



Pharmaceutical Sector Update

Bourne Market Report

1H 2023

Welcome



Amidst a temperate and relaxing summer of cancelled flights and interest rate hikes, we would like to share with you our takeaways on noteworthy pharma M&A, news, and industry developments.

We know that an 80-page research report may not end up at the top spot on your beach reading list, but there's a lot of good content here (we think)! Since we have a feeling not everyone will end up reading this cover to cover, we've tried to make this Executive Summary a simplified series of informative snippets and takeaways that are easy-to-digest, like a good frozen daquiri. For the more the in-depth content, we have enough charts, tables, and graphs in the main section of this report to make you dizzy – also like a good frozen daquiri!

A number of trends have contributed to a choppy M&A environment so far in 2023, however, we expect that well-positioned assets can capitalize in the coming quarters as there are a scarcity of great opportunities in market. We've seen a handful of restructurings/bankruptcies and under-capitalized biopharmas, while on the flip side, some of the more solid businesses are commanding rich valuations that have left some sticker shock among otherwise interested potential buyers. The combination of this pent-up buyer demand with record amounts of dry powder itching to be deployed for accretive M&A or stock buy-backs has led to up-and-down deal activity through the first six months of the year.

The developments below of course impact different companies within the broader pharma landscape and we see middle market players with strong cash flow, ample interest coverage, and working relationships with sponsors and lenders to be the best positioned to entertain an array of opportunities. These include creative licensing or revenue interest deals, merging with cash-strapped biotech with strong pipeline assets, and opportunistic acquisitions as under-capitalized players turn to divestures as a source of alternative financing.

We hope this report is an enjoyable and educational read. Our team has sifted through a lot of material to bring you what we think are the most relevant developments in pharma through the first six months of the year. If you have any suggestions, questions, or would just like to connect with someone at Bourne Partners, please don't hesitate to reach out – we'd love to hear from you.



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Executive Summary

Slowing inflation has given the Fed a path to lower rates after the steepest hiking cycle in 40 years. This has coincided with improved economic sentiment after higher interest rates stifled business growth and M&A activity. The outlook for M&A and capital markets is improving, but with inflation still well above the Fed's 2% target, short term rates above 5% are likely to persist well into 2024, causing concern among debt-burdened companies.

In Q2, there was a significant jump in **pharma deal making**, as deal count increased by 26%, yet total deal value QoQ declined slightly due to the outsized Pfizer/Seagen deal. This uptick in part came from private equity ("PE") firms stepping back in the ring through several notable take privates. Sponsor-backed deals accounted for 34% of quarterly deal value and 13% of deal count, 4.6x and 2.2x the 5-year quarterly average, respectively.

Speaking of PE, **US PE-backed transaction** values fell in Q2 2023 and are down 30% from the first half of 2022. This is consistent with market sentiment, as macro factors have stifled deal making. In addition, leverage remains scarce. Debt for LBOs fell to 43% of enterprise value ("EV"), a 14% year-over-year decline. This has had a knock-on effect as both valuations and transaction volume have declined.

Declining total EV of PE deals has coincided with relatively stable PE transaction volumes over the last four quarters. This indicates that it's **smaller M&A deals** that are getting done, many of which are add-on acquisitions to existing platforms that are easier to finance.

Continuing the smaller deal trend, **corporate divestments** have increased to 50% of total deal count, as big pharma continues to implement a "lean pharma" transition and players look to use divestiture proceeds as alternative financing. This presents an opportunity for Middle-Market Specialty Pharma platforms to be acquisitive.

Executive Summary (Cont.)

While an elevated interest rate environment has led many PE-backed portfolio companies to delay exits until cheaper debt can help bring more buyers to the table and drive valuations, **family-founder** owned companies and growth equity deals are getting more traction in the market as buyers sitting on cash stockpiles are willing to pay a premium for quality opportunities that do become available for acquisition. The pause on the part of sellers has led to a scarcity of good assets in the market and has led some buyers to preempt auction processes, when possible. Bourne Partners has seen this across several deals so far this year and has been able to help sellers take advantage of this market dislocation.

Dry powder, the amount of capital a Private Investment firm has committed to invest but not yet allocated, has been increasing worldwide over the past decade and reached record heights last year, totaling a staggering \$3.4 trillion, up \$500 billion compared to the previous year.⁽¹⁾ US PE firms contributed to \$854 billion of that sum. That said, PE fundraising has slowed considerably this year as inflation and other macroeconomic challenges blunt PE performance. However, middle market funds have outperformed mega funds of late and in turn are having more fundraising success, and the whole industry has benefited from the recent equity market rally, softening the denominator effect.

Where are the **IPOs**? IPO exits for private investors have dried-up more than the weather this summer. This has been a continuation from 2022, but recent developments point to a possible recovery for IPOs. Two recent IPOs were oversubscribed and experienced a trading pop, reminiscent of the good ole days (two years ago). The IPO window has been cracked, but with interest rate and valuation volatility, it is still a shaky exit route for PE.

Historic loss-of-exclusivity (“LOE”) places more than \$390B of US and EU drugmakers' annual sales at risk to generic entrance as 170 products are facing patent expiration in 2023-2030, with easy-to-replicate small molecules making up about a third of the at-risk sales. Market analysts' consensus sees at least \$154B in sales erosion through 2030, with biologics accounting for about 50% of that decline from the LOE patent cliff.⁽²⁾

Biotechs are facing a **drastically different funding environment** than that of the past two years: managing cash burn and focusing on operational success – in addition to therapeutic success – will be crucial to reaching their next inflection points. Biotechs have an average of 5.4 quarters of cash runway left, down from 8.6 in early 2021.

Executive Summary (Cont.)



Mega deals defined pharma M&A activity through Q1 as \$67B of deal value was announced, with an average EV of \$821M. In Q2, deal values totaled \$50B, with an average EV of \$510M – a theme highlighted on the first page. A perfect storm of cash-strapped biotechs with promising pipelines are compelling targets for big pharma players facing patent cliffs, but regulatory challenges and economic volatility has dampened matchmaking thus far. See our outlook [here](#).



Spoiler alert - We believe the above-mentioned underlying factors are too strong to pin down deal making and expect to see a strong pick up 2H. However, even if a flurry of M&A ensues, pharma’s disciplined approach will limit the number of anointed biotechs, leaving many to source funding elsewhere. This has forced would-be-sellers to get creative with [alternative financing strategies](#). Bourne has seen solutions stem from licensing deals and reverse mergers, to more creative options like pipeline divestures, [priority review voucher monetization](#), and [synthetic royalties](#).



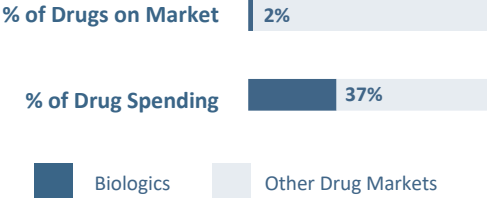
Generic pharma has seen its share of restructurings and bankruptcies so far this year – Akorn, Endo, Lannett, maybe Mallinckrodt... again? It’s a challenged space after years of [price deflation](#), opioid settlements, price-fixing claims, [drug shortages](#), and quality problems. Those left standing may be able to pick up assets at bargain values and capitalize from increased market share.



On the branded side, “drugmakers are ‘throwing the kitchen sink’ to halt Medicare price negotiations” ([NYT article](#)) with Merck, J&J, BMS, Astellas, and the industry’s main trade group having filed [lawsuits](#) to challenge the constitutionality of the Inflation Reduction Act.⁽³⁾ In other litigation news, the [FTC has sued to block Amgen’s \\$28 billion buyout of Horizon](#), which heads to trial in September.



[Biologic medicines](#), containing substances that have been created by using living cells or organisms, have become increasingly more attractive to pharma companies for their difficulty in being “genericized” by biosimilars. The IRA has furthered the appeal of these drugs as the law lets Medicare set prices for some small-molecule drugs 9 years after FDA approval, versus 13 years for biologics. The pricing power of these biologics is shown to the right (data points for USA).



Source: Morningstar Equity Research⁽¹⁸⁾



Table of Contents

| | |
|--|-----------|
| Section 1—Capital Markets Update | 7 |
| Inflation, Rates, & Business Outlook | 8 |
| Valuations, Leverage, & Dealmaking | 9 |
| Private Market & IPO Activity | 17 |
| Section 2—Insights on the Pharmaceutical Sector | 20 |
| Patent Cliffs | 23 |
| FTC M&A Scrutiny & Inflation Reduction Act | 26 |
| Generics & Drug Shortages | 34 |
| Obesity Therapies | 43 |
| Section 3—BioPharma Spotlight | 47 |
| NBI® Therapeutic Market Performance | 48 |
| Cautious & Creative Dealmaking | 49 |
| Priority Review Vouchers & Accelerated Approval | 53 |
| Section 4—M&A Transactions & Public Comps | 57 |
| 1H Pharma Transactions | 58 |
| Trading Multiples | 61 |
| Trading Charts | 66 |
| Operating Metrics | 71 |
| Section 5—Bourne Partners Spotlight | 75 |
| Thought Leadership | 76 |
| Bourne Partners Overview | 77 |
| Appendix | 80 |



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Section One

Capital Markets Update

- i. Macro Developments – Inflation, Rates & Business Outlook
- ii. Private Market Deal Activity – Trends, Leverage, IPOs & Dealmaking
- iii. Healthcare Spotlight – Private Market & IPO Activity

An overhead view of three business professionals in a meeting. A man in a dark suit is on the left, looking at a document. A woman in a white blouse is on the right, also looking at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

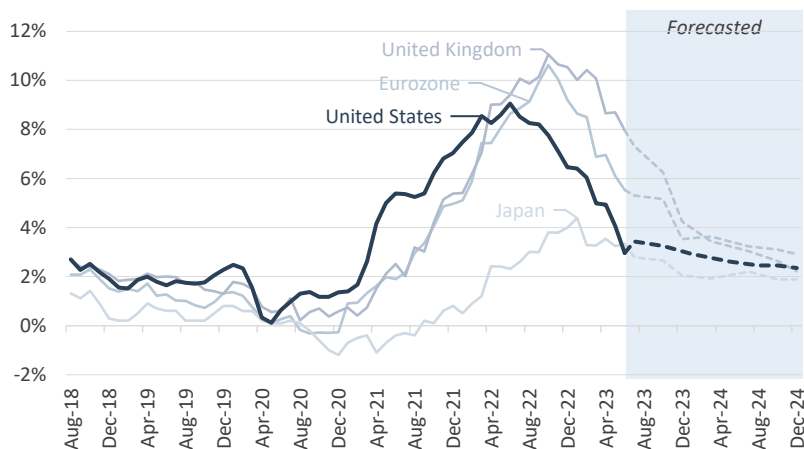
i. Macro Developments

Inflation, Rates & Business Outlook

Macro Developments

Slowing inflation provides a path for the Fed to ease rates - improving M&A and operating environment

Global Inflation Rates (YoY % change)



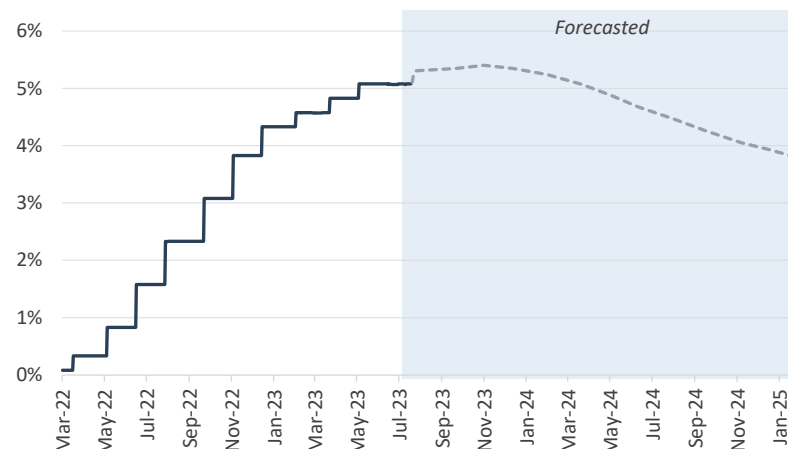
SOURCE: OECD, IMF, & Bloomberg data, Accessed 7.10.2023

The annual US inflation rate slowed to 3% in June, the lowest since March 2021 and down from 4% in May. This was largely due to lower energy and food prices, but core inflation (the Fed's primary concern) has been more stubborn than many expected. Current inflation still exceeds the Fed's 2% target, and while inflation is expected to slow further, the Fed is not content.

