US sales of drug approved in 2022 are set to hit nearly \$27bn within five years.

If accurate this forecast, based on *Evaluate Pharma* sellside consensus, would actually make 2022 the most successful year for US approvals since 2019. This is largely down to Lilly's diabetes drug Mounjaro, which is expected to bring \$6.8bn in 2027 US revenues, a consensus that will likely go up as analysts update their forecasts with an anticipated label expansion into obesity.

### FDA novel drug approvals



Note: CDER and CBER approvals, count excludes non-therapeutics like imaging agents.

Source: FDA and Evaluate.



The approval of Mounjaro in May crowned a **first half in which just 19 new drugs were greenlit**. The second half brought 23 more, including those of Mirati's Kras inhibitor Krazati, Bristol Myers Squibb's Tyk2 inhibitor Sotyktu and Gilead's long-acting HIV drug Sunlenca.

The year's total could have been higher still were it not for delays. Covid-related restrictions meant that agency officials could not travel to China to inspect facilities, meaning that approval action dates were missed for three anti-PD-1 MABs: Beigene/Novartis's tislelizumab, Akeso/Sino's penpulimab and Coherus's toripalimab (at the second time of asking).

Meanwhile, Apellis's intravitreal pegcetacoplan, potentially the second-biggest 2027 seller, was one of three assets **handed three-month Pdufa date extensions that pushed decisions into 2023**. The other two were Traver's sparsentan, over an updated proposed risk-evaluation and mitigation strategy, and Biogen's tofersen, owing to new information constituting a major amendment.

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## 2022's new drug arrivals with biggest potential

Product	Company	2027e US sales (bn)
Mounjaro	Eli Lilly	6.8
Vabysmo	Roche	1.8
Opdualag	Bristol Myers Squibb	1.4
Carvykti	Johnson & Johnson	1.2
Vtama	Roivant Sciences	1.1

Source: Evaluate Pharma.

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[See our website for further analyses of these data and Evaluate Vantage's wider coverage of the regulatory environment for drug makers.](#)



# Medtech Review 2022

## A year to forget for medtech stocks

After a stormy start to 2022, things have not got much better for medtech players on the stock markets. The sector, once considered a safe haven compared with biotech, emerged from last year just as battered as its more risk-tolerant cousin.

True, a few companies managed to buck the trend and see share price gains, an improvement over the half-year point. But for most of the field 2022 will be a year to forget – and there will be hopes that things do not get worse in the year to come.

The full-year change in indices of listed device makers says it all. After several years of plenty there was a big reversal in 2022, with US stocks hit particularly hard.

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### Indices

Stock index	% change in 2022
Stoxx Europe 600 health care	-8%
Dow Jones US medical equipment index	-20%
S&P composite 1500 healthcare equipment & supplies	-23%

Source: Evaluate Medtech.

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Still, US players accounted for the six big-cap groups that did not see a fall in their share price. Of these, five were risers, although their gains were much less impressive than those that have been seen in previous years.

This cohort includes only companies that obtain more than 40% of their revenues from the sale of diagnostic or therapeutic medical technologies.

Here, the top performer was Insulet, despite the departure of its chief executive officer, and rumours of a buyout by Dexcom that came to nothing. The group's Omnipod 5 is becoming the insulin pump of choice – which is seen as bad news for its rival, Tandem Diabetes Care, one of the mid-cap fallers.

Abiomed's gain was down to its acquisition by Johnson & Johnson, while Boston Scientific was rewarded for strong financial execution.

One of last year's big losers, Philips, made it onto the wrong end of the ledger again following the woes with its sleep and respiratory care business. Its new chief exec, Roy Jakobs, will have his work cut out.

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### Large cap (\$10bn+) medtech companies: top risers and fallers in 2022

	Share price 12-mth change	Market cap 12-mth change (\$bn)	Market cap at Dec 30, 2022 (\$bn)
<b>Top 5 risers</b>			
Insulet (\$)	11%	2.1	20.4
Boston Scientific (\$)	9%	5.7	66.3
Abiomed (\$)	6%	0.8	17.2
Henry Schein (\$)	3%	0.1	10.8
Becton Dickinson (\$)	1%	1.1	72.8
<b>Top 5 fallers</b>			
Align Technology (\$)	-68%	-35.3	16.5
Philips (€)	-57%	-19.5	13.4
Sysmex (¥)	-49%	-15.3	13.3
Straumann (SFr)	-45%	-15.7	17.8
Bio-Rad Laboratories (\$)	-44%	-10.0	12.5

Source: Evaluate Medtech.

