

Biopharma Dealmaking In 2023: The Story So Far

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Foreword

Bio International marks the almost-halfway stage of the year. This week, representatives from big pharma, single-asset biotechs and everyone in between come together to meet, learn and above all else, discover the new opportunities and potential partnerships that will deliver the innovations of the future. In short, to make new deals

The challenging economy and the associated state of the stock markets has made the last 18 months tough for players of every size in the industry. As we start to face down the second half of 2023, though, things are starting to look up on a couple of important indicators.

Perhaps most importantly, a string of big acquisitions in April and May was lifting sector spirits. The XBI, a closely watched biotech index, rallied strongly in this timeframe, climbing off a 10-month low. Acelyrin pulled off biopharma's biggest IPO since 2018. <u>Unexpected intervention by the FTC</u> in the Amgen/Horizon buyout threatens to throw a spanner in the works, but the underlying appetite for dealmaking is clear.

While we wait to see what the rest of the year delivers, we've created this exclusive report for Bio International attendees to look at the current state of dealmaking and what's going to drive the next wave.

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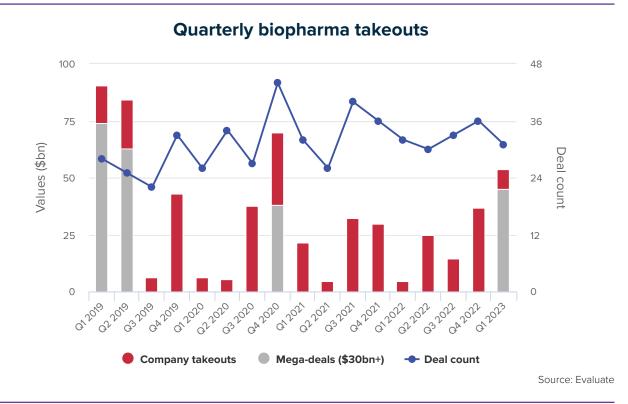


2023: The story so far...

Pfizer's fortunes overshadow first-quarter dealmaking

Let's start with M&A in Q1. Pfizer accounted for almost a quarter of biopharma's buyout spend last year, a contribution that looks set to grow considerably in 2023. This is thanks to the \$45bn it has pledged to spend on Seagen – antitrust approval pending – in the sector's biggest buyout since the Abbvie-Allergan deal in 2019.

Excluding this huge transaction, however, drug developers spent a mere \$8.8bn on buyouts in the first quarter, according to Evaluate Pharma. The second quarter, however, opened with a string of big ticket acquisitions that is raising hopes for a bumper year.



It is worth noting that the figures above include deals that have yet to close.

What of the second quarter so far? Here are three of the top deals:

- April: Prometheus, already tipped as a takeover target in 2022 accepted a \$10.8bn bid from Merck & Co a punchy price tag that points to a competitive process. Prometheus's lead asset, PRA023 has multi-billion
 dollar peak sales potential and the company's work on what could be the first biomarker in ulcerative colitis
 is clearly in their favour.
- May: <u>Astellas</u> swooped on Iveric, surprising some who were expecting a move on Apellis, another key player in geographic atrophy. The \$5.9bn acquisition offers a cheaper and possibly better value alternative for the Japanese group.
- May: GSK, in need of a pipeline boost (see p6) paid \$2bn, more than twice the market cap, for <u>Bellus</u> in a bid to expands its already sizeable respiratory franchise.



Of course, following the recent FTC decision, questions will remain about the certainly of these and other pending deals. But meanwhile, outside of these headline-grabbing transactions, it is clear that tough economic circumstances are forcing many developers to consider their options. This can be seen in the terms that are emerging, with buyers flexing their muscles by insisting on contingent payments. Of the 10 first-quarter company takeouts with disclosed deal terms, eight employed either CVRs or downstream payments, dependent on predetermined future successes.

