Evaluate Vantage 2023 Preview

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Evaluate Vantage

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Contents

FOREWORD	**3**
INNOVATION AND REGULATION	**4**
MONEY MARKETS AND M&A	**10**
CLINICAL CATALYSTS IN 2023	**16**

Foreword

After the market downturn of 2021, 2022 brought little respite to beaten-up biopharma companies. There are some hopes for an improvement in conditions in 2023, though few are expecting a dramatic recovery.

This is partly because the era of cheap money is over. As interest rates rise, the high-stakes world of drug development offers the sort of gambles that many investors no longer need to take. At the same time, the rising cost of capital only makes life more expensive for cash-burning biopharma groups.

For those in need of funds, the start of 2023 is likely to be tough. Many believe an improvement towards the end of the year to be the best-case scenario. Others are bracing for a more protracted slump, caused by global instability and entrenched inflation that is dampening economic growth around the world.

This backdrop should emphasise the so-called "safe haven" attributes of the more established end of the pharmaceutical sector. This means that larger developers could do well next year, particularly if the threat of Zantac litigation continues to fade. Still, several big pharma names are under pressure to fill looming revenue gaps, and the strategic direction and leadership of companies like GSK and Sanofi will be hot topics.

Acquirers will be keen to make the most of compressed valuations in 2023, and opportunistic moves will surely abound. The question of whether bigger deals might occur was answered as this report went to press, with Amgen's $28bn takeover of Horizon. Many are hoping that the coming months will see an uptick in more sizeable transactions.

No such explosion is expected in the IPO world, with the window effectively shut. This means that the venture world is also likely to slow again in 2023. After years of plenty, the private world is well stocked, although all eyes are on valuations – could 2023 be the year of the down round?

Life is harder on the public markets. A big proportion of listed developers will be starting the year trading below cash, and some will not see the start of 2024. Perhaps 2023 will see a resurgence reverse mergers. The sector also feels ripe for investor activism.

Biopharma desperately needs to deliver clinical successes in 2023, to help remind investors why this sector can be worth the risks. Areas of focus next year include Alzheimer's disease, where Eisai and Lilly are hoping to succeed where Biogen failed. And respiratory syncytial virus could become a battleground, with several big names starting to contest the space.

Investors will also be looking for signs that the nascent gene therapy and gene editing fields are maturing and gaining the confidence of regulators. The cancer field, which has attracted huge amounts of money over the past five years, also needs to show that it can deliver new mechanisms.

Not everything needs to work, but in a bear market bright spots are desperately needed. At least the regulatory climate looks set to improve: Evaluate Omnium predicts an uptick in FDA approvals next year, after a slowdown in 2022.

Evaluate Vantage's preview of 2023 seeks to describe these and other challenges facing biopharma in the coming months, as well as the many opportunities that will present themselves. For the first time, the report includes the thoughts of almost 150 public and private investors, bankers and industry employees who responded to our poll.

Read on to discover their opinions on what might be coming next year for IPOs and M&A, as well as several other data-driven analyses of sector performance. We also include Evaluate Pharma's forecasts of the fastest-growing drugs, most valuable R&D projects and most important regulatory approvals – all of which will shape the biopharma sector in 2023, and beyond.

All data pulled and analysed in early November 2022.

INNOVATION AND REGULATION

Growing biopharma's top line: drugs

MAbs and jabs are set to dominate 2023's biggest-selling drugs, in terms of forecast annual revenues as well as new sales generated over 2022. Four products make it into both tables, a result of the huge demand and pricing power that these brands command.

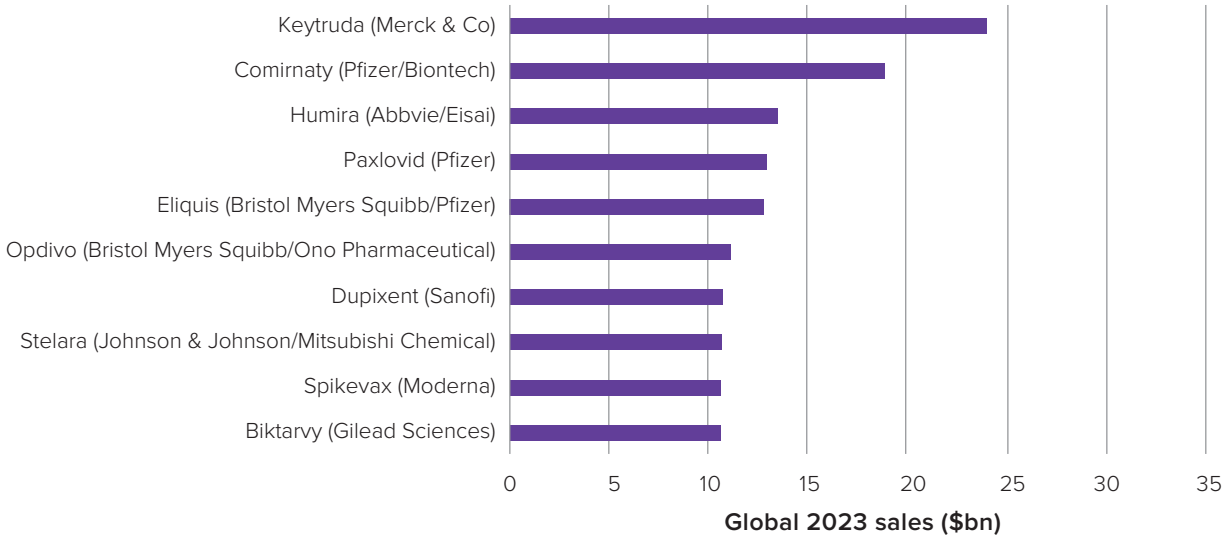
Merck's PD-1-targeted Keytruda is projected to become the world's top-selling medicine next year, and remarkably is also seen adding almost $3bn in new sales in 2023. The checkpoint inhibitor is currently approved in 38 settings across 18 tumour types; perioperative use is expected to drive much of the growth for the PD-(L)1-targeted mechanism in the coming years.

Keytruda will take the top spot from the Covid vaccine Comirnaty, which itself supplanted Humira in 2021. Biosimilars against the Abbvie anti-rheumatic will arrive in the US in January 2023, 20 years after Humira was first launched; how quickly sales will be eroded by lower-cost competition is an open question.

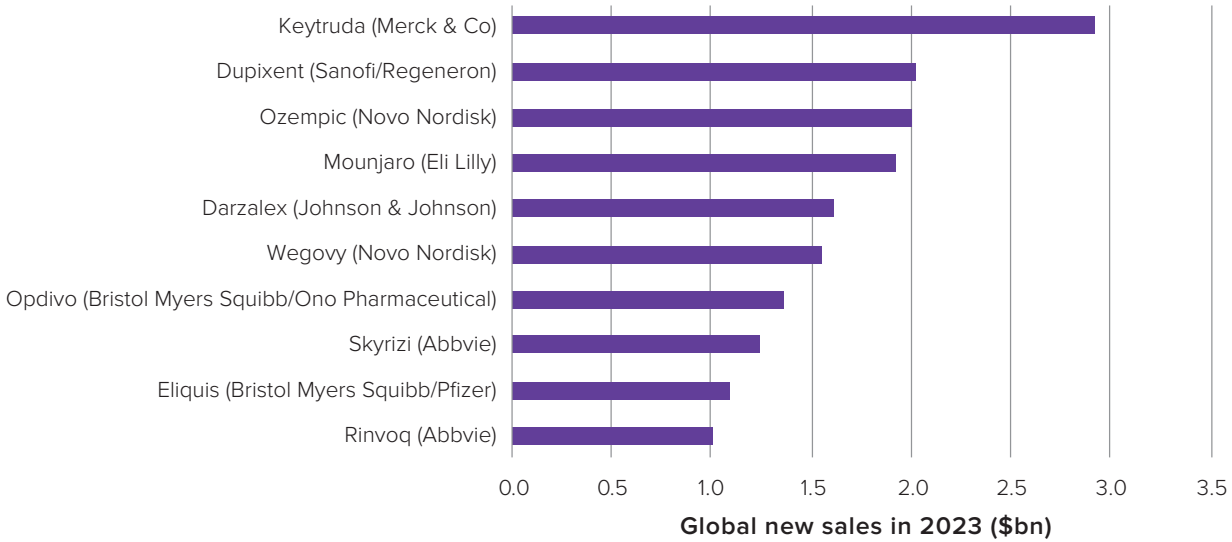
Covid remains an uncertainty next year. Forecasts have been coming down over 2022, and for now the world is well stocked with pandemic products. Much still depends on what the virus does in the coming months or years, in terms of rendering existing treatments ineffective.