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The story was similar among the mid-caps, with most groups experiencing shrinking valuations. The hardest hit, the telemedicine player Teladoc, had also been a pandemic success story, but the company was punished for its unsuccessful acquisition of Livongo.

Two liquid biopsy players also fared badly, with Natera suffering from a short-seller's report and Guardant torpedoed by disappointing data from the Eclipse study of its colorectal cancer screen.

Haemonetics had been the lone riser in the first half of the year – albeit from a low bar – and the blood and plasma specialist continued to climb throughout 2022. It was joined by other players whose earnings impressed: Convatec, which also appears to be coming out of a funk, Merit Medical and Inspire Medical.

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### Mid cap (\$2.5-10bn) medtech companies: top risers and fallers in 2022

	Share price 12-mth change	Market cap 12-mth change (\$bn)	Market cap at Dec 30, 2022 (\$bn)
<b>Top 5 risers</b>			
Haemonetics (\$)	48%	1.3	4.0
Weigao Group (RMB)	32%	1.7	7.4
Convatec (\$)	15%	0.9	6.1
Merit Medical Systems (\$)	13%	0.5	4.0
Inspire Medical Systems (\$)	9%	1.0	7.3
<b>Top 5 fallers</b>			
Teladoc Health (\$)	-74%	-10.9	3.8
Guardant Health (\$)	-73%	-7.4	2.8
Tandem Diabetes Care (\$)	-70%	-6.7	2.9
Natera (\$)	-57%	-4.9	3.9
Masimo (\$)	-49%	-8.4	7.8

Source: Evaluate Medtech.

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The small-cap universe saw bigger gains than the mid and big-cap sectors, as is often the case for this high-risk, high-reward segment of the market. Natus and Meridian Bioscience were buyout stories, while EDAP TMS climbed in the second half of the year after reimbursement was raised for its high-intensity focused ultrasound.

The falls seen by these small companies were also more dramatic than those suffered by their larger cousins. The genetic testing specialist Invitae will hope that cost-cutting efforts will pay off, while Caredx is contending with slowing growth in the organ transplant space.

With macroeconomic factors showing no signs of improving, life could become yet more precarious for many medtech players.

### Small cap (\$250m-2.5bn) medtech companies: top risers and fallers in 2022

	Share price 12-mth change	Market cap 12-mth change (\$m)	Market cap at Dec 30, 2022 (\$m)
<b>Top 5 risers</b>			
EDAP TMS (€)	88%	185	385
Bonesupport (SKr)	83%	221	543
Meridian Bioscience (\$)	63%	568	1,456
Natus Medical (\$)	39%	330	1,140
Apollo Endosurgery (\$)	18%	72	406
<b>Top 5 fallers</b>			
Invitae (\$)	-88%	-3,005	452
Caredx (\$)	-75%	-1,790	611
Fulgent Genetics (\$)	-70%	-2,124	877
Pacific Edge (NZ\$)	-62%	-486	274
Senseonics (\$)	-61%	-698	493

Source: Evaluate Medtech.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of sector share prices.](#)