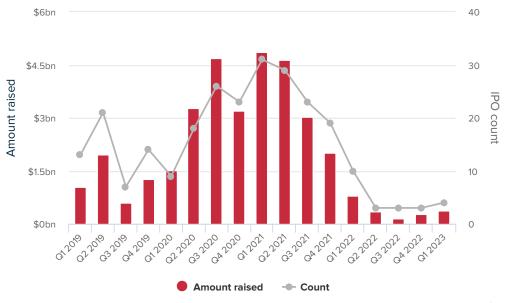
Reverse mergers and business combinations also on the rise, frequently being struck from positions of weakness in one or both parties – think Adaptimmune and TCR2 or Flame and Leap. Unless a strong recovery in the equity markets develops in the coming months, the remainder of the year will also see a healthy flow of deals struck out desperation.

FLOATING BIOTECHS PROMPT TINY SPARKS OF HOPE

The best that can be said for the biotech IPO scene in the <u>first quarter of this year</u> is that, with a grand total of four flotations collectively raising \$375m, it was at least better than the previous three months.

But green shoots of hope can be found. For the first time since the second quarter of 2021 the cohort on average priced at a premium to their preannounced ranges, rather than a discount. And they have, again on average, seen their shares rise since floating, no mean feat in this environment.

Biotech IPOs by quarter on Western exchanges



Source: Evaluate

As the second quarter continued, there was bigger news afoot. After raising one of biopharma's largest venture rounds in 2022, Acelyrin pulled off one of 2023's biggest biopharma IPOs. At the start of May, the group raised \$540m in an offering that was upsized by a huge 46% and priced at a top-of-the-range \$18.

That haul catapults the group into third place in sums raised by pure-play drug developers since 2018 – no mean feat given that the IPO window is only barely open. The stock also rallied strongly after floating.



There was also the J&J spin-off, Kenvue, which arrived on the New York Stock Exchange in May, raising \$3.8bn. As a mature, profitable business it is perhaps not the perfect biotech bellwether, but it was reassuring to see investors give it a warm reception.

Still, as of mid-May the IPO queue was sparse, with few developers attempting anything of Acelyrin's size. Those green shots are still very small indeed.



GENE EDITING: OVERHYPED OR UNSTOPPABLE TIDE?

Only 10 years since Crispr made a splash as a possible therapeutic approach, the first product using Crispr/Cas9 gene editing is on the verge of approval. Vertex and Crispr Therapeutics' exa-cel, for sickle cell anaemia and beta thalassaemia, has been filed with US and European regulators.

Alongside this breakneck speed of development, however, are doubts about whether gene editing will become mainstream. A new report from Evaluate Vantage, which features interviews with some of the major players, takes a look at the big questions facing the field.

And what about the way these therapies are delivered? Delivery, once an overlooked piece of the puzzle, is getting increasing attention, and several recently-launched players are developing new technologies that go beyond viral vectors and lipid nanoparticles (LNPs).

Topics discussed in the report include:

- The upcoming approval decision on Vertex/Crispr Therapeutics ex vivo edited project exa-cel, and the candidates coming behind;
- The potential advantages of new modalities like base and prime editing over Crispr/Cas9;
- New delivery modalities including "barcoded" LNPs, protein nanoparticles and virus-like particles

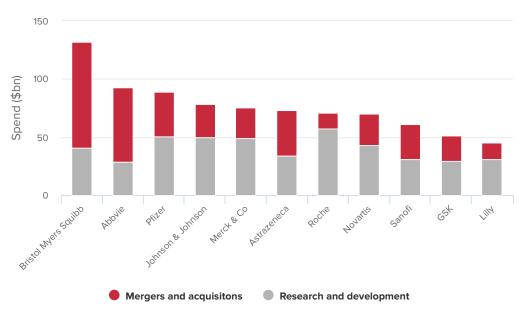
CLICK HERE to download the report.



2023: What's to come?

If that's the dealmaking story for 2023 so far, what's next? First, let's go a little further back to see which of the big players are really in need of securing some new assets to fill looming patent cliffs.