For now, these Covid products are seen pushing drugs like Regeneron's Eylea and Novo Nordisk's Ozempic – names that are likely to feature in coming years – out of the top 10. The diabetes drug Ozempic does make it into the fastest growers, with a forecast $2bn in new sales on the way in 2023. Lilly's newly launched Mounjaro is the product to watch, however. An incredibly strong launch has sent forecasts shooting higher, and the biggest risk for now is that Lilly will not be able to make enough to keep up with demand.

Top selling drugs in 2023



Biggest new sales generators: drugs



Note: includes sales booked by global partners, where relevant.

Source: Evaluate Pharma and Evaluate Vantage.

Growing biopharma's top line: companies

Sales of Comirnaty and the Covid antiviral Paxlovid are expected to keep Pfizer at the top of the table next year, in terms of prescription drug sales. Even the might of Keytruda cannot help Merck & Co, in second place, close the gap. But with waning demand for pandemic products, Pfizer's pole position is not likely to last much longer.

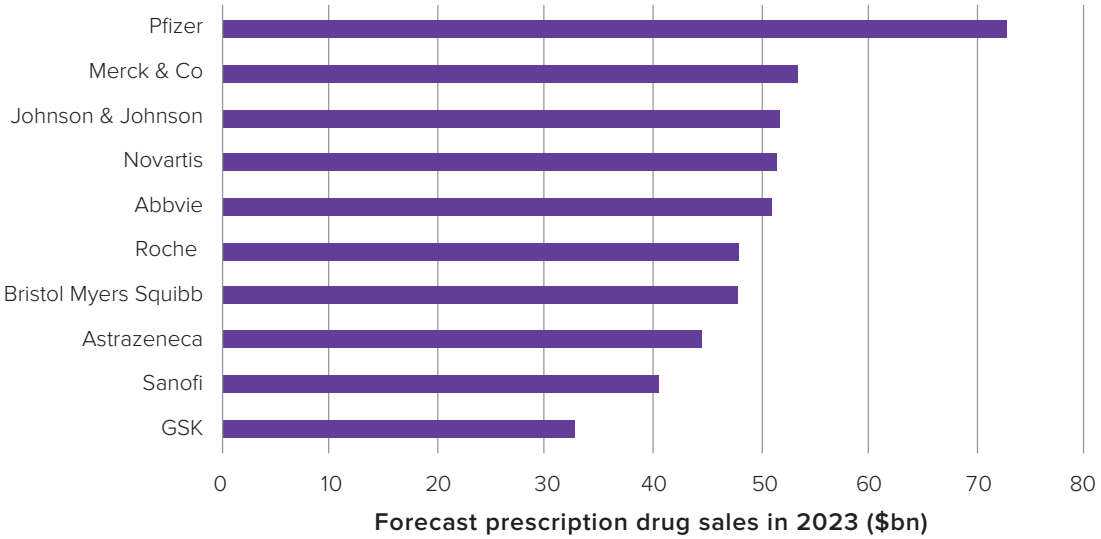
The list of companies with fast-growing top lines looks quite different from the top 10 by sales. Novo Nordisk and Lilly feature because of high demand for the type 2 diabetes and obesity agents that were highlighted in the previous analysis – Ozempic, Wegovy and Mounjaro. Huge expectations behind the last of those, Lilly's newly launched dual GLP-1/GIP agonist, mean that the group is likely to move into the top 10 companies by sales in coming years.

Several non-big pharma names feature in this second analysis. CSL is riding surging demand for immunoglobulins, while last year's acquisition of Vifor is also giving the Australian vaccines and blood products group a boost. Grifols is another big player in the blood plasma and immunoglobulin space.

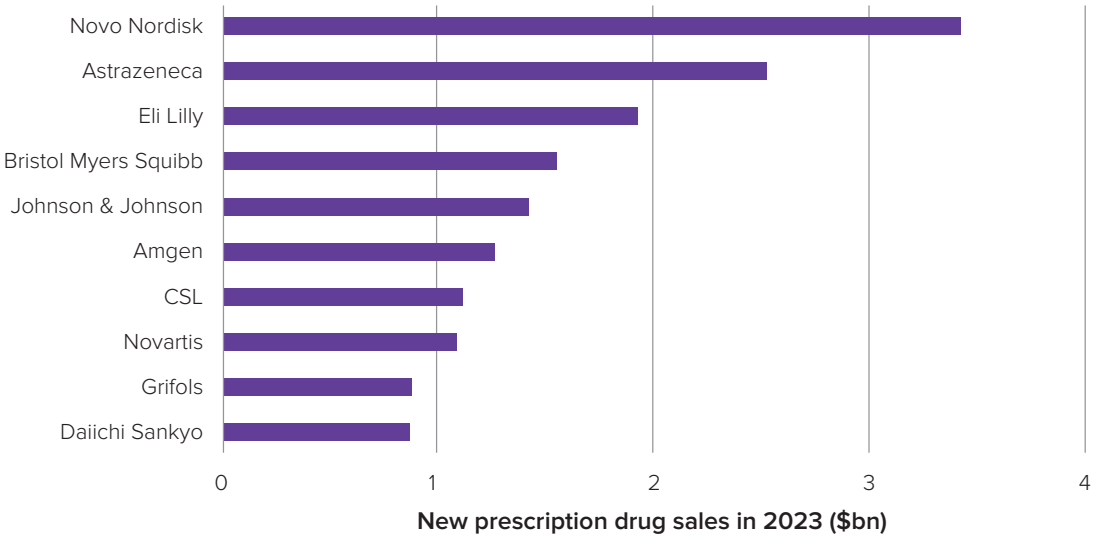
The Japanese developer Daiichi Sankyo has the Astrazeneca-partnered Enhertu to thank for its growing top line. The Her2-directed antibody-drug conjugate is making fast inroads into breast cancer on the back of highly impressive clinical data.

Astrazeneca's success in oncology more widely is largely responsible for its showing here, as well as the group's move into rare diseases via its 2020 Alexion acquisition. That deal brought the fast-growing brand Ultomiris, which is sold for various autoimmune conditions.

Biggest companies in 2023



Biggest new sales generators: companies



Source: Evaluate Pharma and Evaluate Vantage.

Waiting in the wings: biggest launches

Alzheimer's disease will be a major focus for biopharma followers next year, as Eisai and Lilly attempt to get their respective amyloid plaque-clearing antibodies onto the market. The read out of donanemab's pivotal trial in mid-2023 is likely to be one of the biggest events for the sector next year.