## Few big bangs in a quiet year for medtech mergers

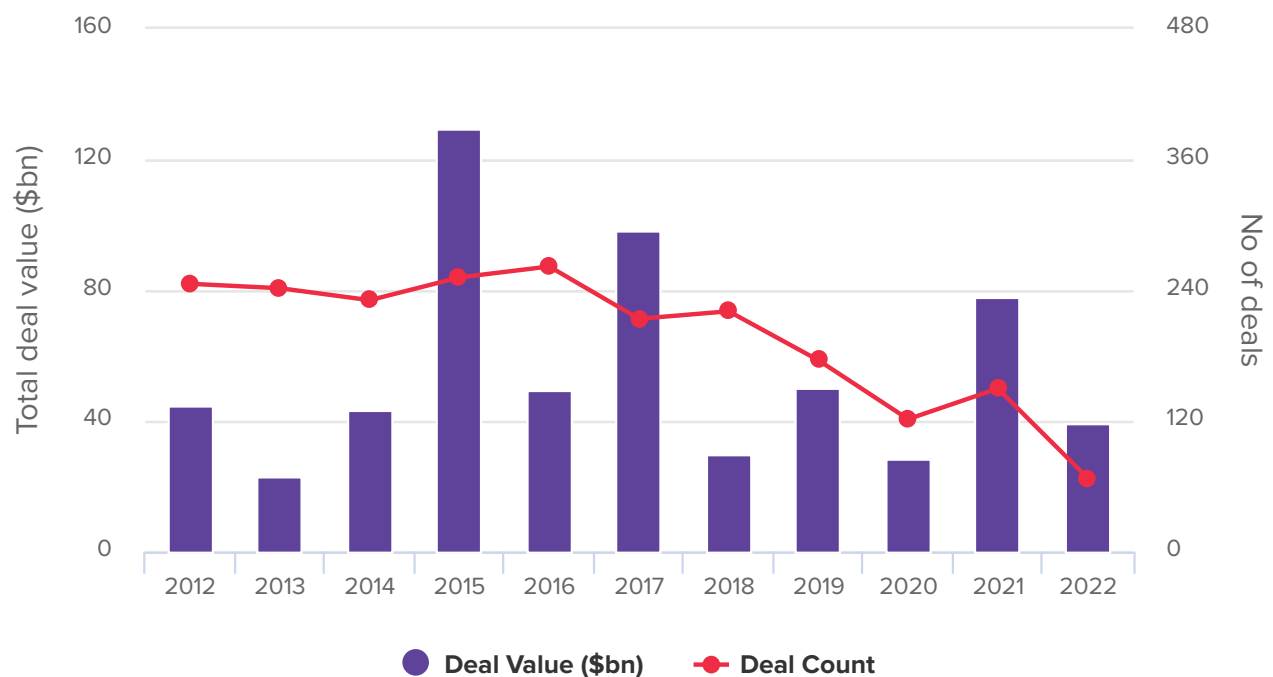
2022 was always going to have trouble following a [bonanza 2021 for medtech mergers and acquisitions](#). In the event, last year turned out to be the most disappointing in recent memory, at least in terms of the numbers of deals closed.

On the plus side, the total spent on buyouts was relatively healthy, and in fact surpassed that seen in three of the past 10 years. However, this was largely down to Johnson & Johnson's \$16.6bn takeover of Abiomed, which accounted for a whopping 42% of M&A spend. Without this transaction, 2022 would have looked very lacklustre indeed.

Remarkably, J&J's Abiomed takeout was the second-largest in the life sciences sector as a whole, behind only Amgen's \$28bn swoop for Horizon. Medtech megadeals on this scale do not come around all that often, so the chances of a big buyout coming to the rescue again in 2023 look slim.

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### M&A over the past decade – number and value of deals closed



Source: Evaluate Medtech.



There are other reasons to be cautious about this year, the consulting company EY notes in its annual M&A Firepower report. Industry-specific issues include hospital staffing shortfalls, which have made it difficult for centres to maintain procedure volumes, and have also driven up payroll costs, leading to cuts elsewhere.

The medtech sector has also been hit by broader financial worries.

Gareth Down, head of European healthcare at the investment banking group William Blair, agrees that there is unlikely to be a big rebound in medtech M&A – at least during the first part of this year.

“A lot of people at the moment are waiting for some balance to come back into the market before they make decisions on transactions,” he tells *Evaluate Vantage*.

How long will this be the case? “I’d like to think that as we get through the year things will ease, and volume and activity will come back normal,” he replies, pointing to the fact that companies – and the private equity community – will need deals to get done.

At least one large deal is already on the books for 2023: Thermo Fisher closed its £2.3bn (\$2.8bn) purchase of The Binding Site in January.

Other big groups that have expressed an interest in buying include Abbott and Medtronic, although they are mostly focused on sub-\$1bn tuck-in deals.

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## Top 5 deals closed in 2022

Completion date	Acquirer	Target	Value (\$bn)	M&A focus
Dec 22	Johnson & Johnson	Abiomed	16.6	Cardiovascular
May 1	Quidelortho	Ortho-Clinical Diagnostics	6.0	In vitro diagnostics
Jan 1	Coloplast	Atos Medical	2.4	Ear, nose & throat; general hospital & healthcare supply
Jan 1	ICU Medical	Smiths Medical, business of Smiths Group	2.4	Anaesthesia & respiratory; patient monitoring
Feb 1	Boston Scientific	Cardiology business of Baylis Medical Company	1.8	Cardiology

Source: Evaluate Medtech.