Despite recessionary fears and unfavorable credit conditions, the overall economy is growing at a moderate pace. Consumer spending, which is primarily driven by income rather than credit, remains positive as a result of high employment and above-average (though moderating) wage growth. The Federal Reserve acknowledges that monetary policy has "long and variable lags" and paused for the first time in June to assess.⁽⁴⁾ While the Fed opted not to raise interest rates at its June meeting, ongoing high inflation boosts the chance of short-term rates lingering over 5% long into 2024.⁽⁵⁾

The Fed will most likely commence raises in the future sessions.

US Federal Funds Rate



SOURCE: Bourne Analysis of Bloomberg, Accessed 7.10.2023

The market currently expects two to three more hikes, reaching a terminal rate of 5.4%, with the Fed starting to lower rates as early as December. The consensus economic outlook has improved, and the once contrarian "soft landing" scenario is becoming more likely. Higher interest rates have certainly made an impact; severely hampered business growth and M&A initiatives, particularly leverage dependent deals. However, the outlook for M&A and capital markets is improving.

The global pharma industry experienced a 20% increase in sentiment in Q2 2023 compared to the previous quarter, according to GlobalData's analysis.⁽⁶⁾ This is consistent with the results of May's business outlook surveys, which showed improved labor and supply chain conditions. This report, however, also indicated a decline in business activity and an inability to pass on pricing pressures.⁽⁷⁾ Companies are still feeling inflationary pressures and high interest rates are squeezing free cash flow. With more rate hikes on the way, the second half of the year could be a slog for debt-burdened companies.

An overhead photograph of three business professionals in an office setting. A man in a dark suit is at the top, looking at a document. A woman in a white blouse is on the right, also looking at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The desk is cluttered with papers, a coffee cup, and a smartphone. The image is semi-transparent, serving as a background for the text.

ii. Private Market Deal Activity

Valuations, Leverage & Dealmaking

Private Market Deal Activity

Valuations Slowly Reset

PE transaction value fell in Q2 and is down 30% from the first half of 2022. This is unsurprising and consistent with market sentiment, as macro factors engulfed deal making and wider mean-reversion to pre-pandemic levels of M&A seems inevitable. The industry remains in limbo as valuations reset.

Any private market that experiences value resets does so slowly, owing to fewer transactions as buyers and sellers both pause, with buyers wanting to gain the largest discount and sellers wanting to retain as much value as possible. Eventually there is capitulation, (currently on the part of sellers), and markets resume.

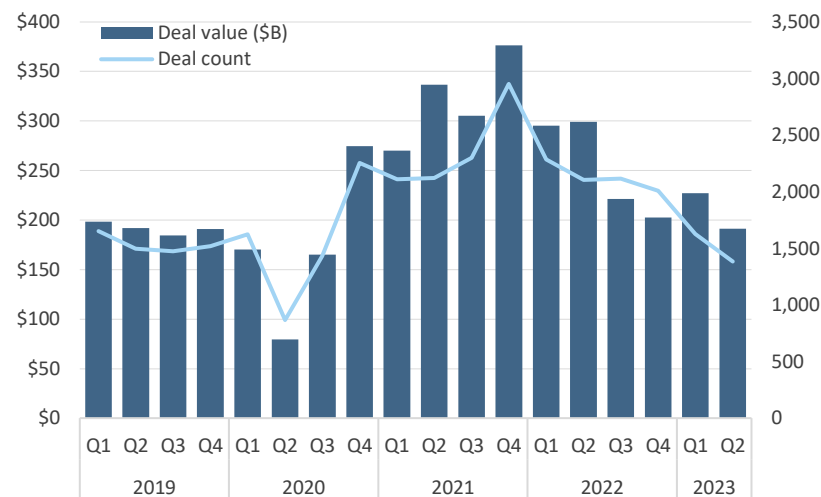
Declining PE deal value coincided with relatively stable (during the last four quarters) PE deal volumes. This indicates smaller transactions and lower valuations. However, the pause on the part of sellers has resulted in a scarcity of good assets, leading to fierce buyer competition for quality assets, keeping select valuations high and prolonging a reset.

How This Is Impacting Dealmaking

Leverage remains scarce. Debt for LBOs fell to a 43% share of EV, down from the five-year average of 52%. An 18% decline from the trailing 5-year average, and 14% YoY decline. This has certainly had a knock-on effect as both valuations and volume have declined.

This has exacerbated an already poor exit environment for PE backed firms, leading to a drop off in sponsor-lead processes. Although PE firms don't have easy access to new leverage to match their equity, they have still been deploying their cash stockpiles, albeit in smaller amounts. PE firms are continuing to deploy capital into easier to finance add-on acquisitions as they buy time for a better exit environment.⁽⁸⁾

US PE deal activity by Quarter



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

We are still seeing misaligned value expectations as discussed above, but smaller deals, especially family-founder owned companies and growth equity deals are finding better alignment, and we have been very active within this section of the market.

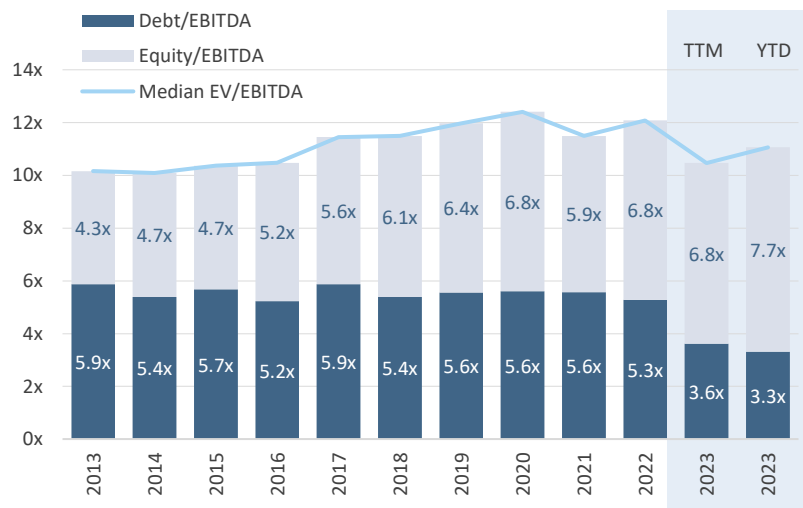
The pause on the part of sellers has led to a scarcity of good assets in the market and has forced firms to preempt processes. We have seen this across several deals this year and have helped sellers take advantage of this market dislocation.

Overall, we are starting to see a slight uptick in activity as macro concerns ease and firms look to close processes before year end.

Private Market Deal Activity - Valuations & Leverage

Valuations decline as leverage crimps TEV, but green shoots appear

US PE Median EBITDA Multiples

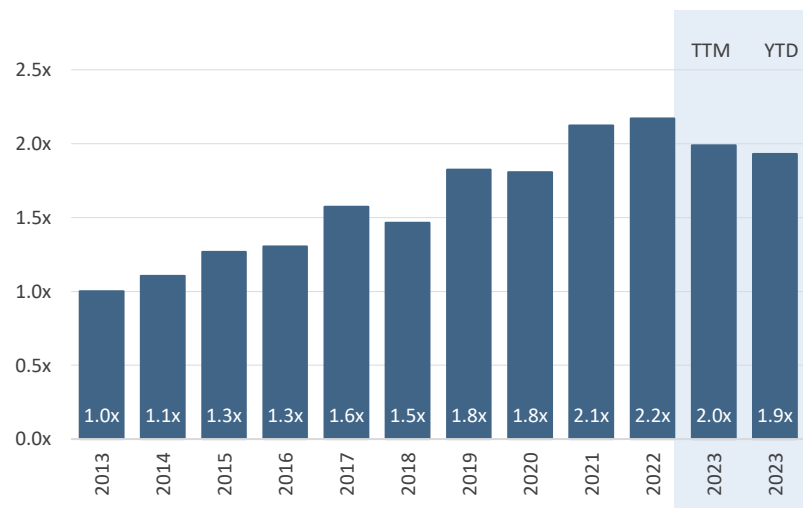


SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

- Median EV/EBITDA Multiples collapsed 18.5% to 10.5x for TTM ending 6/30/23, down from 12.1x in 2022. A significant decline after the past five years have traded in a tight band between 11.5x and 12.4x
- TTM Median EV/Revenue Multiples show a similar story, declining a less severe - but still significant 10%, to 2.0x TTM vs. 2.2x in 2022

Exceptions to declining multiples include some healthcare & tech transactions, where revenue multiples are holding up much better than the broader industry, at 2.5x and 4.9x, respectively, but less so on an EBITDA basis where multiples have declined 11% and 13%, respectively.

US PE Median EV/Rev Multiples



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

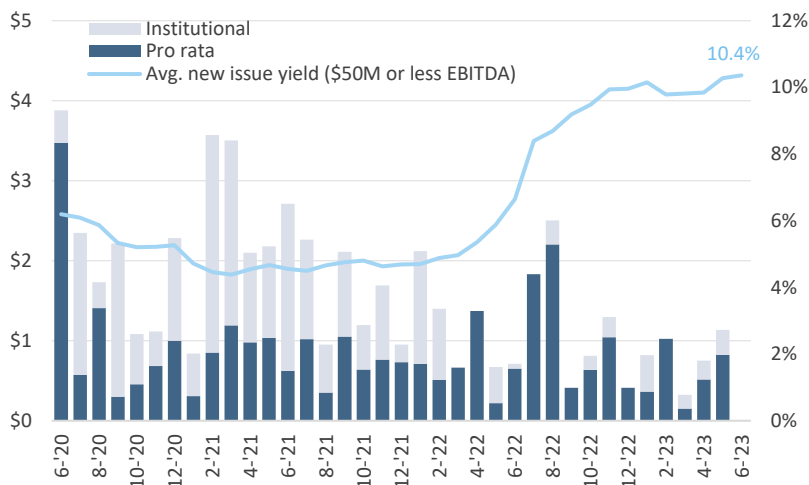
This shows PE buyers are willing to pay up for revenue in these two secular growth areas—but only if paired with expanding EBITDA margins year-over-year,⁽⁸⁾ which has been difficult for any businesses subject to cost inflation and labor shortages—ruling out many healthcare firms.

On the bright side, there has been a slight pick-up in median EV/EBITDA valuations in 2023 YTD when compared to the TTM medians, on even less leverage, while the same analysis of EV/Revenue has not reversed but intensified. Though potentially skewed by outlier deals, this indicates that PE firms are becoming more comfortable deploying capital into businesses that have not yet seen a pickup in sales or realized the effects of lowering inflation. Perhaps a leading indicator of a brighter outlook on the near-term operating environment.