Securing full reimbursement in the US is also likely to take time, should FDA approvals be won. This uncertainty makes it hard to estimate how quickly sales of lecanemab and donanemab might build. The same can be said for Sarepta and Roche's gene therapy for Duchenne muscular dystrophy; predicting demand is hard owing to lack of precedents, and securing reimbursement for what will be a very expensive product is bound to present a problem. Regulatory risks should also not be ignored.

Another space on which opinions are divided on the size of the opportunity is respiratory syncytial virus, an infection that vaccine makers have finally managed to hit after years of trying. GSK is seen as ahead here although Pfizer is close on its heels, and late-stage readouts from the likes of J&J and Moderna are due soon.

Apellis's progress with its geographic atrophy project will be closely watched after the company rattled investors by filing more data with the FDA during the review process, a move that delayed the PDUFA date by three months. Only one of the company's two phase 3 trials hit, and while a green light is expected a positive outcome is far from assured. Under normal circumstances an advisory committee would have reviewed the submission, but the FDA's ophthalmic committee has not resumed its panel hearings in the wake of Covid, making the verdict even harder to call.

Biggest potential launches of 2023

Project	Companies involved	Description	Status	2028e sales
Lecanemab	Eisai/Biogen	Anti-amyloid-beta MAb for Alzheimer's disease	PDUFA Jan 6, 2023 (accelerated approval)	$3.0bn
SRP-9001	Sarepta/ Roche	Gene therapy for Duchenne muscular dystrophy	PDUFA May 29, 2023 (accelerated approval)	$2.2bn
Intravitreal Pegcetacoplan	Apellis	Complement factor C3 inhibitor for geographic atrophy	PDUFA Feb 26, 2023; EMA filing planned for December 2022	$2.0bn
Donanemab	Lilly	Anti-amyloid-beta MAb for Alzheimer's disease	FDA decision on accelerated approval expected in February 2023	$1.9bn
RSVPreF3 OA (GSK3844766A)	GSK	Vaccine for older adults against respiratory syncytial virus	PDUFA May 3, 2023. European approval likely mid-late 2023	$1.8bn
Epcoritamab	Abbvie/ Genmab	Anti-CD20 bispecific for lymphomas	PDUFA May 21, 2023 (possibly accelerated decision), filed in EU, for diffuse large B cell lymphoma	$1.7bn
Zuranolone	Biogen/ Sage	Gaba A modulator for major depressive disorder and postpartum depression	NDA for MDD and PPD to be completed by YE'22 with potential for priority review. Analysts assume mid-late 2023 US approval	$1.5bn
Mirikizumab	Lilly	Anti-IL-23 MAb in development for ulcerative colitis and Crohn's	PDUFA date May 2023 (ulcerative colitis). MAA filed Q1'22, decision expected 2023	$1.2bn
Etrasimod	Pfizer	S1P 1 modulator for ulcerative colitis	Regulatory filings planned for 2022. Analysts assume late 2023 launch	$1.2bn
Sotatercept	Merck & Co	Activin receptor 2a regulator for pulmonary arterial hypertension	Filing expected early 2023. Fast track/breakthrough designations in place in US and Europe. Analysts assuming late 2023 launch	$1.0bn

Source: Evaluate Pharma and Evaluate Vantage

Waiting in the wings: R&D projects

Moving on to projects coming behind those already filed with regulators, two novel antibody-drug conjugates from Daiichi Sankyo stand out. The Japanese group hopes to build on the success of Enhertu, and a pivotal readout early next year for a second Astrazeneca-partnered project, datopotamab deruxtecan, is a big event for both companies and the ADC space more widely.

Elsewhere, talquetamab was one of the stars of Ash in 2022 and all eyes are on how J&J decides to push forward here – either seeking an early approval for the bispecific in a small use or waiting for controlled data in earlier myeloma settings.

Karuna delivered a rare win in the psychiatric space in 2022 with its novel schizophrenia project KarXT. More data are expected in 2023 and the company plans to file for approval mid-year. Some huge expectations lie behind the agent, and while the company has said it wants to launch the drug itself in the US many believe Karuna is a takeover target.

Intellia and Regeneron, meanwhile, are waiting for the FDA to green light the start of clinical trials of NTLA-2001 in the US. The agency's caution around certain gene-editing projects is a theme to watch for 2023.

Finally, tiragolumab is included here despite huge doubts around the anti-Tigit mechanism. Forecasts for the Roche MAb have more than halved since the first phase 3 readouts disappointed, but with Merck & Co also heavily invested here this approach remains of interest for now.

Ones to watch: biopharma's most valuable R&D projects

Project	Companies involved	Description	NPV
Datopotamab deruxtecan	Daiichi Sankyo/ Astrazeneca	Trop-2 targeted antibody-drug conjugate; first phase 3 data due H1'23	$9.6bn
NTLA-2001	Intellia/Regeneron	Crispr-Cas9 gene editing therapy for hereditary transthyretin amyloidosis; further cuts of ph1 data due over 2023, pivotal plans awaited	$6.3bn
Nipocalimab	Johnson & Johnson	FcRn antagonist for autoimmune conditions; ph3 in myasthenia gravis ongoing, further pivotal plans awaited	$5.4bn
mRNA-1647	Moderna	Cytomegalovirus vaccine; ph3 ongoing	$4.7bn
Talquetamab	J&J/Genmab	T-cell redirecting bispecific targeting GPRC5D for multiple myeloma; mid-stage readouts due over the year	$4.5bn
KarXT	Karuna Therapeutics	M1/M4-muscarinic agonist for schizophrenia; pivotal programme ongoing, further data and US filing slated for 2023	$4.2bn
Aficamten	Cytokinetics	Cardiac myosin inhibitor; ph3 data in hypertrophic cardiomyopathy due H2'23	$3.7bn
Tiragolumab	Roche	Anti-Tigit MAb; further overall survival readouts due in 2023	$3.2bn
Patritumab deruxtecan (U3-1402)	Daiichi Sankyo	Her3 targeted antibody-drug conjugate for for breast and lung cancer; potentially pivotal ph2 data due 2023	$2.9bn
CTX001 (exagamglo-gene-autotemcel)	Crispr/Vertex	Crisr-Cas9 gene editing therapy for sickle cell disease and beta-thalassaemia; US and European filings anticipated by Q1'23	$2.4bn

Source: Evaluate Pharma and Evaluate Vantage

The regulatory environment: reading the runes

Next year should see a return to the 50+ novel approvals that has become the norm in recent years, after a dip in 2022. This is according to Evaluate Omnium, which has pinpointed 57 agents with a high probability of reaching the finish line in 2023.