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The largest deal Medtronic closed last year involved the sinusitis specialist Intersect ENT, which at \$1.2bn made it into the top 10. Of late, that group has been more interested in downsizing, rather than buying.

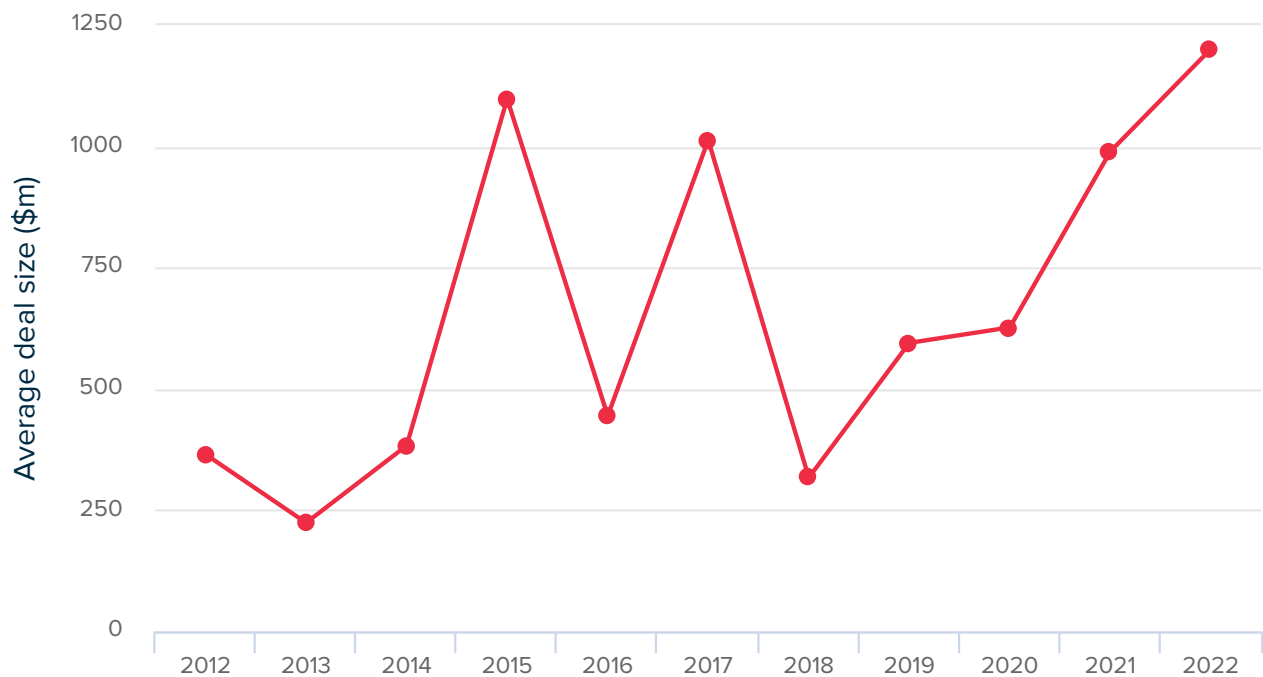
Aside from J&J-Abiomed and Quidel's move on Ortho-Clinical Diagnostics, the other deals in the top five have been about consolidation in the hospital sector.

Average deal size was bumped up by J&J's largesse – without the Abiomed transaction, the average takeout in 2022 was \$719m, short of the mean in 2021.

Still, the overall trend towards fewer, bigger buys seen in the last few years seems to be continuing.

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### Average deal size – deals closed over the past decade



Note: Only includes deals with known value. Source: Evaluate Medtech.

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[See our website for further analyses of these data and Evaluate Vantage's wider coverage of sector M&A activity.](#)

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# Medtech investments hold up despite market turmoil