Debt Capital Markets

US Middle Market Loan Value(\$B) & Average New Issue Yield



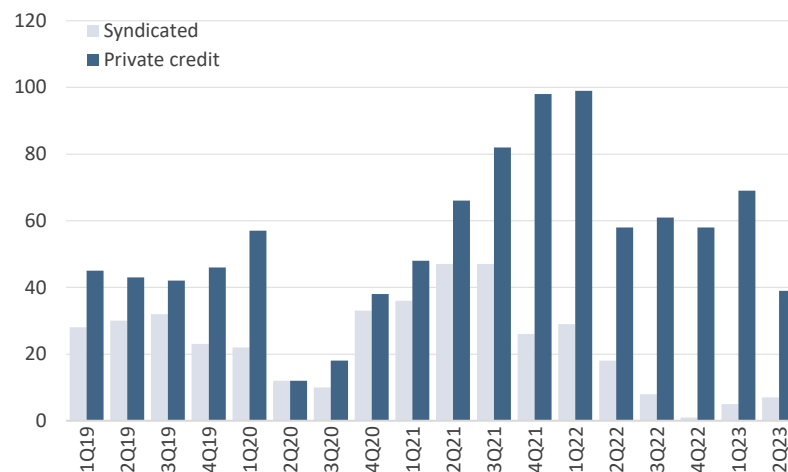
SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

Average Yield and New Issuance

The average middle market new issuance is currently pricing in line with single B borrowers around 10.3% as of June 30th, 2023. This has caused debt for LBOs to plummet to 43% of EV, down from the five-year average of 52%, an 18% decline from the trailing 5-year average, and 14% YoY decline.⁽⁸⁾

However, debt markets are finally (mostly) functioning again, albeit at a slower pace. Big banks have slowly waded back into the leveraged loan market after taking an eight-month sabbatical, which will be a welcome reprieve from an exhausted direct lending market.

Count of LBOs financed by BSL* vs private credit markets



SOURCE: LCD Data via Pitchbook, Accessed 7.20.2023

Private Credit Still Favored for LBO Financing

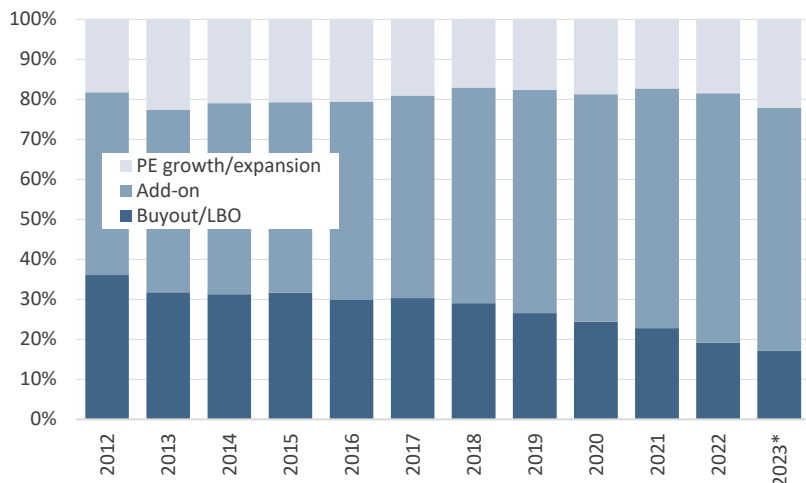
Private credit continued to dominate LBO lending, funding 100% of large-cap buyout financings in our Q2 data set, and ~80% of overall middle market lending. Private credit funds have continued to lend all along and were the main reason the LBO market and PE deal flow, in general, did not collapse coming out of the steepest rate hikes in more than 40 years.⁽⁹⁾ But the class has started to show signs of fatigue despite outpacing BSLs again in Q2.

SOURCE: Pitchbook; Dates as of 6/30/2023

*Note: Based on available data; ("BSL") Broadly Syndicated Loans

Private Market Deal Activity - Smaller Deals

US PE Deal Count by Type



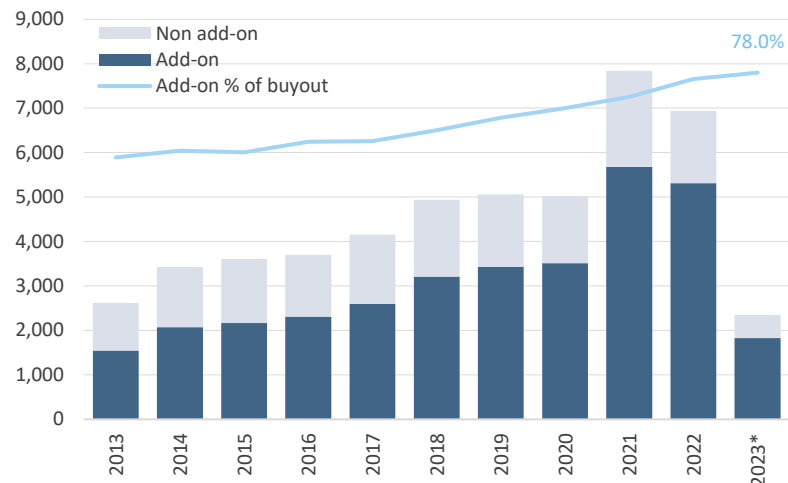
SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

Smaller Deals Prevail

Due to leverage constraints, the average deal size has declined driven by both valuation declines and deal types. A growing emphasis on add-on acquisitions, growth equity, and divestures deals have pushed the median deal value to \$50M, the lowest level since 2017, barring a blip in 2020. This is indicative of PE firms adapting to a higher interest rate environment and forgoing platform investments.

Growth equity investors have found attractive opportunities to put capital to work at lower valuations and are empowered by being less reliant on debt and better value alignment with sellers. Growth equity deals have made up 22.2% of total deal mix so far in 2023, up 18.5% from last year and nearing a 10-year high of 22.7% in 2013.

Add-Ons as a Share of US Buyouts



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

ICs Are More Receptive to Add-ons

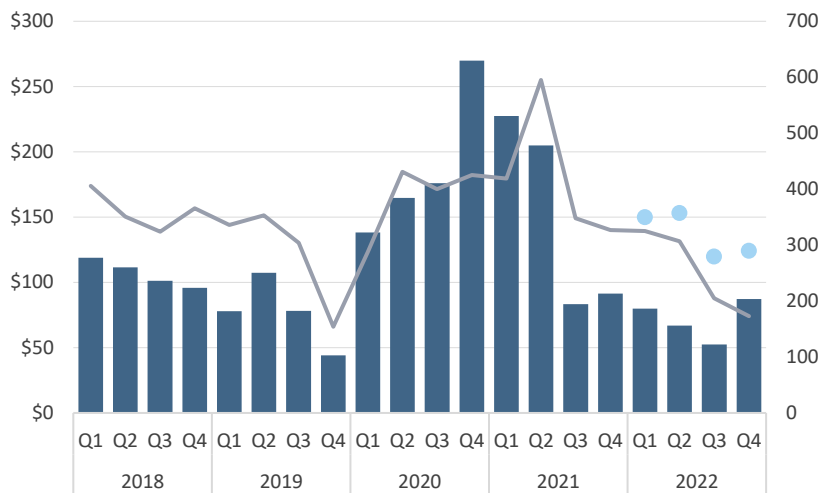
Add-on activity reached a 15-year peak of 78.5% in Q2 2023. Furthering QoQ increases since Q1 2021, increasing 400 bps in total up from 72.5%. Add-ons continue to be a go-to for implementing PE firm's roll-up strategy, but this has taken on outstretched importance in a time of tight credit and a particularly bad exit environment.

The Leverage Loan Market is still open for sponsors wanting to do add-ons – and many draw on existing facilities that were secured shortly after a platform LBO and therefore have advantageous base rates.⁽⁸⁾



Private Market Deal Activity - PE Exits

US PE exit activity by quarter



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

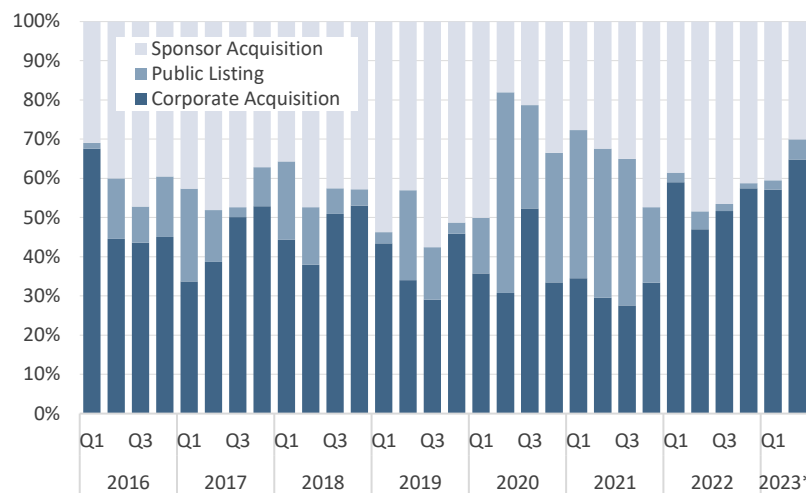
PE Exits Rebound in Q2

A dismal exit environment is to thank for Add-on's record setting highs, however, PE exit values were a rare bright spot in Q2, reversing three quarterly declines and surging 67% over Q1 2023.

This is a welcomed sign for GPs, but this activity is still not significant enough to stave off a quickly approaching maturity wall and falling even further behind the pace of buying at 3.02 investments to every 1 exit (excluding add-ons), a 15-year high.⁽¹⁰⁾

SOURCE: Pitchbook; Dates as of 6/30/2023

Share of PE Exit Value (\$B) by type



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

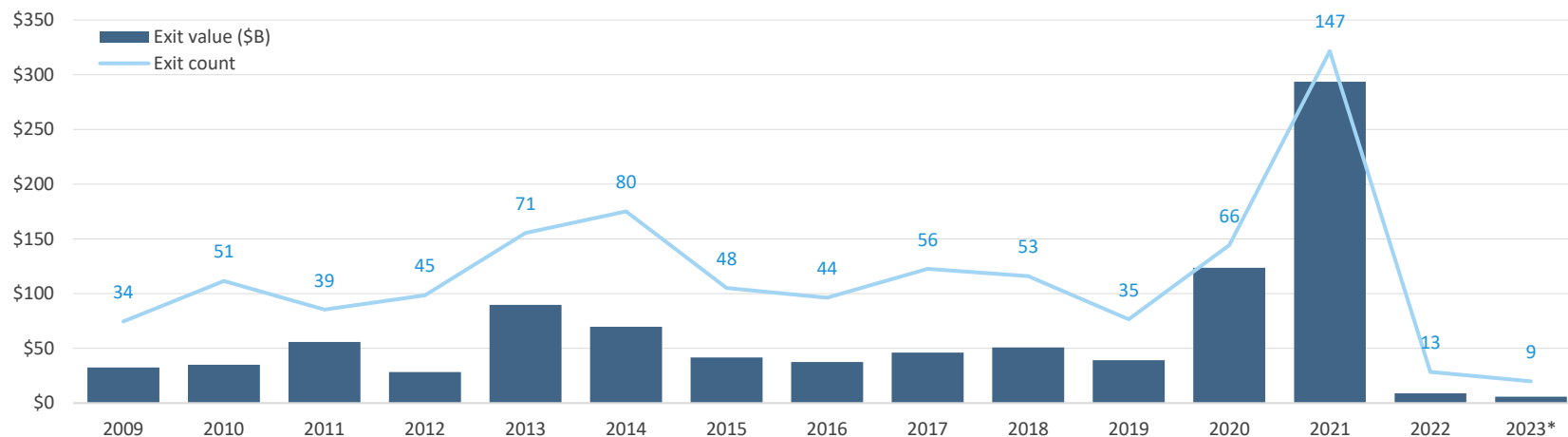
Boosted by a Few Well Capitalized Corporates

There were four big exits to end the quarter: two via M&A (Adenza and Apttio) and two via IPO (Savers Value Village and Kodak Gas Services)

Exits to corporates gained steam in Q2 and accounted for a record 64.8% of total PE exit value, and 61.9% of deal mix. Corporates with strong balance sheets have contributed the most to PE exit value, while sponsor-to-sponsor activity is still mostly frozen, and the IPO market, though tested by a few with moderate success, is still a shaky path to exit.