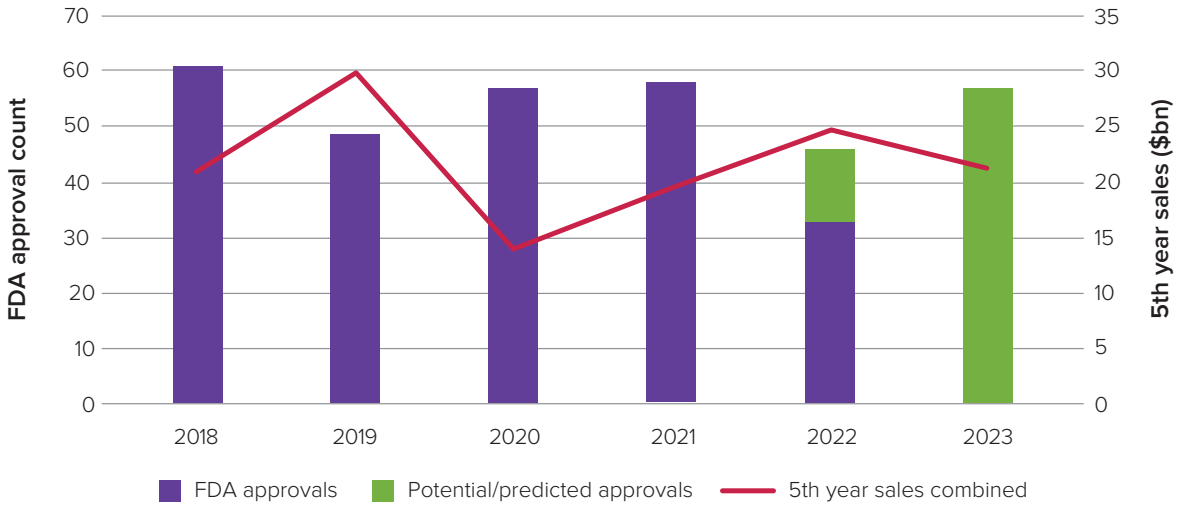
Should this come to pass it would mean that the apparent slowdown in 2022 was just a blip rather than any tapping of the breaks by the FDA. This should provide some reassurance to a sector heading into another tough year on the financing front.

Much focus in 2023 is likely to fall on the accelerated approval pathway, where the FDA has been tightening up. The agency and industry have been criticised for foot-dragging when it comes to demanding and providing confirmatory evidence, but it is becoming clear that this permissive period is over.

Data provided by the agency point to a big drop in the number of conditional approvals granted, with 2022 way down on previous years. It is worth noting that 2020 was boosted by 16 applications by Merck & Co for alternative Keytruda dosing regimens. Even removing these, the 29 accelerated approvals granted that year is likely to be the peak.

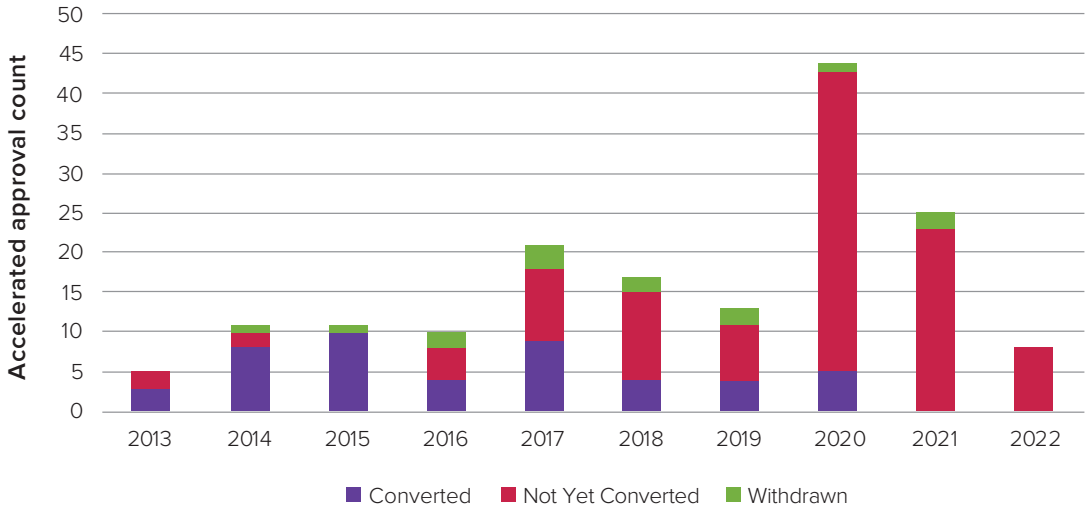
The FDA is making it clear to developers that confirmatory phase 3 trials must be well under way before the accelerated pathway can be considered. It is also ensuring that drugs are pulled swiftly from the market should firm evidence not arrive. This tightening means that smaller developers hoping to use this pathway to generate early revenues must think again. And further change might also be on the way. More extensive reform of the accelerated approval pathway was dropped in the recent user fee reauthorisation, but advocates have every intention of trying again in the coming months.

Tracking US approvals: back to business in 2023?



Note: Count includes novel therapeutics approved by both CDER and CBER. Source: FDA and Evaluate Pharma for 5th year sales.

FDA tightens up on accelerated approvals



Note: 2022 count to end September. 2020 inflated by 16 accelerated applications by Merck & Co for alternative Keytruda dosing regimens. Source: FDA.


MONEY, MARKETS AND M&A

Stock market performance

The protracted downturn from the peak of the market in early 2021 looks to have bottomed out, at time of writing in November 2022, although sentiment is expected to remain depressed throughout 2023. The war in Ukraine and rising global interest rates will remain live issues next year, providing a poor backdrop for the high-risk drug development sector.

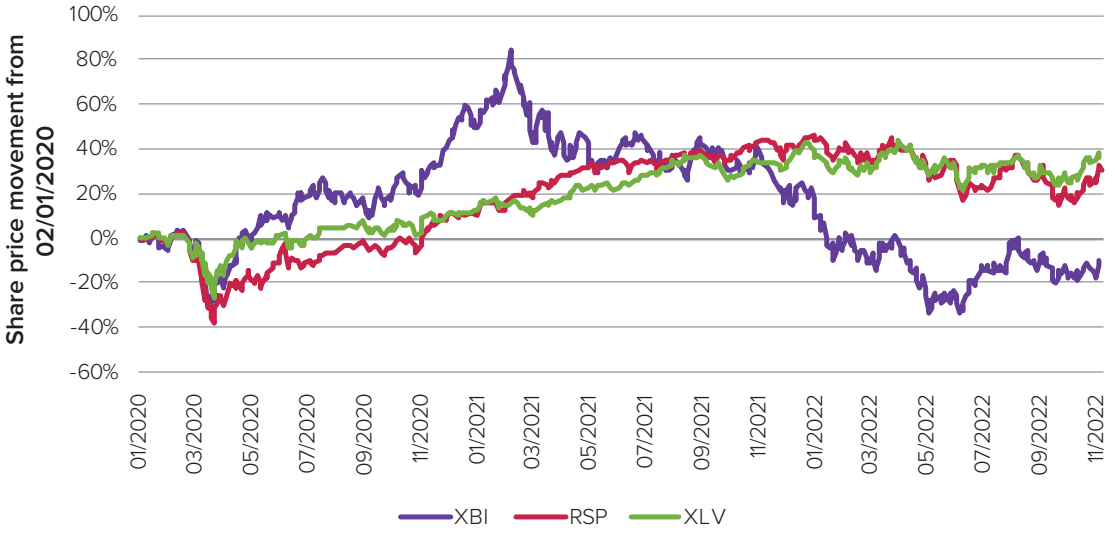
Even so-called "safe haven" big pharma names could struggle next year, with investors concerned about the impact on future earnings from drug price reform in the US. As a result of the November mid-terms the US has a divided government, dashing industry's hopes that a Republican majority could weaken certain aspects of the Biden administration's Inflation Reduction Act (IRA), enacted in August 2022.

The Democrats' ability to strengthen the law, for example by expanding the number of drugs included in new Medicare negotiations, has also been blown. Either way, the fallout of the IRA remains hard to predict, and figuring out its longer-term implications will be a big focus in 2023.