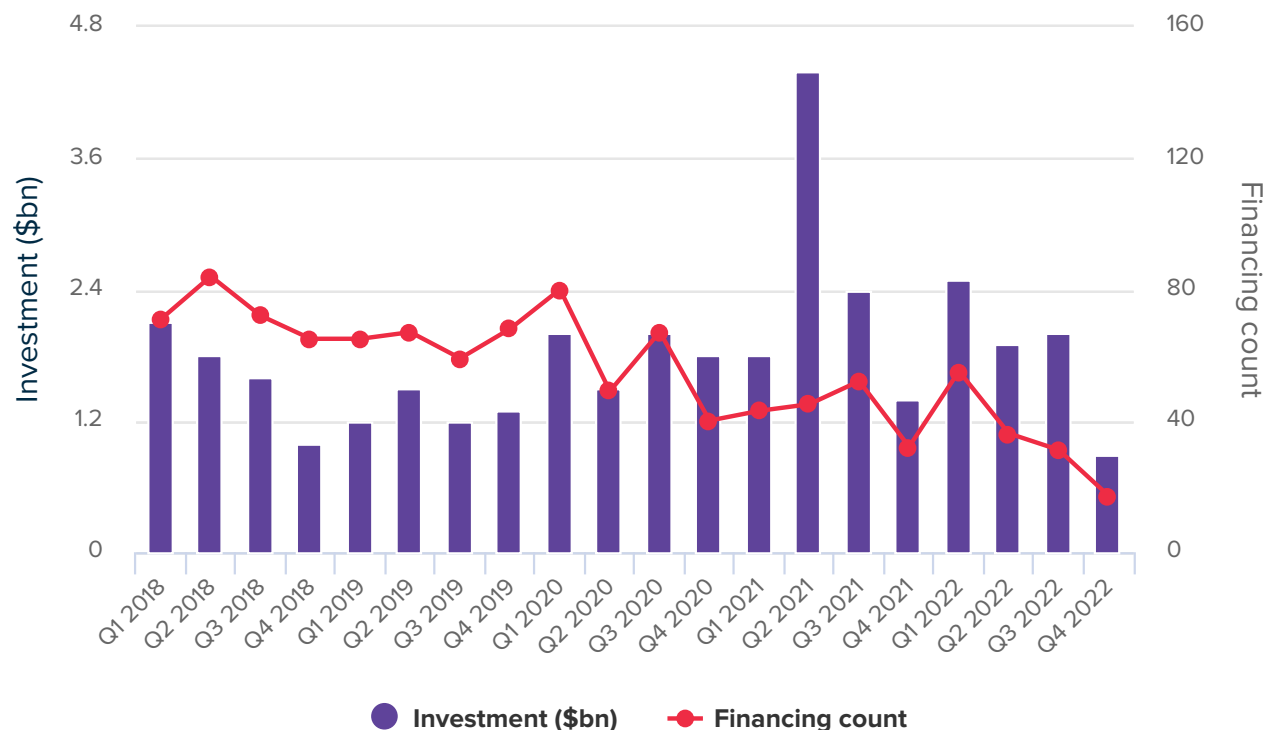
After 2021's \$9.9bn outlier year for medtech venture money, on the surface the \$7.4bn raised in 2022 looks like a return to normality, with last year's tally on a par with the \$7.3bn raised in 2020. But what might come as a concern is the huge fall in both the amount invested and the number of investments seen in the fourth quarter.

The \$900m pumped into private companies in the fourth quarter is the first time the figure for quarterly investment has failed to hit a billion dollars since 2016. And the meagre 17 placements is the lowest number in over a decade. The 139 rounds for all of 2022 was also down significantly, from 236 in 2020 and 259 in 2019.

*Evaluate Vantage* has previously covered the trend of fewer companies getting larger pots of cash, but if the first three months of the coming year – traditionally a strong period for investment – show no sign of recovery then existing concerns about curbs on innovation will only be heightened.

The paucity of flotations is unlikely to help the situation. Venture firms are having to support their portfolio companies for longer, leaving little appetite for new investments.

## VC quarterly investment



Source: Evaluate Medtech.



This analysis incorporates VC rounds from developers of medical devices, telehealth products and diagnostics. It excludes biotech and pharma groups.

For those that did manage to raise venture cash last year, digital health companies were among the biggest winners, with the \$300m series D Biofourmis pulled off in April remaining last year's largest investment. The Boston-based company attracted investors with the promise of AI to monitor the progress of medical treatment, and to deliver at-home care.

Other digital health beneficiaries included Cleerly and Kry International. Cleerly scooped \$223m for its AI software designed to predict the risk of heart attacks. For Kry, however, things have not gone particularly well since its \$160m cash injection in the summer. The Swedish hybrid telehealth and physical care company laid off 10% of its 3,000-strong workforce in October. These job cuts came on top of a 100-person cut in May, and its move to pull out of the German market.