Private Market Deal Activity - IPO Exits

Public Listing PE Exit Activity



SOURCE: Bourne Analysis of Pitchbook Data, Accessed 6.30.2023

IPO Tested, but Still Shaky at Best

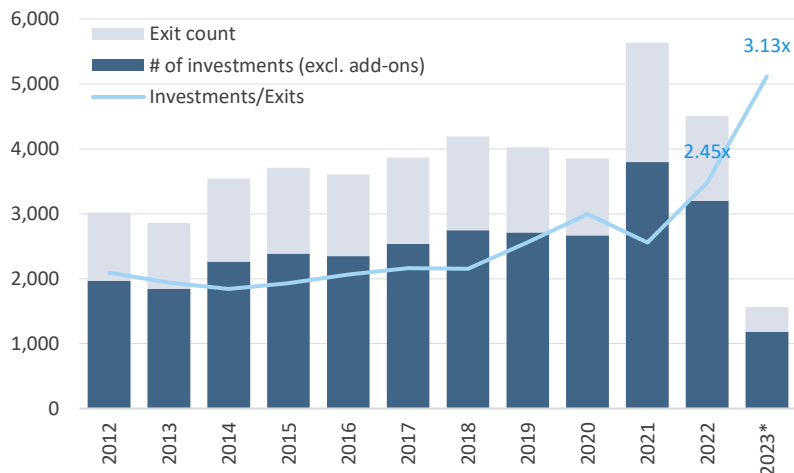
Public listings remained quiet, but recent developments point to a possible recovery for IPOs. Cava, Ares's Savers Value Village, and EQT's Kodiak Gas Service tested the waters. Kodiak fell short of the intended \$328M raise, with just \$256M. The latter two were well received, both exceeding the prescribed raise amounts, and experienced the IPO pop reminiscent of 2021.⁽⁸⁾

The IPO window has been cracked, but with interest rate and valuation volatility, it is still a shaky exit route for PE.



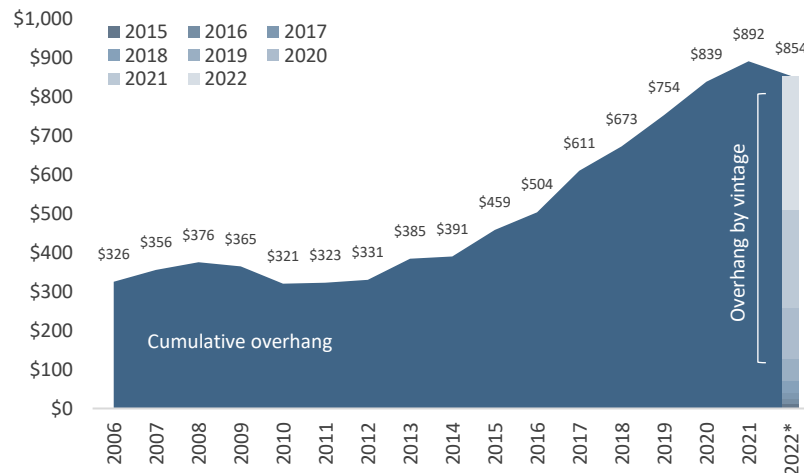
Private Market Deal Activity - One-Sided Dealmaking

US PE Investment/Exit Ratio



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

US PE Cumulative Capital Overhang "Dry Powder"



SOURCE: Pitchbook's 2023 Q2 US PE Breakdown Summary, Accessed 7.15.2023

One-Sided Deal Making Fueled by Dry Powder

Also at a 15-year high, PE Investment-to-Exit ratios topped 2008 levels, rising to 3.13x investments to every 1 exit. This has come as a result of a dismal exit environment made less attractive by declining multiples, while record amounts of dry powder propel dealmaking.

Delayed exits that are expected to persist for the next few years, will lead to a significant pileup of not-yet-exited PE assets as investors struggle to sell the portfolio companies that are entering their exit time frames. The mismatch between the explosion of deals made in the last few years and a challenged exit market will cause the backlog of investments to swell.⁽¹⁰⁾

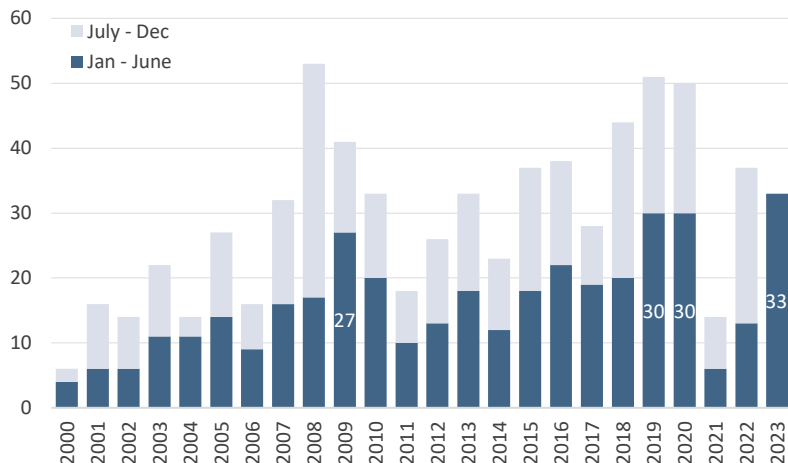
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iii. Healthcare Spotlight

Private Market & IPO Activity

Healthcare Spotlight

Total Healthcare Bankruptcies 1H vs 2H 2000-2023

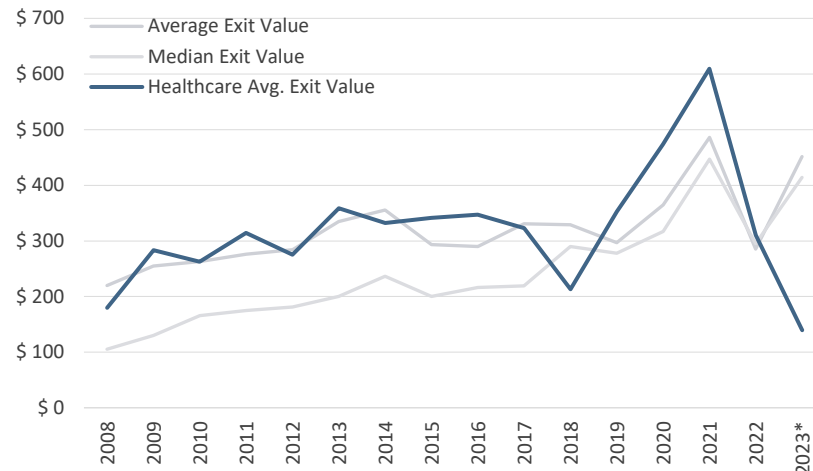


SOURCE: Bourne Analysis of CapIQ Data, Accessed 7.1.2023

Healthcare Bankruptcies Exceed Prior Peaks

Rising rates have claimed several healthcare companies through the first half of 2023, surpassing prior pandemic and 2009 peak levels. Among these are well-known generic manufacturers Akorn, Lannett, and Endo. These occurred at a time when drug shortages were already a major concern but have since been exacerbated.

HC Avg. Exit Value vs. Total Avg. Exit value (\$M)



SOURCE: Bourne Analysis of Pitchbook Data, Accessed 7.15.2023

Healthcare Lags Other Sectors

Healthcare was a bright spot in terms of exit value the past two years but has significantly dragged down the total average and median exit value in 2023.

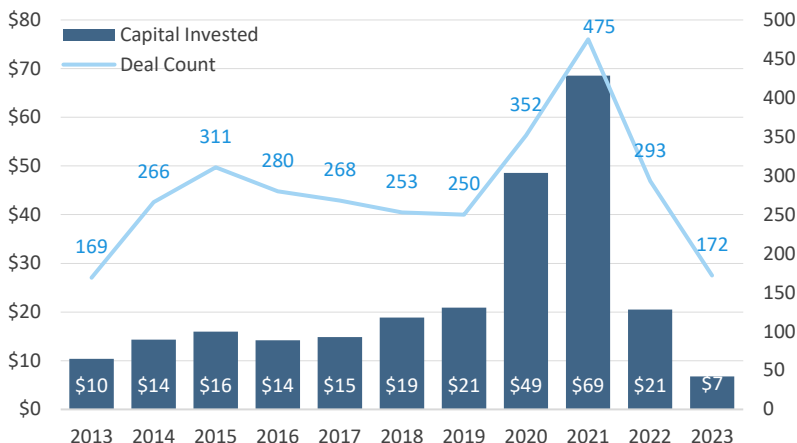
Subdued activity is likely the result of several notable bankruptcies (KKR's Envision, Blackstone Team Health restructuring talks) amid cost and labor inflation, and reimbursement issues have several hurt business with out-of-network payor exposure.⁽⁸⁾

SOURCE: Pitchbook, CapIQ; Dates as of 7/5/2023



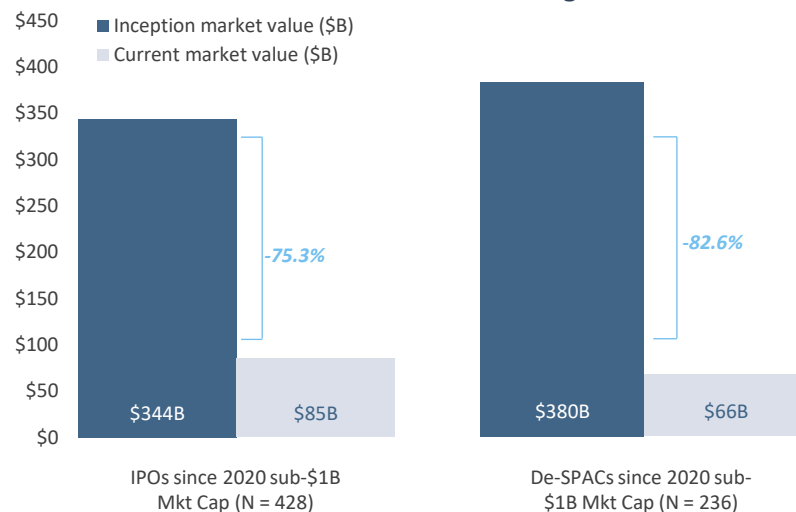
Healthcare Spotlight - Life Science IPO Activity

Pharma and Biotech IPO Market Thaws



SOURCE: Bourne Analysis of CapIQ Data, Accessed 7.1.2023

Sub-\$1B IPOs since 2020 now trading below \$1B



SOURCE: Pitchbook Data, Accessed 6.28.2023

IPOs Are Slowly Opening Up

Biotechs have been facing a drastically different funding environment than that of the past two years, largely in part to the lack of IPO opportunities. The group has largely been shut out of public markets in dramatic fashion from the heights of 2021, but a handful of biotechs did raise secondary offerings in the later weeks of Q2 with moderate success, raising a combined \$764M across 6 companies. The public financing arena has been dismal the past several quarters, but recent activity shows green shoots are emerging.