It is smaller, cash-hungry developers that will take the brunt of inclement market conditions next year, however. Should the poor financing climate persist throughout 2023 – few harbour hopes for any improvement in the first half of the year – the sector will inevitably see more cash conservation efforts. This means portfolio prioritisation, job cuts and deals struck out of desperation – and a rise in investor activism.

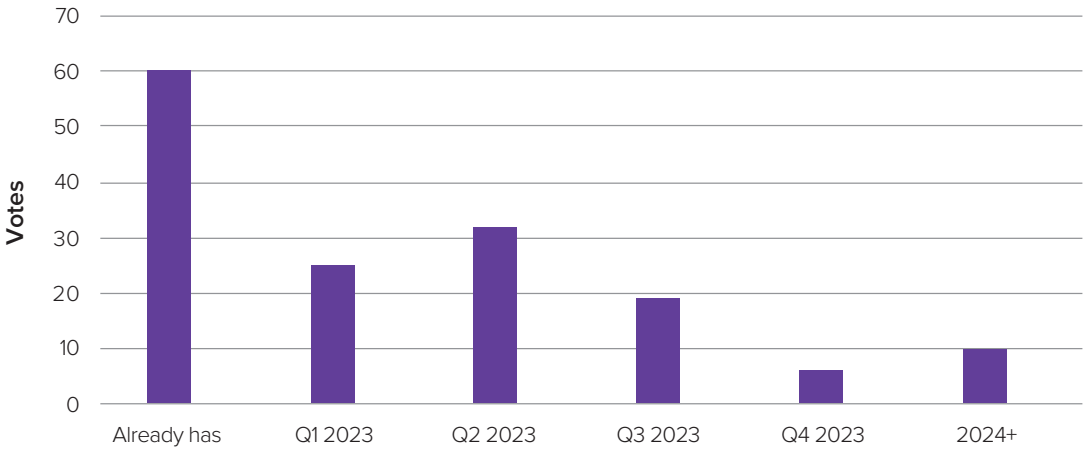
Encouragingly, a survey conducted by Evaluate Vantage for this report found that most sector followers believe that the US biotech market has already hit the bottom. A sizeable proportion of responders think that the market still has further to fall in 2023, however. All of this suggests that those developers already struggling with financing will find little respite in the coming months.

Stock market performance



Note: This chart shows three equal weighted exchange traded funds tracking US listed companies. XBI includes biotech stocks from across the market cap spectrum. XLV includes healthcare equipment and medtech as well as pharmaceutical companies. RSP includes all stocks in the S&P 500.

When will the US biotech market hit the bottom?



Note: Survey conducted in early November 2022. Reponses are from public and private investors, bankers and other biopharma industry employees.

Thoughts on the IPO window

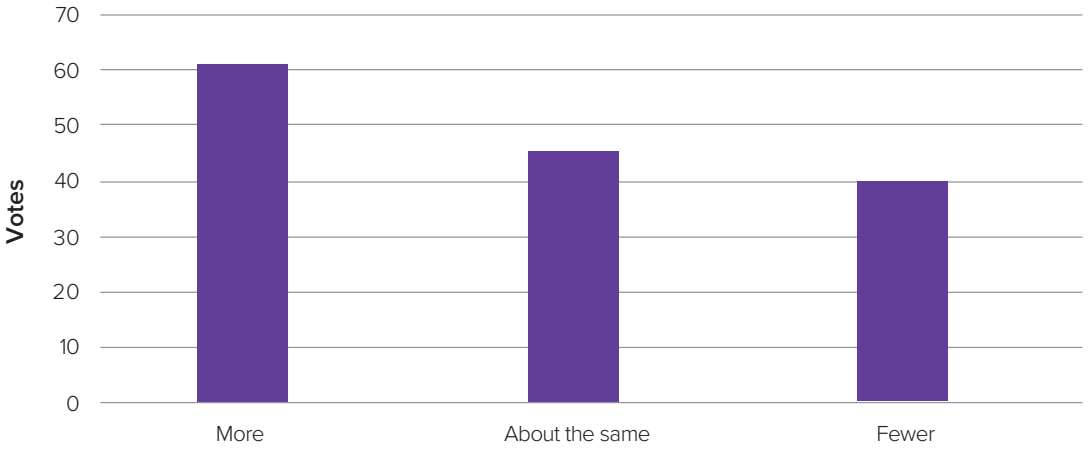
The health of the IPO market is a strong proxy for investors' appetite for high-risk biotech, and it is clear from 2022's record that sentiment is poor. By the end of the third quarter 16 pure-play drug developers had floated on Western exchanges, a big drop on the previous few years. Eight managed to raise more than $100m, pointing to some latent support for certain offerings, although these flotations required substantial insider support to get away.

In our survey, 41% of respondents expect to see more of these larger offerings in the US next year. This proportion is not vastly ahead of the 31% of people who think 2023 is likely to look the same as 2022, however. It is comforting that the smallest proportion of responders reckon the IPO market will retrench further.

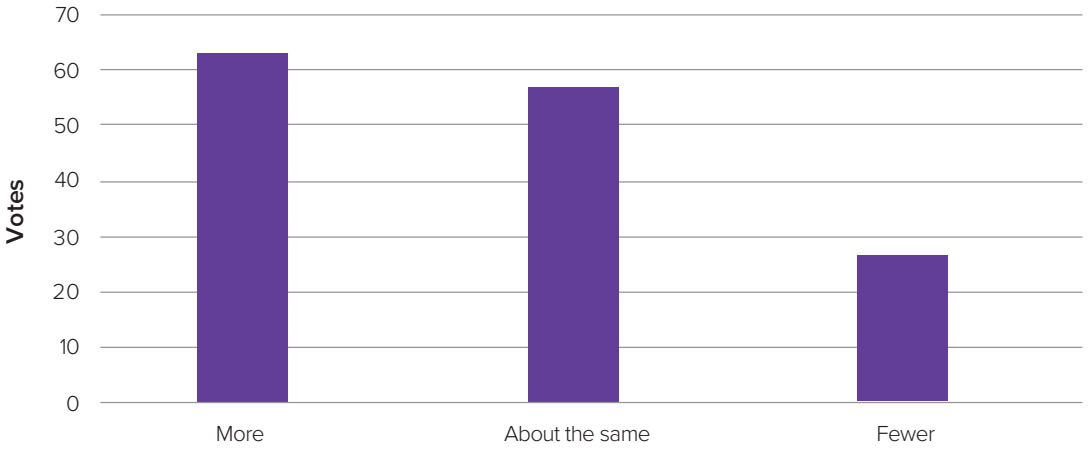
When it comes to Europe most respondents expect the situation to improve in 2023, although the continent's IPO market could not get much worse. At time of writing only one biotech, Aelis Farma, had managed to float in the region in 2022. Even if volumes stay the same next year, as 39% of people in our poll reckon, this will still equal a dire financing situation.

The US market will inevitably recover first, which means that Europe-based developers with public ambitions and sufficient support will likely have to turn to Nasdaq rather than Euronext.

Eight pure-play drug developers raised more than $100m at IPO in 2022. How many flotations of this size will we see in 2023?



One pure-play drug developer floated in Europe in 2022. What will we see in this region in 2023?



Note: Survey conducted in early November 2022. Reponses are from public and private investors, bankers and other biopharma industry employees.

IPOs: historical performance and future trends

Those looking to apportion blame for the bursting of the biotech bubble frequently point fingers at the IPO market, and the flood of early-stage companies that arrived in 2020 and 2021. A look at the disappointing performance of recent new issues shows why investors have cooled, although it should be remembered that the whole market is also significantly down.