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## Top 10 VC rounds of 2022

Date	Company	Investment (\$m)	Round	Focus
Apr 26	Biofourmis	300.0	D	Digital health
Jul 18	Delfi Diagnostics	225.0	B	In vitro diagnostics
Jul 25	Cleerly	223.0	C	Digital health
Jan 27	Enable Injections	215.0	C	Drug delivery
Jul 21	Kry International	160.0	E	Digital health
Jan 12	Noah Medical	150.0	B	Robotic surgery
Aug 16	AliveCor	150.0	F	Cardiology; patient monitoring
Mar 30	BillionToOne	125.0	C	In vitro diagnostics
Mar 2	Saluda Medical	124.4	D	Neurology
May 27	Biolinq	115.8	B	Patient monitoring

Source: Evaluate Medtech; Vantage; Pitchbook

In vitro diagnostic companies also proved popular with investors, with the liquid biopsy company Delfi Diagnostics and prenatal screening player Billiontoone both managing to make it into the top 10 rounds of 2022. In an indication of just how hot cancer blood testing is, Delfi managed to more than double the amount it raised in a 2021 series A round.

The total amounts raised in 2022 show that not all was bad in the medtech venture world; money is flowing into the sector. But the volatile market conditions that were a feature of 2022 and caused the fourth-quarter slowdown are likely to remain a problem this year, and could increase investor caution.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of venture financing.](#)



# An annus horribilis for medtech flotations

If any more evidence was needed that the IPO window had shut in 2022, look no further than the paltry number of medtech companies that made it onto the market last year.

It was always going to be hard to match the record-breaking 2021, but in a stunning slump only five companies listed in 2022, and there were no new entrants after July – making it the lowest year for IPOs in over five years. Indeed, almost as many new medtech companies were formed by spin-outs.

The total amount raised through listing was also significantly down, with only 2017 recording a lower annual haul. If not for Bausch & Lomb's \$630m debut, 2022 would have seen just \$86.5m raised. Dire market conditions meant that even this profitable eyecare company was forced to price its shares at a 20% discount.

## 2022's medtech IPOs

Date	Company	Focus	Amount raised (\$m)	Premium/Discount	Share price change to Dec 30	Exchange
Feb 16	Meihua International Medical Technologies	General & plastic surgery	36	0%	-17%	Nasdaq
Apr 27	Tenon Medical	Orthopaedics	16	0%	-68%	Nasdaq
May 6	Bausch & Lomb	Ophthalmology	630	-20%	-14%	NYSE
Jul 20	Virax Biolabs	In vitro diagnostics	6.75	0%	-85%	Nasdaq
Jul 21	Lunit	Healthcare IT	28	-35%	-2%	Kosdaq

Source: Evaluate Medtech.



The pain was universal as market volatility, rising interest rates and geopolitical instability hit flotations across the board. The lack of IPO activity after July suggests that investors were taking a wait-and-see approach in the hope of better conditions in 2023. Biopharma also saw one of its worst IPO hauls in years.

Of the companies that did get away none was trading above its float price at the end of December. One of the biggest losers, the UK company Virax Biolabs, has fallen further since the end of last year; now only seven months into its existence as a listed company it is trading 93% below its August high. The company had to raise another \$3.8m just a few months after listing, to fund development of its T-cell test technology.

Tenon Medical only had \$414,000 in revenues, and losses of \$10.4m, in the nine months to September, so the \$16m it raised in 2022 might not stretch too far. The spinal implant company focusing on sacroiliac joint pain will need to ramp up sales of its newly approved surgical fusion technology if it is to arrest its 93% share price slide since hitting a high last May.