This lift comes at a much-needed time as biotechs have an average of 5.4 quarters of cash runway left, down from 8.6 in early 2021.

However, managing cash burn and focusing on operational success in addition to therapeutic development success will be crucial for biotechs to reach their next inflection point, despite an improving funding environment.⁽¹¹⁾

Hampering this trend, companies who went public in 2020 or later, with sub-\$1 billion market caps, both via SPACs and traditional IPOs have since declined 82% and 75%, respectively, as risk-adverse sentiment grew among investors. This cohort of 664 companies is skewed biotech-heavy, with 208 firms being biotech and life science companies.

Section Two

Insights on the Pharmaceutical Sector:

i. Industry Drivers – Patent Cliffs

ii. Regulatory Challenges – FTC M&A Scrutiny & Inflation Reduction Act

iii. Sub-Sector Spotlight – Generics & Drug Shortages

iv. Emerging Markets – Obesity Therapies

Pharma M&A Recap & 2H Outlook

Outlook

Going forward, we believe the underlying fundamentals of dealmaking are too strong to keep activity muted, despite the persistence of regulatory uncertainty.

Defining Trends

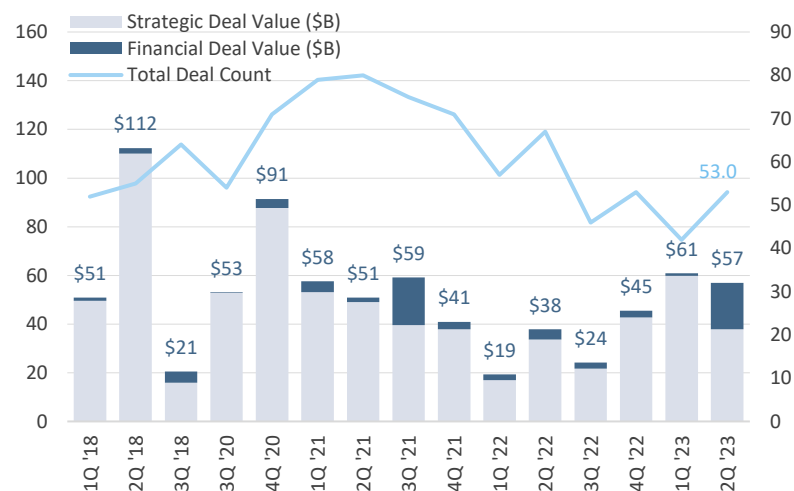
- Corporate Divestitures continue to provide opportunities for specialty pharma and PE backed platforms to be acquisitive
- Big pharma cash balances and impending patent cliffs are expected to drive transformative M&A
- FTC regulatory concerns have led to a disciplined approach to M&A, and IRA implications are reshaping deal making

Pharma M&A Green Shoots

Following a strong start in Q1, the preceding months saw subdued M&A activity, but the second half of Q2 finally began to show signs of a much-anticipated surge in deal making. Quarter over quarter, deal values fell from \$60.8B to \$56.9B, owing largely to the outsized Pfizer/Seagen deal announced in Q1 (\$42B of the total \$60B announced), while deal count increased by 26%, to 53 total deals.

The headline figures were mostly driven by Big Pharma acquiring biotechs to fill pipeline gaps, but private equity firms that had recently avoided the pharma industry reemerged. Deals backed by financial institutions accounted for 34% of deal value, 4.6x the 5-year quarterly average, and 13% of deal count, 2.2x the 5-year quarterly average.

Global Life Science Deal Activity by Quarter



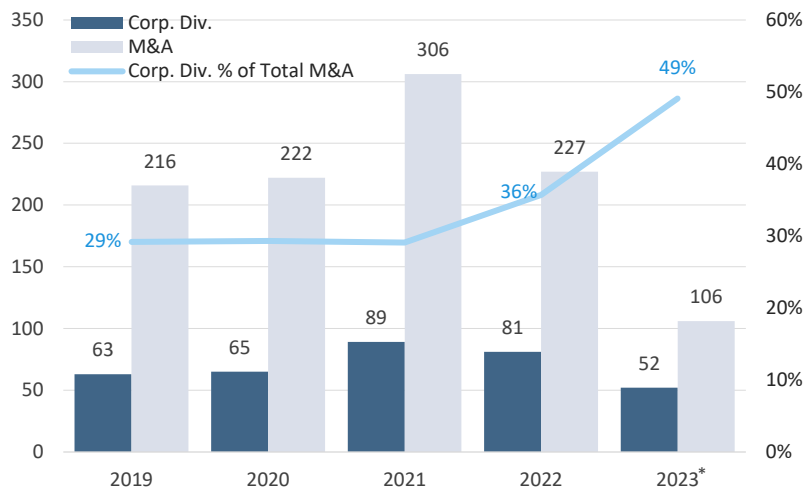
SOURCE: Bourne Analysis of CapIQ Data, Accessed 7.20.2023

This dealmaking boost was driven by a number of notable take privates, including Luxinva/EQT's \$6 billion acquisition of animal drug maker Dechra Pharma and Novo/Gurnet Point's \$462 million acquisition of antibiotic company Paratek Pharmaceuticals.

This was part of a broader take-private trend in the pharma ecosystem, as Baxter's BioSolutions CDMO was spun out to Warburg Pincus/Advent, and CRO conglomerate Syneos Health was acquired by a consortium of private investment firms.

Pharma M&A Recap & 2H Outlook (cont.)

Life Sciences Corporate Divestitures as a % of Deal Count



SOURCE: Bourne Analysis of CapIQ Data, Accessed 7.23.2023

Pharma M&A Green Shoots (continued)

Outside of take privates, PE firms have benefited from a precipitous rise in corporate divestitures, which has been a defining trend in 1H 2023. Corporate divestments have increased to 50% of total M&A count, as big pharma continues to implement a "lean pharma" transition and players across the spectrum look to use divestiture proceeds as alternative financing, with some deploying a divest-to-invest strategy and others scrambling to sure-up balance sheets as rising interest rates crimp free cash flow. ([See Bourne Partners' Market Insight Using Divestitures to Deliver Excess Return for more](#)) We believe that this will continue to be an opportunity for both sponsor-backed and non-sponsor-backed Middle-Market Specialty Pharma platforms to be acquisitive and grow market share.

Another factor influencing dealmaking is the impact of the US Inflation Reduction Act on pricing and exclusivity in more traditional drug classes. Regarding Specialty Pharma, French-based Ipsen and its two recent acquisitions in oncology and rare disease are examples. 1H dealmaking has prioritized rare diseases, most likely in response to the IRA. Biologics exhibit a similar effect, which we discuss in greater detail in the following slides.

Returning to Big Pharma/Biopharma M&A, IRA implications are also prominent, but impending patent cliffs and pharma's need to replenish pipelines are driving transactions. According to consensus estimates, the highly publicized historical loss of exclusivity (LOE) event puts more than \$390 billion of US and EU large drugmakers' annual sales at risk of generic entry, as 170 products face patent expiration in 2023 - 2030.² Another driver for Pharma M&A is the health and flexibility of balance sheets, which is of extreme importance in the current environment. Estimates project that pharmaceutical companies have up to \$700 billion available for acquisitions.⁽¹²⁾

LOE, combined with pharma's cash piles, has resulted in a much-anticipated surge in M&A activity, but this did not materialize in Q1 after Amgen/Horizon faced significant regulatory scrutiny, stalling large transformative M&A deals. This resulted in several smaller (sub-\$1B) transactions defining activity in 1H, but these deal have likely lubricated the M&A gears for heightened 2H activity.

Going forward, we believe the underlying fundamentals of dealmaking are too strong to keep activity muted, despite the persistence of regulatory uncertainty.

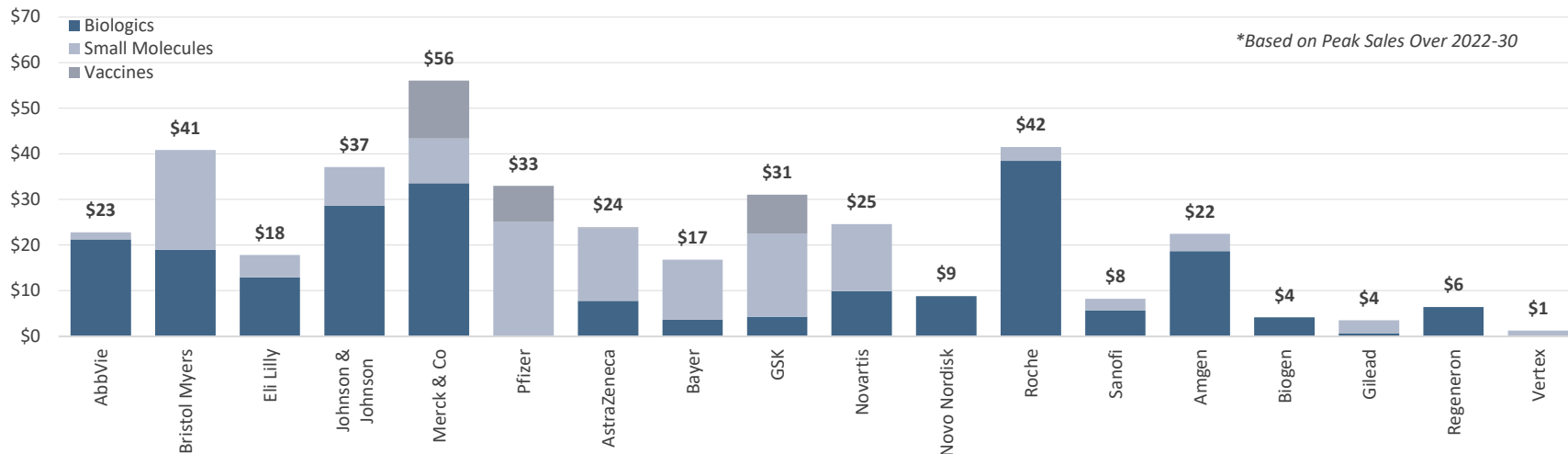
An overhead view of three business professionals in a meeting. A man in a dark suit is on the left, looking at a document. A woman in a white blouse is on the right, writing on a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

i. Industry Drivers

Patent Cliffs

Patent Cliffs

2023-30 US Drug Patent Expiration - Global Sales At Risk* (\$B)



SOURCE: Bloomberg Intelligence, Accessed 7.12.2023

Unprecedented LOE Puts \$390B at Risk

A historic loss of exclusivity (LOE) event places more than \$390B of US and EU large drugmakers' annual sales at risk to generic entrance as 170 products are facing patent expiration in 2023 – 2030, according to Bloomberg analysis.⁽²⁾

Easy-to-replicate small molecules make up about a third of the at-risk sales, while biologics represent the largest copycat opportunities, which have seen soaring uptake since 2019, especially amongst oncology-branded mAbs. Consensus estimates sees at least \$154B in sales erosion through 2030, with biologics behind about 50% of that decline.² This impending cliff has been highly publicized but regulatory impediments have limited dealmaking thus far as companies take a disciplined approach to restocking pipelines. This has come in the form of earlier

stage acquisitions, licensing deals, and prioritizing internal R&D though the first half of the year. In-licensing, in particular, has grown in popularity as a more secure way to expand pipelines. In the aftermath of COVID, oncology has also resurfaced as a focus. Cancer products accounted for 38% of acquisitions, while biologics accounted for 25% of transactions.