By comparison, the class of 2022 is faring fairly well, although many of the groups in this cohort have yet to reach milestones. Small deals are a feature of the downturn: six of 2022's 16 IPOs raised less $20m, and four of these groups are already trading more than 60% below their offer price.

These developers have struggled to hold onto their valuations post-float because in most cases the IPO failed to satisfy funding needs. Until the market starts supporting larger raises again, it is hard to see the volume of flotations rising.

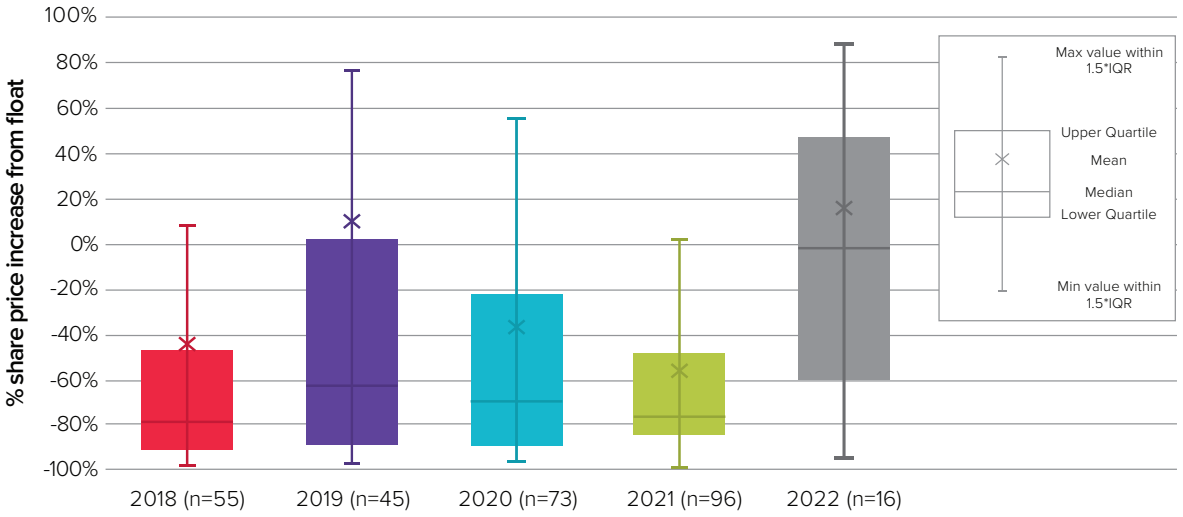
The type of companies being supported by investors next year is also a trend to monitor, in terms of assessing any potential fallout from the IRA. Critics contend that the new law makes small-molecule investments less attractive than those in biotech products, because the former can be selected for Medicare price negotiations seven years after approval, and the latter after 11 years.

Some companies have already blamed this disparity for deprioritising certain assets. Certain investors claim to be changing how they value opportunities. If the IRA really is shifting allocation of capital, this will turn up in the data.

To kick off the monitoring of this trend *Evaluate Vantage* split recent IPOs into technology type – biotech or small molecule – a measure that is also a proxy of sorts for venture investment trends. The split over the last five years is almost even, with 48% of new issues built on the former and 52% on the latter. That proportion will shift towards biotech if the aforementioned concerns prove accurate.

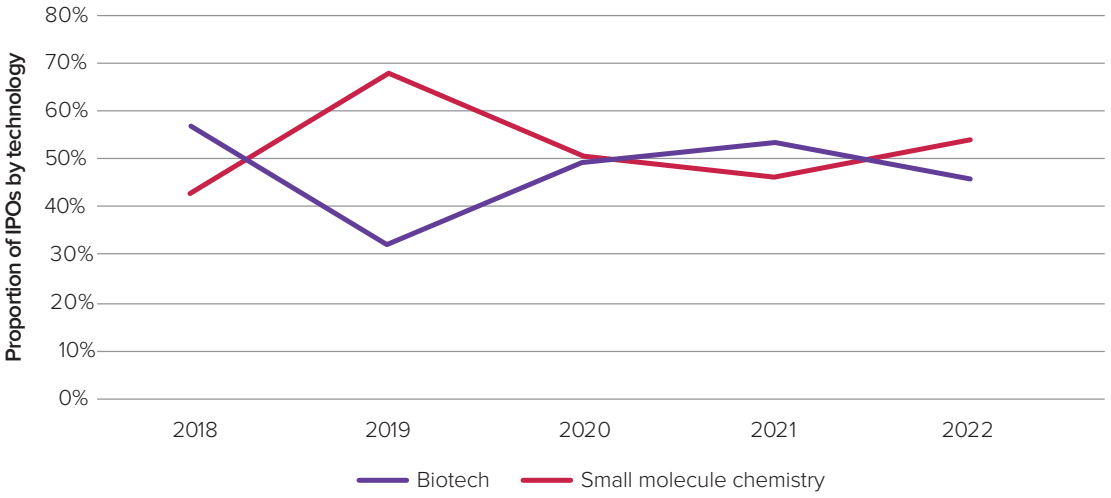
INNOVATION AND REGULATION

Performance of annual IPO cohorts, to November 2022



Note: IPOs of pure-play drug developers on Western exchanges only. Only includes companies still trading, so excludes M&A or reverse merger targets, bankruptcies etc.

Tracking the impact of IRA: IPOs by company technology



Note: IPOs of pure-play drug developers on Western exchanges only. Sectors like medtech and digital health excluded.

Venture funding: circle the wagons

The venture capital world has also been feeling the pain of the biotech bear market, and 2023 is likely to see further retrenchment. Many firms are well stocked for now, but with the investment world "risk-off", the days of largesse are over.

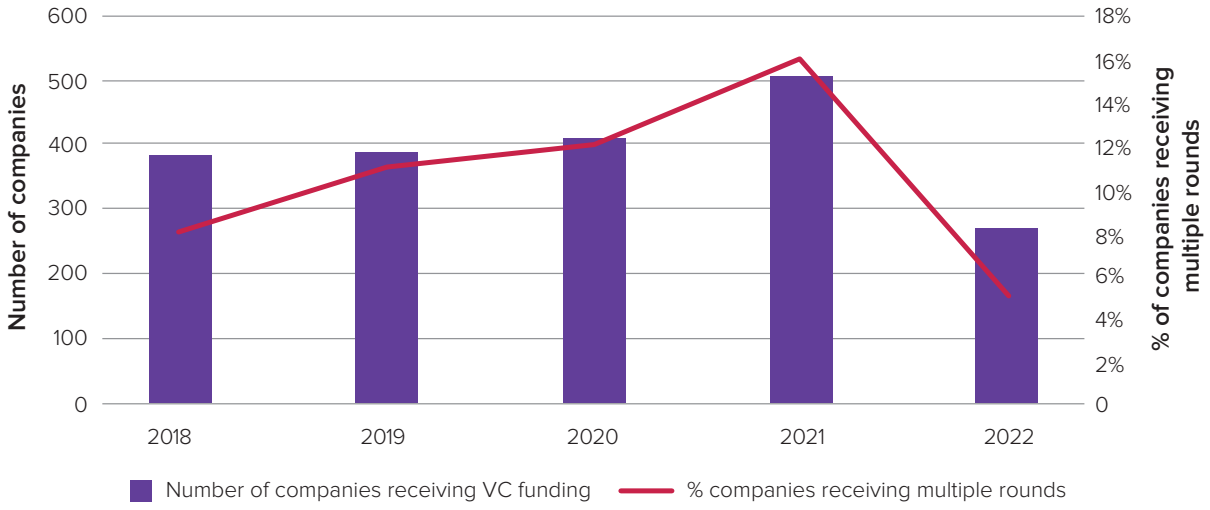
The shutting of the IPO window has also had a big impact on the private world. Deep-pocketed crossover investors who supported large pre-flotation rounds have retreated, and traditional venture funds cannot pass on their portfolio companies as quickly.