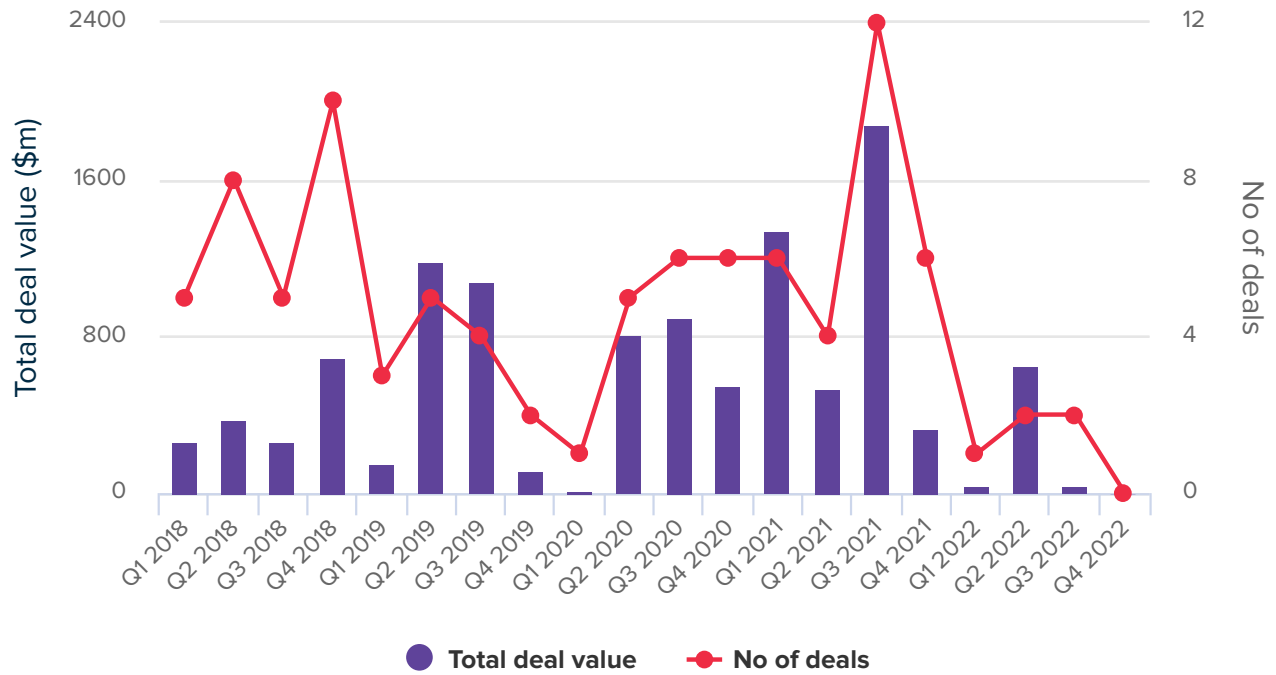
The Chinese hospital equipment supplier Meihua is down 3% from its float price, while Lunit has suffered the least depreciation to its original list price, with shares now up 8% from float. But Lunit did experience one of the biggest haircuts, with the group having to accept a 36% reduction in its original range.

The South Korean group is, however, in the hot space of AI-based medical software, and counts GE Healthcare and Philips among the companies it does business with, something that could account for its shares outperforming fellow debutants.

Although the new year is only weeks old, the factors that caused 2022's market volatility have not gone away. With many predicting a global recession, the options are shrinking for private medtech companies looking to take the next step in their development.



### Quarterly IPOs



Note: Graph does not include IPOs that raised more than \$1bn. Source: Evaluate Medtech.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of sector IPOs.](#)