Regulatory uncertainty will remain an issue, but the increasing need for a pharma restock will discount these concerns – driving science focused M&A in 2H.



Patent Cliffs - Most at Risk

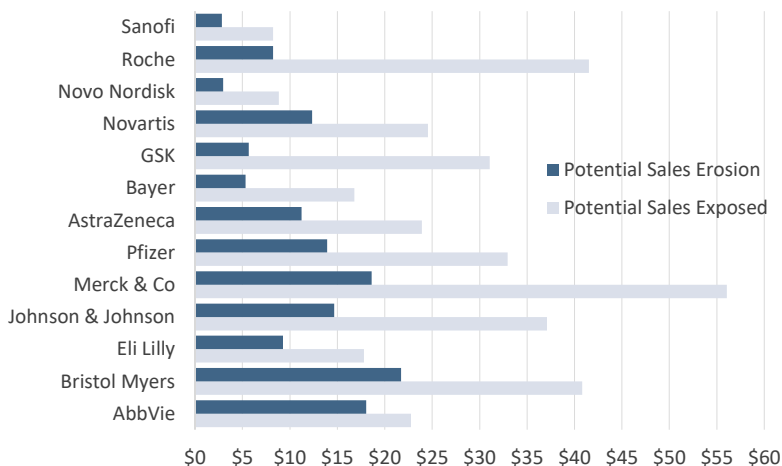
AbbVie felt the bite of biosimilar entrance this year as it's blockbuster drug, Humaira lost exclusivity. The biosimilar is priced at \$995 for a carton of two autoinjectors, an 85% discount from AbbVie's price of \$6,922. This drug has contributed to 36.6% of the company's total drug sales in 2022. While an extreme example, this puts LOE in perspective.

The players most at risk to generic entrance are Bristol-Myers, Merck, Abbvie, and Amgen. These players alone are facing revenue exposure of \$135B in aggregate, with consensus estimates totaling \$72B in sales erosion.⁽²⁾

Luckily, these players all have more than \$6B in cash and investment grade credit ratings, providing the runway to seek transformative M&A.

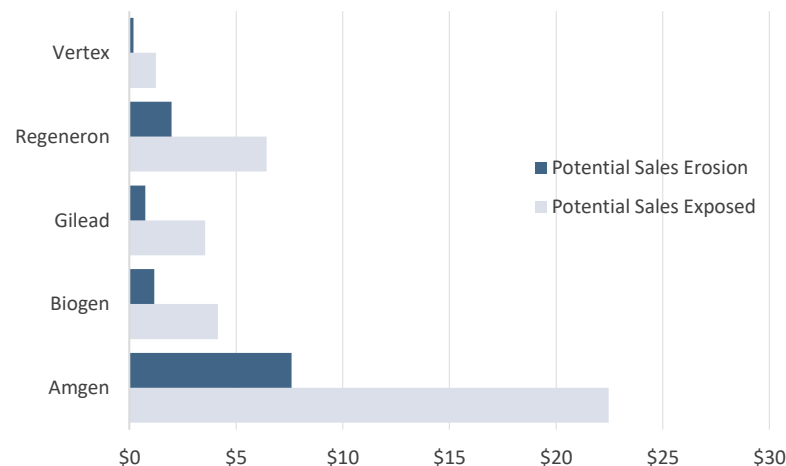
Big pharma as a whole is sitting on \$200B in cash with ~\$500B more in balance sheet flexibility to fuel M&A.⁽¹²⁾

Pharma: 2023-30 Patent Expirations: Sales Erosion vs. Exposure



SOURCE: Bourne Analysis of CapiQ Data, Accessed 7.23.2023

Biotech: 2023-30 Patent Expirations: Sales Erosion vs. Exposure



SOURCE: Bourne Analysis of CapiQ Data, Accessed 7.23.2023

An overhead view of three business professionals in a meeting. A man in a dark suit is at the top, looking at a document. A woman in a white blouse is on the right, also looking at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

ii. Regulatory Changes

FTC Scrutiny & Inflation Reduction Act

FTC - Increased M&A Scrutiny

Amgen—Horizon Suit and the Potential Behind the FTC’s Apparent Strategy Shift

While big drugmakers teeter closer to a patent cliff’s ledge, in which more than \$390B in annual revenue is at risk to expire through 2030, pharma companies should be scrambling to backfill R&D pipelines. But the FTC’s suit to block Amgen’s acquisition of Horizon may have cast a pall over an industry where nearly \$70B (albeit \$43B from one deal alone) in deals have already been announced since the start of the year.

The announcement of the FTC’s planned injunction caused HZNP stock to fall 14% lower than the price before the news—17% lower than the takeover price Amgen agreed upon to secure the deal—and has hovered in that range since. Amgen was not spared either. It’s stock sank 2% on the FTC’s news. Even firms uninvolved in pending deals were hit hard. Alnylam Pharmaceuticals Inc, BioMarin Pharmaceuticals, and Sarepta Therapeutics all saw their stocks drop 3-7% based solely on the perceived change in their acquisition potential.

This is the first transaction the FTC has challenged in over 40 years, and the first ever in pharma. The FTC cites the “conglomerate” theory of competitive harm: concerns based on neither a horizontal nor a vertical relationship, but rather preemptive concern that the parties could create a product portfolio that allegedly enables an anticompetitive business strategy. If the FTC’s block is successful, there would be massive ramifications for any pharma company with a leading position for one or more products attempting to acquire a firm that also has a leading position in products sold to the same customers - in this case PBMs - regardless of whether there is any vertical or horizontal overlap between the two. New risks factors would have to be accounted for. Risk factors such as the competitive conditions in each party’s market, whether the parties’ respective drugs are typically bought together in one transaction, and any offsetting strategies available to the merged firm’s customers.

HSR-Filed Pharma Transactions Completed Since 1Q22

| Deal | Announce Date | Days to Close |
|------------------------------------|---------------|---------------|
| Invidior-Opiant | Nov-22 | 108 |
| Merck-Imago BioSciences | Nov-22 | 51 |
| Eli Lilly-Akouos | Oct-22 | 44 |
| Pfizer-Global Blood Therapeutics | Aug-22 | 58 |
| Pfizer-Biohaven | May-22 | 146 |
| Bristol Myers Squibb-Turning Point | June-22 | 75 |
| CSL Ltd-Vifor Pharma AG | Dec-21 | 238 |
| GSK-Sierra Oncology | Apr-22 | 79 |
| Halozyme-Antares | Apr-22 | 41 |
| Hikma-Custopharm | Sep-22 | 206 |
| Pfizer-Arena | Dec-21 | 88 |
| UCB SA-Zogenix | Jan-22 | 47 |

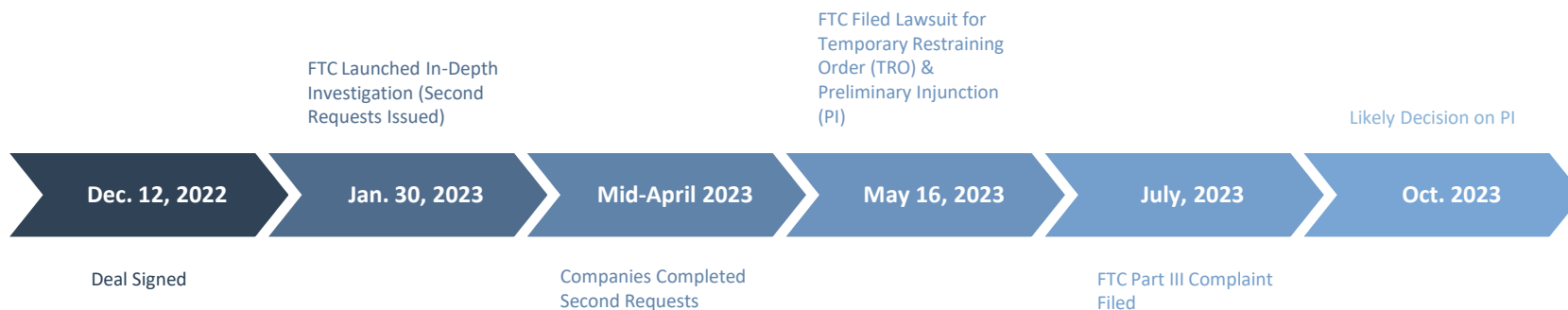
SOURCE: Bloomberg Intelligence⁽¹³⁾

The FTC seems to have a low likelihood of success, since it rests on its ability to present persuasive, concrete evidence that adding Horizon’s drugs to Amgen’s portfolio would entrench monopoly positions—enough evidence that it warrants prohibiting a transaction on concerns of potential future anticompetitive behavior rather than just challenging if the conduct actually happens.

Even if the FTC’s theoretical concern manifested, its challenge may still be on shaky grounds. The practice of bundling and drug-by-drug overlaps have been assessed inconsistently by the courts. The most recent decisions holding that it only violates the law if it amounts to predatory pricing—meaning generally it must be proved that the rebated price is below the company’s incremental cost to produce them, with later price increases planned to recoup the loss.

FTC - Increased M&A Scrutiny (cont.)

Estimated Timeline of Key Events in Amgen-Horizon Suit



So long as the FTC loses in the preliminary injunction hearing and fails to get an emergency order to stop the closing, it is believed that the Amgen-Horizon deal has a high chance of closing in Q4. The average time from complaint to decision in these types of cases is 5.2 months, putting the decision likely in October. While premonitions of harm a transaction may have the potential to produce seem unlikely to hold up in court, they still add uncertainty and delay in the pharma M&A market.

The FTC is at a crossroads in regard to Pharma M&A. Pending pharma/biotech deals before the FTC, the main being Pfizer-Seagen and Merck-Prometheus, may be the next indicators of which path it has chosen to take. Seagen stock dropped 5% after the FTC's challenge of the Amgen-Horizon acquisition was announced

But it is not believed that a Pfizer-Seagen acquisition raises any traditional antitrust issues. Especially since Pfizer ceded global rights to the drug Bavencio—a treatment for bladder cancer that may have been perceived as overlapping with Seagen's Padcev—to Merck KgaA in exchange for 15% royalties on net sales. Still, in light of the agency's challenge to Amgen's Horizon deal, the FTC may theorize Pfizer as seeking to gain the ability to wield market power in a broader oncology segment in a harmful manner.

While Pfizer isn't required to divest assets for FTC clearance, depending on how broad the FTC's new holistic approach is, it may force some divestitures to appease the FTC. Although, even if no amount of divestitures will suffice for this FTC, this approach hasn't led to success in court as judges have more often than not been open to reasonable divestiture offers.

The FTC filed a second request for more information on the Pfizer-Seagen acquisition on July 17th, which can extend the timeline for review by six to nine months.

FTC officials have stated that forthcoming FTC/DOJ merger guidelines will address conglomerate theories of harm, which would hopefully shed light on the agencies' new outlook. The groundwork being laid now by the FTC is also under consideration in the UK and EU after the formation of a multilateral pharma merger task force in 2021, meaning it's possible antitrust clearances may be needed there for Pfizer as well. The microscope the FTC, Canada, EU and UK have placed on pharma M&A, analyzing whether their current methods address competition concerns, seems set to widen its focus outside of the current status quo.