Make no mistake – the financing wheels were spinning fast in 2021. A remarkable 16% of venture-backed companies received more than one round of financing that year, a figure driven by the wide-open IPO window. In 2022 that number is sitting at 5%, and while the year is not yet over, the absence of flotations means it is unlikely to move higher.

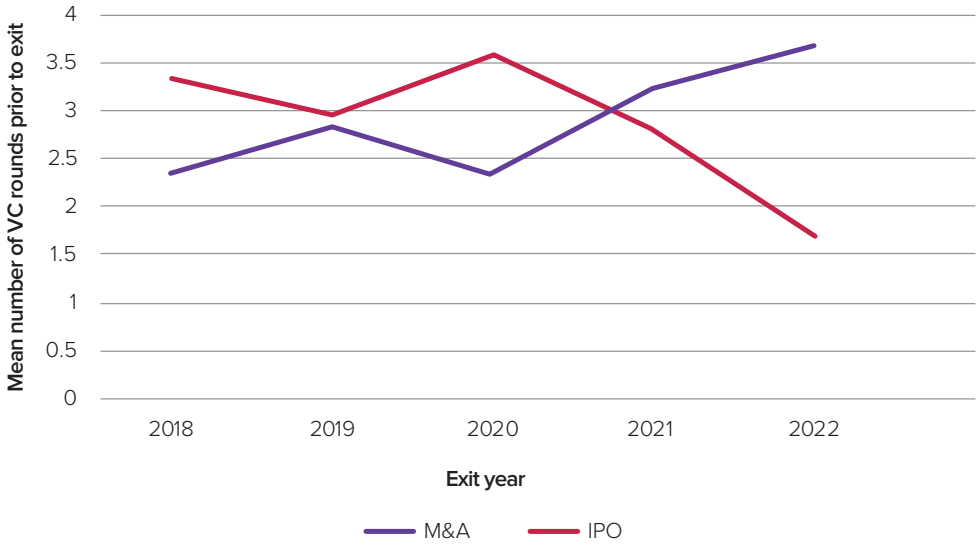
The second chart maps out another trend that will be monitored next year – the average number of venture financing rounds a company receives before floating or being bought. With the IPO window all but shut, being able to exit an investment via acquisition has become an even juicier prospect for these funds.

Again, 2022 is not yet over but investors have had to wait longer for this year's buyouts, with developers having received almost four rounds of investment ahead of a deal. Venture firms will not want to see that line creeping higher.

The money wheels are slowing down



Heading for the exit



Note: all data concerns deals and financings struck by global, pure-play drug developers only. Sectors like medtech and digital health are excluded. 2022 data to mid-November. Source: Evaluate Pharma.

M&A: potential targets

2022 was not a terrible year for M&A but, at the time of writing in late November it had not delivered the big bang that many were hoping for. A sizeable deal looks to be brewing, however, with Horizon Therapeutics confirming preliminary interest from Amgen, Johnson & Johnson and Sanofi.

With three marketed products Horizon has long been considered desirable, and disagreement over valuation is probably the only barrier to this happening. The developer was highlighted as a target by respondents to our poll; Biogen and Vertex were also popular choices, and all would represent very sizeable transactions. Analysts reckon Horizon could go for $25-30bn, which would make it the biggest biopharma deal since Astrazeneca announced its takeover of Alexion in late 2020.

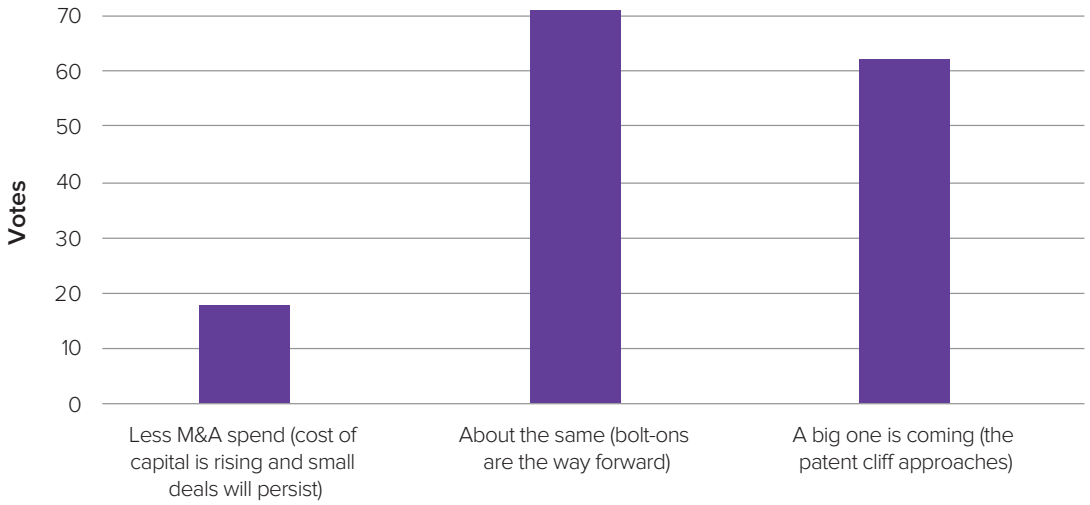
A good proportion of respondents to our survey were hopeful that 2023 would be a bigger year for M&A than 2022, although most expect more of the same. That means a healthy flow of mid-sized transactions, as well as plenty of deals done out of desperation. With valuations still at rock bottom more developers will be faced with the choice of giving up or selling out.

Next year is also likely to see a good number of reverse mergers, particularly if the IPO window remains closed. Also consider the cash-rich preclinical companies that amassed funds in the boom but are now struggling to keep investors interested. Could they come to the rescue of some more advanced but cash-strapped developers?

Another possibility is a rise in collaborations between biotechs and the firms that are typically contracted to carry out the work – could this era of cash conservation prompt some risk-sharing up and down the supply chain?

The big deals are always the big story, however. A buyout of the other most named target highlighted in our poll, Seagen, looks increasingly unlikely. The stock is back to levels seen before rumours of Merck & Co's interest surfaced. Biogen is considered a target for its Alzheimer's link; it is notable that Lilly is the only big pharma group with a potential Alzheimer's project anywhere near the market.

Western drug makers have spent just over $40bn on M&A so far this year. What might 2023 look like?



Which big developers should/could get acquired in 2023?

Note: Survey conducted in early November 2022. Reponses are from public and private investors, bankers and other biopharma industry employees.