Big spenders? Five-year investments by company 2018-2022



Source: Evaluate

When Evaluate Vantage undertook this analysis in May 2022, Pfizer was towards the bottom of the table in terms of five-year acquisition costs. If a lowly ranking on this measure signals the time is right for big moves then perhaps news should be expected from Roche, Lilly or GSK. The first of these is in particular need of a pipeline boost, while GSK recently unveiled the \$2bn acquisition of Bellus.

Lilly has less need to make any big M&A moves, of course, thanks to the spectacular success of Mounjaro, an internally discovered compound that some analysts have suggested could become biopharma's first \$100bn-a-year drug.

SHOPPING LIST

While early-stage assets can fill some pipeline gaps, the urgency that some of the potential buyers are facing means that later-stage assets must be on shopping lists. And when it comes to potential blockbusters, 2023 might provide rich pickings. In fact, if forecasts prove accurate 2023 could be the biggest year for blockbuster launches for some time.

At the start of 2023, sellside analysts were forecasting <u>22 potential blockbuster launches</u>, consensus forecasts from *Evaluate Pharma* suggest. This level of productivity was rivalled only by 2021, when pandemic approvals swelled the numbers.

Which products are creating all the excitement? A handful of significant new agents have already been approved, in Alzheimer's disease, geographic atrophy and respiratory syncytial virus, and there is no shortage of pending regulatory news for the remainder of the year. Obviously many of these are already in the hands of big pharma, but there are still late-stage assets out there that look ripe for a deal of some sort.



The recently-announced acquisition of Iveric Bio by Astellas is a case in point. Zimura is due to hear on FDA approval by August 19; the geographic atrophy asset is forecast to reach sales of \$1.2bn in 2028.

Others that might appeal include Madrigal, which achieved a rare hit in Nash and plans to file its asset for approval by mid-year. And Reata, which won a surprising approval for Skyclarys in Friedreich's ataxia earlier this year; the launch has hit a hitch but analysts reckon it has \$1bn peak sales potential. Biopharma has plenty of other examples like this to be found.

There is plenty of 2023 ahead of us and more than enough to keep pharma watchers busy in the coming months. Those green shoots were already small and the impact of the FTC baring its teeth in an expanded remit may squash them entirely. Only time will tell.



ORPHAN DRUGS 2023-2028: IS THE SHINE COMING OFF?

Orphan drugs continue to march ahead. They are the fastest-growing segment of the pharma market and dominate FDA approvals. The top ten biggest orphans will be worth \$64 billion globally in 2028, by which time orphans will comprise almost a fifth of all non-generic prescription drug sales.

These trends are by now familiar. Orphan drugs have out-grown their non-orphan counterparts for each of the last ten years, apart from 2021 and 2022 when Covid impacted the numbers. Even a pandemic affecting the global population didn't fundamentally alter orphans' trajectory. These 'niche' treatments will grow two thirds faster (11.6% vs 7%) than non-orphan innovative drugs in the next five years according to Evaluate consensus. By 2028, they will be worth \$300 billion.

Is orphan drug growth flattening out? There's little quantitative evidence - yet. Several legislative and technological factors have come into play, however. The US Inflation Reduction Act (IRA) puts the costliest Medicare drugs on course for price cuts – including orphan drugs with more than one indication. Six of 2028's forecast top ten orphans fall into that category.

Meanwhile commercial successes across more prevalent conditions are drawing attention away from rare conditions as big pharma face a loss of exclusivity on blockbusters.

These potential headwinds won't slow orphans this decade: the net present value (NPV) of the top largest orphans in 2028 (currently in Phase 3 or filed) is over \$40 billion – *three quarters* of the equivalent figure for non-orphans (\$54 bn). But as the IRA digs in, the shine may start to come off.

In the full report, we look at:

- The top selling orphan drugs in 2028
- The orphan R&D pipeline broader applications and new formulations
- The potential impact of the IRA and calls for Orphan Drug Act $2.0\,$

 $\underline{\text{CLICK HERE}}$ to download the report and watch the on-demand webinar.



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