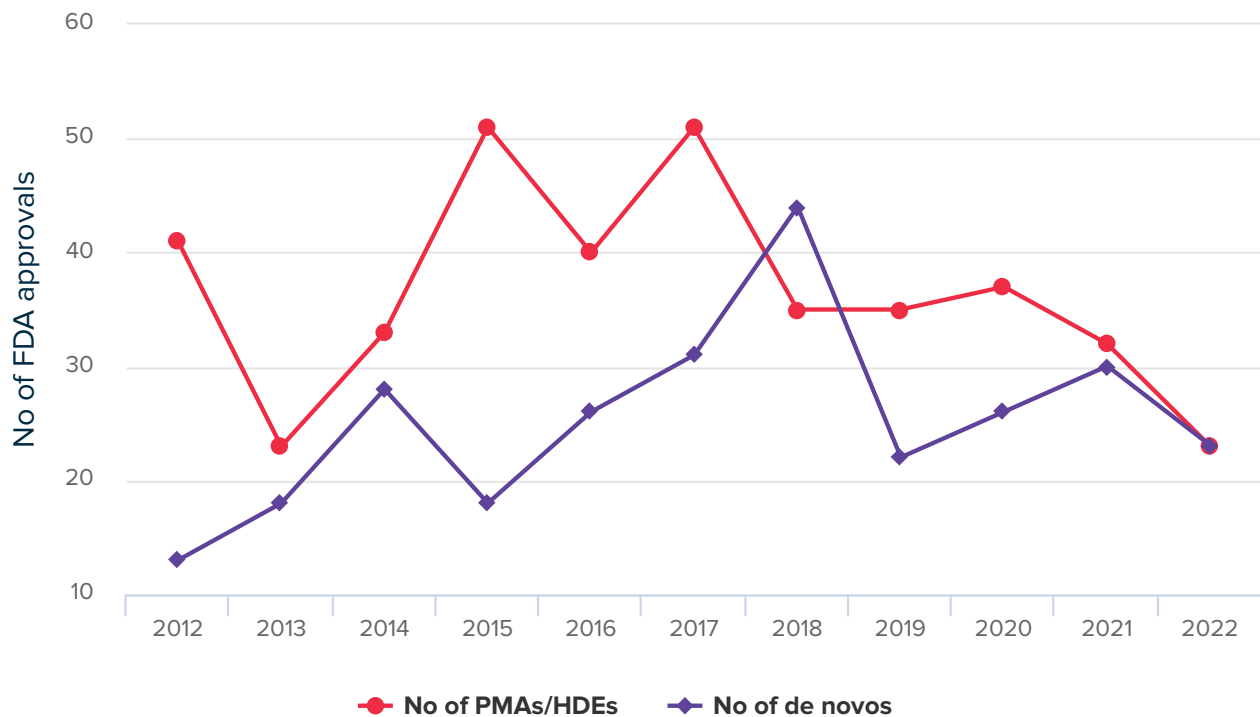
## Medtech approvals stagnate

At the halfway point of 2022 there was hope that the FDA's efforts to increase throughput might lead to an uptick in medical device approvals. However, this optimistic scenario did not play out, and the 46 green lights last year represented the lowest total since 2013.

These approvals also took a relatively long time to come through – although the regulator picked up speed in the second half of the year. With medtech M&A and IPOs faltering amid a broader market malaise, a pick-up in approval numbers will be needed to convince investors of the underlying health of the sector.

This analysis looks at premarket approvals – the route used by high-risk devices unlike anything yet approved – and de novo clearances – the pathway for similarly novel low-risk products. Standard 510(k)s and supplemental approvals are not covered.

### US device approvals over the past decade



Source: Evaluate Medtech.



The 23 PMAs and humanitarian device exemptions took 17.8 months on average, the greatest lag between submission and approval since 2016. Meanwhile, the 23 de novos took a mean 12.7 months.

These are both slower than the speeds seen in 2021, which themselves represented a deceleration from 2020, the peak pandemic year. Such a dropoff is to be expected, with the FDA warning in late 2021 that it was under strain after being deluged by requests for emergency use authorisations.

Still, approvals are taking longer now than pre-pandemic, and industry watchers will not want this trend to continue.

## 2022's approvals by therapy area

Evaluate Medtech classification	PMAs & HDEs		De novos	
	Number	Avg approval time (mths)	Number	Avg approval time (mths)
Anaesthesia & respiratory	2	14.9	2	7.8
Cardiology	8	23.0	-	-
Endoscopy	-	-	3	8.6
In vitro diagnostics	6	11.9	7	18.2
Neurology	2	24.4	1	7.4
Ophthalmics	2	22.5	1	19.0
Orthopaedics	2	6.3	2	8.9
<b>Total</b>	<b>23</b>	<b>-</b>	<b>23</b>	<b>-</b>
<b>Average</b>	<b>-</b>	<b>17.8</b>	<b>-</b>	<b>12.7</b>

Note: table only shows areas with at least three approvals.

Source: Evaluate Medtech, FDA.



The device with the most tortuous path to approval was Abbott's leadless pacemaker Aveir VR, which took over six years to get its PMA. Other cardiology products had a much smoother ride. Edwards' Pascal mitral valve repair system got the nod in September after a review that took just six months. The group could find it tough going up against Abbott's MitraClip, however.

The devices that got to market quickest in 2022, in 4.9 months, were Medtronic's Prodigy traction magnet, used in endoscopic submucosal dissection, and Phagenesis's Phagenyx neurostimulation system for dysphagia.

The in vitro diagnostics sector saw the highest number of approvals in 2022, boosting hopes that things are returning to normal after a couple of years in which the FDA prioritised Covid tests.

Faster review times have also been promised with the Mdufa V agreement signed into law in October. This must all be borne out with a rebound in approval numbers – and the speed at which they are granted – in 2023.



[See our website for further analyses of these data and Evaluate Vantage's wider coverage of the regulatory environment for device makers.](#)

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