CLINICAL CATALYSTS IN 2023

Big cap events

2023 clinical catalysts: the big developers				
Project	**Company**	**Detail**	**Timing**	**Clinical trial ID**
Tiragolumab	Roche	Ph3 (+Tecentriq) Skyscraper-01 OS readout in NSCLC, anti-Tigit MAb	Interim Q1, final H2	NCT04294810
Fidanacogene elaparvovec	Pfizer	Ph3 Benegene-2 haemophilia B gene therapy	Q1	NCT03861273
Crovalimab	Roche	Ph3 Commodore-2 in complement inhibitor-naive PNH pts	Early 2023? (primary completion Jan)	NCT04434092
Rybelsus (oral semaglutide)	Novo Nordisk	Ph3 Pioneer Plus (25mg and 50mg dosing) in type 2 diabetes, Ph3a Oasis 1 (50mg) in obesity	H1	NCT04707469 NCT05035095
Nipocalimab	J&J	Ph2 in rheumatoid arthritis, Ph3 in myasthenia gravis	H1 (RA) Primary completion in Nov for myasthenia	NCT04991753 NCT04951622
Datopotamab deruxtecan	Daiichi Sankyo/ Astrazeneca	Ph3 Tropion-Lung01 in 2nd/3rd-line NSCLC	H1	NCT04656652
Dupixent	Sanofi/Regeneron	Ph3 Boreas in COPD	H1	NCT03930732
Enhertu	Daiichi Sankyo/ Astrazeneca	Ph3 Destinty-Breast06 in Her2-low 2L+ metastatic breast cancer, includes a Her2-0 cohort, primary is PFS	H1	NCT04494425
Mounjaro (tirzepatide)	Lilly	Ph3 Surmount 2, 3 & 4 in obesity data	Q2	NCT04657003 NCT04657016 NCT04660643
Semaglutide	Novo Nordisk	Ph3 STEP-HFpEF in HFpEF + obesity	Q2? (primary completion Mar)	NCT04788511
MK-7684 (vibostolimab)	Merck	Coformulation with Keytruda, Ph2 Keyvibe-002 2L NSCLC, anti-Tigit MAb	2023 (primary completion May)	NCT04725188
Donanemab	Lilly	Confirmatory Ph3 Trailblazer-Alz 2 (filed for accelerated approval) in Alzheimer's disease	Mid year	NCT04437511
Wegovy (semaglutide injection)	Novo Nordisk	Ph3 Select CVOT cardiovascular outcomes study in obesity (important given Lilly's impressive obesity data with tirzepatide)	Set to complete mid year	NCT03574597
Rybrevant + lazertinib	J&J	Ph3 Mariposa-2 in 2L EGFR-mutant NSCLC	Mid year	NCT04988295
PF-07252220 (BNT161)	Pfizer/Biontech	Ph3, quadrivalent modified mRNA influenza vaccine	2023 (primary completion June)	NCT05540522
Talquetamab	J&J/Genmab	Further readouts likely from Ph2 MonumenTAL-1 trial in relapsed/refractory multiple myeloma	H2	NCT04634552

Big cap events

continued

2023 clinical catalysts: the big developers				
Project	**Company**	**Detail**	**Timing**	**Clinical trial ID**
Mounjaro (tirzepatide)	Lilly	Ph3 Summit in HFpEF + obesity	H2 (primary completion Nov)	NCT04847557
Tolebrutinib	Sanofi	Ph3 Gemini-1 & Gemini-2 in relapsing MS	H2 (primary completion Aug/Sep)	NCT04410978 NCT04410991
Imlunestrant	Lilly	Ph3 Ember in ER+ve/Her2-ve breast cancer	H2? (primary completion June)	NCT04120493
Patritumab deruxtecan (U3-1402, Her3-DXd)	Daiichi Sankyo	Potentially pivotal Ph2 Herthena-Lung01 in late-line EGFR+ NSCLC	2023 (primary completion Nov)	NCT04619004
Kisqali	Novartis	Adjuvant HR+ breast cancer, Ph3 Natalee study	Interim at end of 2022, final in 2023	NCT03701334
Camizestrant + CDKi	Astrazeneca	Ph3 Serena-6, 1L metastatic Hr+/Her2- breast cancer ESR1m, oral serd	Q4	NCT04964934
Opdivo + Yervoy	Bristol Myers Squibb	Ph3 Checkmate-9DW 1L liver cancer	Q4	NCT04039607
Epcoritamab	Abbvie/Genmab	Ph3 Epcore DLBCL-1 trial, relapsed/remitting setting (could support full approval)	Late 2023	NCT04628494
Sabatolimab	Novartis	Ph2 Stimulus-AML1, Tim3 project in unfit acute myeloid leukaemia	2023	NCT04150029
Iptacopan	Novartis	Ph3 Applause-IgAN (proteinuria data for accelerated filing) in IgAN, Ph3 Appear-C3G in C3 glomerulopathy	2023	NCT04578834 NCT04817618

Source: Evaluate Pharma, company statements and clinicaltrials.gov.

Other events

2023 clinical catalysts: outside of the big developers				
Project	**Company**	**Detail**	**Timing**	**Clinical trial ID**
Pemvidutide	Altimmune	Ph2 Momentum, obesity data, GLP-1/glucagon dual receptor agonist	Q1	NCT05295875
KarXT	Karuna Therapeutics	Second Ph3 data (Emergent-3) due; US filing planned mid-2023	Q1	NCT04659161
Magrolimab	Gilead	Interim look at Ph3 Enhance in 1L high-risk MDS	Early 2023	NCT04313881
Elahere (mirvetuximab soravtansine)	Immunogen	Confirmatory Mirasol study (approved under accelerated approval) in FRα-high, platinum-resistant ovarian cancer	Early 2023	NCT04209855
mRNA-1647	Moderna	Ph3 CMVictory ongoing, cytomegalovirus vaccine	2023 (primary completion Jan)	NCT05085366
mRNA-1345	Moderna	Pivotal ConquerRSV Ph3 1st interim analysis in adults (≥60 yrs) with RSV	Winter 22/23	NCT05127434
Tarpeyo	Calliditas	Ph3 Nefigard Part B eGFR data at 2 years (confirmatory data, approved under accelerated approval) in IgAN	H1	NCT03643965
Vax-24	Vaxcyte	Ph2 in adults aged 65 and over in pneumococcal disease (24-valent vaccine)	H1	NCT05297578
AMT-130	Uniqure	US Ph1/2 1-2yr data	Q2	NCT04120493
PNT2002	Point Biopharma/Lantheus	Pivotal Ph3 Splash in metastatic castration-resistant prostate cancer	Mid year	NCT04647526
MVA-BN RSV	Bavarian Nordic	Ph3 in adults (≥60 yrs) with RSV	Mid year	NCT05238025
Evobrutinib	Merck KGaA	Ph3 evolutionRMS 1 & 2 in relapsing MS	H2 (primary completion Sep)	NCT04338022 NCT04338061
Aficamten	Cytokinetics	Ph3 Sequoia-HCM in obstructive hypertrophic cardiomyopathy	H2	NCT05186818
ALN-HBV02 (VIR-2218)	Alnylam/Vir Biotechnology	Part B of March trial, in combo with VIR-3434, and in triple combo with VIR-3434 + interferon in hepatitis B	H2	NCT04856085
VERVE-101	Verve	First (ex-US) data from ph1 Heart-1 trial in familial hypercholesterolaemia	H2	NCT05398029
Sparsentan	Travere	Ph3 Protect eGFR data at 2 years (confirmatory data, filed for accelerated approval) in IgAN	H2	NCT03762850
Atrasentan	Chinook	Ph3 Align proteinuria data in IgAN (for accelerated filing)	Q3	NCT04573478
SRP-9001	Sarepta/Roche	Confirmatory Embark study (filed for accelerated approval) in Duchenne muscular dystrophy	End of 2023	NCT05096221
NTLA-2001	Intellia Therapeutics/Regeneron	Further updates from Ph1 in ATTR amyloidosis	2023	NCT04601051

Source: Evaluate Pharma, company statements and clinicaltrials.gov.

CLINICAL CATALYSTS IN 2023

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a norstella company

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