Inflation Reduction Act (IRA) - Overview

Impacts on R&D & the Drug Development Cycle

While controlling the price of brand-name drugs may help improve access to drugs currently on the market, it's a band-aid solution that addresses the problem in time for the next election cycle but increases the issue long-term; because the government can't negotiate discounts for drugs that don't exist.

If the IRA had been in place in 2014, there would have been a 40% reduction in revenue on impacted drugs. Since it costs more than \$2B on average for the R&D to bring a drug to market, it's estimated that 37 of the therapies developed over the past decade would most likely not have come to market under the IRA.

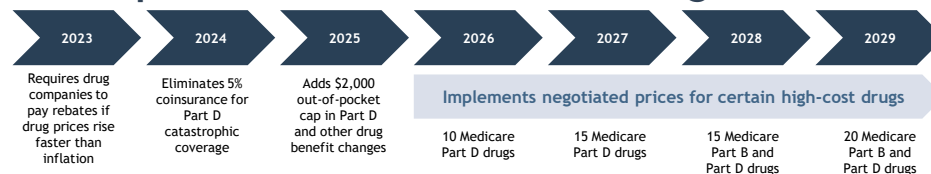
Projecting that methodology forward, as many as 139 therapies are estimated to not be developed and therefore not get to patients over the next decade because of the IRA.⁽¹⁵⁾

Due to large molecule drugs being given 13 years before they are eligible for negotiations, versus 9 for small molecule drugs, it is expected that the development of biologics will be incentivized, whether intentionally or not, despite the typically higher cost.

According to a survey by BioCentury, the only few companies that didn't expect to experience any impact were among those with fewer than 250 full-time equivalent employees. Even then, out of the surveyed companies that size, 55-60% expected at least minor but potentially major changes.⁽¹⁶⁾

| Aim | IRA Provision for Medicare | Provision Description |
|---|---|--|
| Reducing Pharma Prices | Introduces Drug Price Negotiations | The federal government is required to negotiate prices for high-priced, small-molecule, single-source drugs and biologics that are covered by Medicare and have been approved by the FDA for more than 9 and 13 years, respectively. |
| | Penalizes Price Increases | Drug manufacturers will have to pay a rebate if the prices of their single-source drugs (that are used by Medicare beneficiaries) exceed that of the inflation-adjusted price of the drugs that year. In other words, a rebate must be paid by the drug manufacturers if their drug prices increase more than the inflation rate of the wider economy. |
| | Expands Required Discounts | Drug Manufacturers will be required to pay discounts of 10% during the initial coverage phase and 20% in the catastrophic coverage phase for brand-name medications. |
| Reduced Patient Cost Sharing and Premiums | Caps Out-of-Pocket Spending | By eliminating the 5% coinsurance for Medicare Part D catastrophic coverage in 2024 and enforcing an annual \$2,000 out-of-pocket spending cap for prescription drug costs covered by Medicare in 2025, Medicare patients will have a hard out-of-pocket maximum similar to many patients with commercial insurance. |
| | Expands Eligibility for Low-Income Subsidy (LIS) | The IRA expands the eligibility for full LIS benefits to individuals with incomes between 135% and 150% of the federal poverty level and with resources up to \$9,900 for individuals and \$15,600 for couples in 2022. |
| | Eliminates Vaccine Cost Sharing | For adult vaccines covered under Medicare Part D, cost sharing has been eliminated. |
| | Limits Patients Cost Sharing for Insulin Products | Beginning in 2023, copayments for insulin products covered under Medicare Part D will be limited to \$35 per month. Furthermore, for insulin products administered via traditional pump and thus covered under Medicare Part B's durable medical equipment benefit, no deductibles can be enforced in addition to the mentioned cap in copayments. |
| | Limits Part D Premium Incr. for Beneficiaries | The IRA limits annual increases in Part D base premiums to 6% per year between 2024 and 2029. |

IRA Implementation Timeline of Drug Provisions



SOURCE: USC Schaeffer⁽¹⁴⁾

IRA - Legal Challenges

Currently, lawsuits challenging the IRA have been filed by Merck, PhRMA, the US Chamber of Commerce, BMS, Astellas, and J&J.

Here are the main claims made:

Separation of Powers

Congress delegated to HHS broad, unrestrained authority to set prices within Medicare, with no meaningful constraints on the agency's exercise of this authority.

Viability: Federal agencies' ability to regulate when they are acting within the statutes set by Congress has typically been defended by courts, so it will likely be an uphill battle to successfully argue a program established through an act of Congress as unconstitutional authority.

Judicial Review

Under provisions in the IRA, the court cannot review how Medicare defines a "unit" of a drug, which drugs are chosen, or what the negotiated price is set to be.

Viability: While the Court has mainly had a very narrow reading on provisions meant to limit lawsuits, there's at least one case in which the Supreme Court upheld limitations to jurisdiction of the federal court on Medicare claims in certain circumstances. There's compelling argument, given fuzzy spots in the IRA, that specific agency actions are still open to legal challenges.

First Amendment

Freedom of Speech is infringed by requiring firms to agree that the negotiated prices are fair. This falsely implies that they are voluntary participants, coercing them to mirror the government's political message.

Viability: The negotiation rules were revised so drugmakers are now allowed to publicly discuss the negotiations at their discretion. Since the primary argument for a violation hinged on manufacturers being forbidden to speak publicly about the negotiations, the validity of this claim is further weakened.

Fifth Amendment

The Takings Clause protects patented drugs from being taken for public use without proper compensation. Once a drug is selected for inclusion in the price negotiation program, its manufacturer is required to sell the drug for at least a 25% to 60% discount.

Viability: This seems to represent the best chance for success, if drug companies can prove the IRA's financial impact is as high as they fear. The fundamental legal question of whether a drug patent constitutes protected private property and if Medicare's price negotiations would constitute a taking under the Takings Clause are issues yet to be addressed by federal appellate courts.

The Due Process Clause, typically used in criminal procedures, is breached because the public is denied input on how the IRA will be implemented. Companies are required to charge a lower price without any opportunity to challenge the price set by Medicare.

Viability: The distinction between Due Process and Judicial review may allow a multi-pronged argument, increasing the likelihood of at least one claim sticking.

The main difference being that while Due Process relates to the public's ability to have input on a law's implementation, Judicial Review is the public's ability to challenge how a law has already been implemented in court.

Eighth Amendment

An Excessive Fine is imposed on drugmakers, since the IRA forces a tax that starts at 186% of a drug's annual revenue, increasing to a maximum of 1900%, for noncompliance, which is a disproportionate fine relative to the 'offense' it seeks to punish.

Viability: Factors to determine excessiveness include the nature of harm the offender caused, whether the law was designed to target them, and the nature of the infraction. A court may also consider whether the fine would deprive the offender of their ability to make a living in the future.

The tax is clearly meant to target pharmaceutical companies, but how it harms drug makers that refuse to comply is less consistent. Since the size and financial stability of companies varies wildly, how the excise tax impacts a company's financial future also varies. It has not yet been addressed in the Supreme Court whether those kind of differences affect whether a fine is excessive.

IRA Adverse Effects

1. **Reduction in Discovery of New Treatments**
2. **Reduction in Discovery of New Uses for Existing Drugs**
3. **Further Incentivize Biologics**
4. **Harm the Plan's Abilities to Negotiate Prices for Drugs with Promising but Uncertain Benefits**
5. **Increase Barriers for Generic Entry & Reduce Generic Competition**

1. Reduce Discovery of New Treatments

The typical costs for the research and development (R&D) required to bring a drug to market is over \$2B, and currently the biopharma sector allocates 50% more of its revenue to R&D than the next closest sector. In its entirety, the provisions in the IRA are estimated to reduce pharmaceutical revenues by 31% in the US, leading to as many as 139 new drugs not being developed that otherwise would have been over the next ten years.

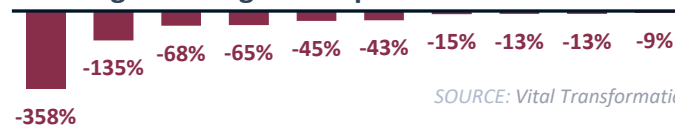
Price controls may reduce incentives to develop drugs for large consumer markets like seniors—who account for a disproportionate amount of the drug utilization in America, such as cancer—that target diseases such as heart failure, or Alzheimer's disease. In a survey conducted by pRMA, 78% of the member companies expect to cancel some of their early-state development projects.⁽¹⁴⁾

In the EU, the 10% drop in price of medicines in the price-controlled environment led to a 14% decrease in venture capital funding, as well as a 9% decrease in biopharma startup funding for each 10% decrease in price relative to the US.

Meanwhile in the UK, price controls meant that of all new medicine launched between 2012 and 2021, 30.6% fewer treatments were available in the UK compared to the US over that time. Many of the uncovered drugs in the UK representing significant clinical advances. Price controls have led to repeated trends of decreased investment and withdrawals in developing novel therapies for rare diseases in other countries—such as Germany, France, and Italy—as well.⁽¹⁴⁾

The provisions in the IRA may likely kill drug innovation and hamper the development of new treatments.

Percent Loss of EBIT from IRA Impact on 10 Firms with Highest Drug Development Losses



SOURCE: Vital Transformation⁽¹⁵⁾

2. Stall Discovery of New Uses for Existing Drugs

New applications of existing drugs often can be efficiently developed since repurposed medications already have built up extensive breadth of information that leads to reduced development time—typically 3-12 years compared to 17 years for new molecules—and development costs are 85% less than that for new drugs.

The IRA reduces the net present value of investments in new indications or other Phase IV evidence as it shortens the horizon over which firms can earn returns on these investments. Price-negotiations set by the IRA would result in reduced return on R&D investments even if new indications are identified.

Drug manufacturers receive no pricing premium if they conduct a confirmatory trial with a positive result. Similarly, a drug price negotiation late in a drug's life cycle may curtail R&D investments in determining whether a new drug works well in the real world (effectiveness estimates) or for treating diseases (new indications).



IRA Adverse Effects - Incentivization of Biologics

3. IRA May Widen the Gap Even Further for Profits of Biologics Versus Small Molecules

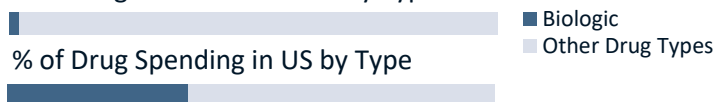
In a survey conducted by the Pharmaceutical Research and Manufacturers of America, it was found that 63% of member companies plan to shift their R&D investments away from small molecules and towards biologics due to the impact of the IRA.

Some have raised concerns about the law's potential harm to innovation and affordability, particularly for small molecules. The IRA's impact may lead to an accelerated shift towards biologics, causing deprioritization of small molecule programs. This could negatively affect patients with challenging diseases, as small molecules have shown breakthroughs in treating conditions like Alzheimer's and certain cancers.

Investors may favor companies focused on biologics due to the changes hindering the ability of small molecule manufacturer's to recoup R&D costs, leading to a shift in drug development strategies.

Overall, the IRA's impact on the pharma industry may exacerbate existing trends, such as a focus on biologics and innovative therapies. However, feeding this trend may cause life-saving small molecule treatments to die in development and average therapy costs to rise due to more biologics and less small molecules reaching market, contradicting the law's intent.

% of Drugs on Market in US by Type

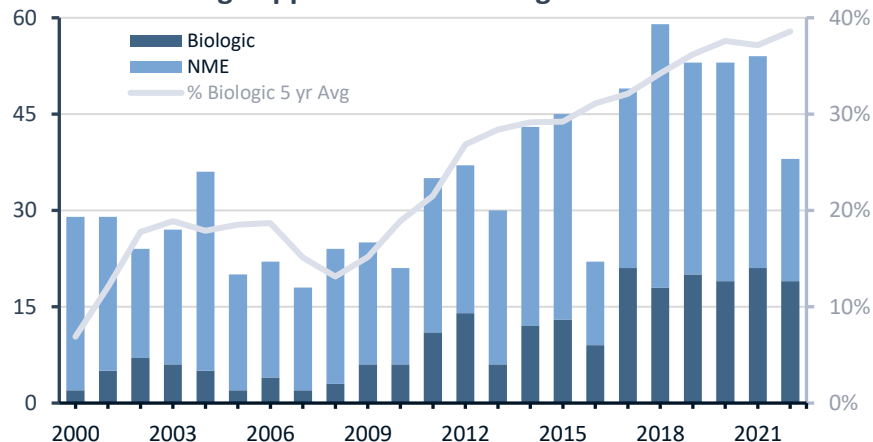


% of Drug Spending in US by Type



Source: Morningstar Equity Research⁽¹⁸⁾

Annual Drugs Approvals vs. % Biologic



Source: Nature Biotechnology⁽¹⁹⁾

4. Inflation Rebates Hurting Negotiations for Drugs with Promising but Uncertain Benefits

Forcing manufacturers to pay a rebate to CMS if their prices increase faster than inflation, is designed as if the value of a drug is a known fact at the time of launch. In reality, a drug's value fluctuates over time as additional information is revealed after approval.

Drug manufacturers are less likely to accept lower launch prices since they know that their ability to increase prices is limited, regardless of how effective their drug proves to be. Manufacturers may also have little incentive to invest in researching new evidence if the findings are unable to change the drug's price. Tying the evolution of drug prices to inflation rather than new information about a drug's true real-world value, deemphasizes the usefulness of the drug itself and likely will only succeed in driving up launch prices.

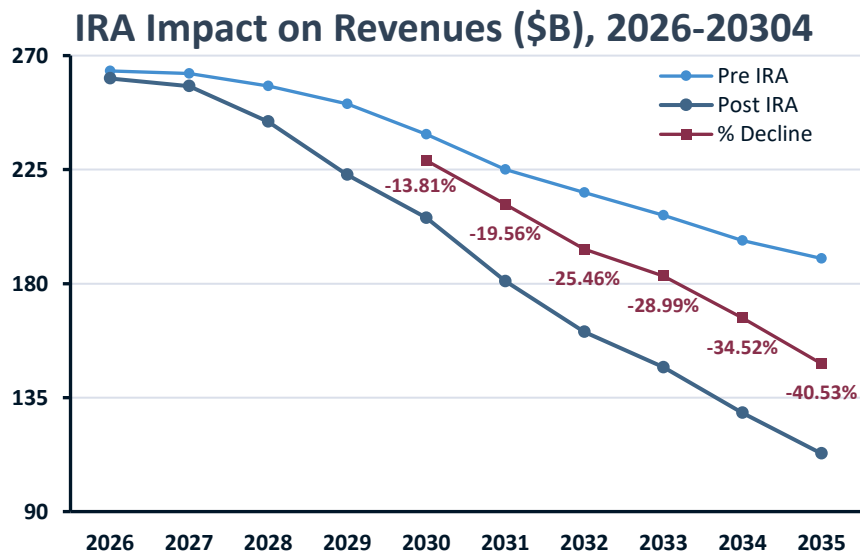
IRA Adverse Effects - Rebates & Generic Competition

5. Cripple Generic Competition

Unlike branded drugs, generic drugs are 16% cheaper in the U.S. compared to markets abroad, comprising only 18% of all U.S. drug costs despite being the vast majority of the drug volume.

A healthy generic industry is crucial to not just lowering brand-name drugs prices but also the stability of the healthcare system as a whole. It's thought that the IRA will likely price-set brand-names up to 40% cheaper than the average first-to-market generic point and as much as 60% beneath list prices.

With discounts depending on how long ago the branded drug was approved, predicting price-entry level for generics becomes much less apparent. Margins shrink on long-monopoly branded drugs; therefore, first-to-market generics could face around a 40% discount to what the current average expected entry price is now, making generic entry unviable.



Pricing Pressure & Consolidation of Generics

The more generics enter, the more the brand-name drug's price is forced to lower. According to a 2005 FDA analysis, the average relative price per dose of a branded drug was reduced by nearly 90% with 15 or more generic entries. The level of generic market entry depends strongly on financial incentives. Although smaller than their branded peers, there are still significant upfront costs to develop a generic drug. On top of that, to break a large portion of the market share away from the branded market, the generic must also be sold at a sufficient discount.

Rather than the 15 generic entrants the FDA touted back in 2005, today 40% of generic markets are supplied by one manufacturer, with exit rates exceeding those of entry. If the one advantage first-to-market generic entries have—the ability to be granted a 180-day exclusivity period under the Hatch-Waxman Act before other generics can enter behind—is castrated by branded drugs' prices fixed so low by the IRA that there's simply not enough potential volume and revenue for a generic manufacturer to justify entering the market, it may disincentive generics from entering the market altogether, effectively threatening the viability of the entire generic industry.

When a market has only one generic manufacturer, if that manufacturer exits for any reason, whether due to bankruptcy or to shift resources to a more lucrative market, it can take years before a new entry can meet the level of production needed. The lack of incentive for a generic manufacturer to produce more complex and less profitable generic drugs is already a significant issue for supply chain reliability and a leading cause in the surge of drug shortages.

Generic prices seem to be stabilizing but at levels potentially too low to sustain the level of production certain critical, life-saving drug's require—this stability partly being due to manufacturers resorting to threatening to exit certain product categories. If the IRA kneecaps generics further, it will cripple the legs on which the entire healthcare system stands.

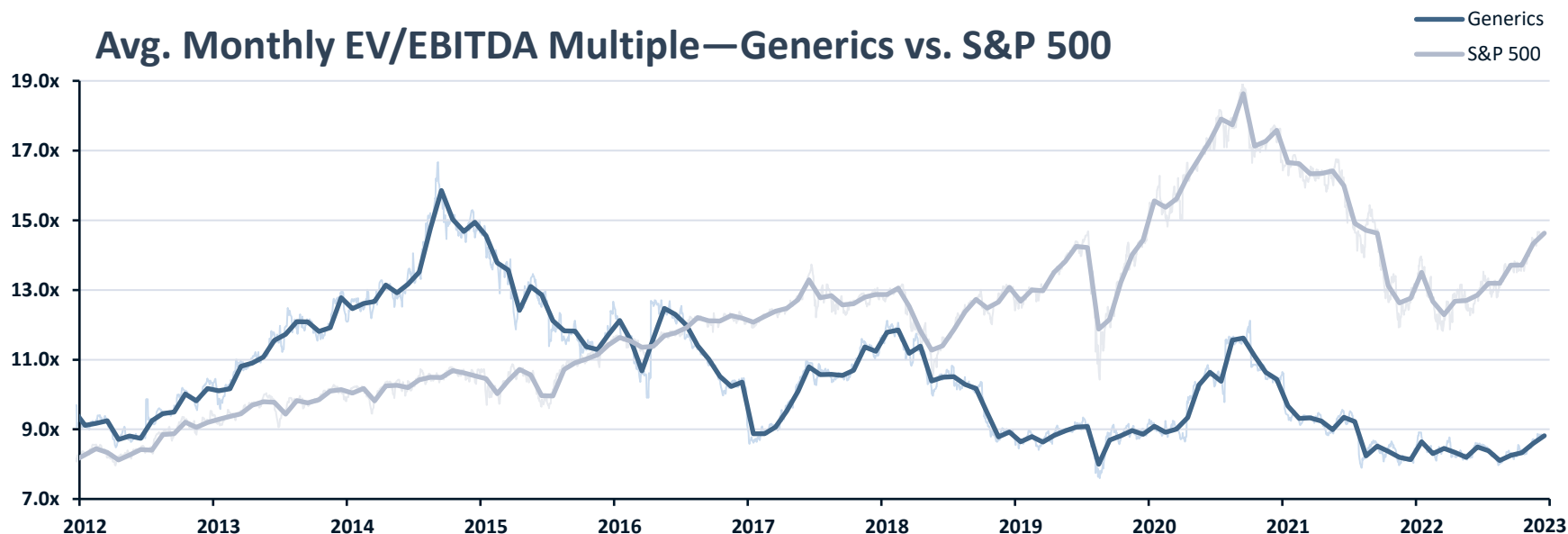
An overhead view of three business professionals in a meeting. A man in a dark suit is at the top, looking at a document. A woman in a white blouse is on the right, pointing at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

iii. Sub-Sector Spotlight

Generics & Drug Shortages

Generics - Potential Start to Upcycle

Avg. Monthly EV/EBITDA Multiple—Generics vs. S&P 500



Upcoming Patent Cliff May Jump Start Generic Upcycle

The market landscape appears primed for a major upcycle, akin to FY2011-15, through FY23-28.

The most notable parallel being another instance of a looming patent cliff, as well as rising instances of drug shortages. Brand-name drugs coming off patent through CY22-30 open a \$200B opportunity, over half the current market size of major biopharma companies' entire drug portfolio.

Of that \$200B, \$118B (\$42B in biologics and \$75B in small molecule drugs) in opportunity may present itself for generic manufacturers by 2026.

The \$75B in new product opportunity for small molecule drugs is roughly three times the size of new product opportunity in 2019 through 2021.⁽²⁰⁾

The patent cliff will also likely benefit the rest of a generic manufacturer's portfolio by reducing competition as other companies shift their focus from fighting for market share of pre-existing products to claiming new opportunities.

This may also improve pricing for older products. New opportunities allow the industry's bandwidth to become more spread out, rather than forced to compete in already cramped spaces, meaning the patent cliff likely benefits even smaller players without any significant new product opportunities.

After the upsides of new opportunities granted by a patent cliff subside, pricing erodes as players shift focus from fueling growth by expanding into new spaces back to competing in market share in older products. From 2015, this annual price erosion slowly worsened from low single-digit to mid-high single-digit by the time COVID lockdowns began in 2020.

Due to US generic distributors stockpiling massive inventories of products in the early parts of the COVID19 lockdowns in fear of supply chain disruptions, then when those disruptions failed to materialize by the time that stock with distributors hit demand in FY22, suppliers were left with extra inventory.



Generics - The Give & Take Effect of Drug Shortages

Unsustainable Price Erosion

Generic manufacturers in FY22 were confronted by annual revenue declines in the face of their growth targets, forcing them to chase market share even more fiercely. Due to that increased voraciousness, prices severely eroded across the market, averaging low-mid double digits and as much as 40-50% for specific products. This partly led to the rise in product shortages as the intensity of price erosion forced many players out of many products.

Once prices drop below minimum profitability level and a player exits a product entirely, the logistics and manufacturing chain break down, making quick re-entry an arduous task.

It also means new players are disincentivized from investing in product developments to fill that space. The sudden spike in drug shortages began in Q1FY22, when pricing pressure turned its most acute, leading to an all-time high of 301 drugs in short supply by Q4FY22.

There often only exists one to two companies with the ability to supply a certain product at short notice. If those one to two companies discontinue manufacturing it, it takes at least two years for a new player to develop a product and launch it in the US market.

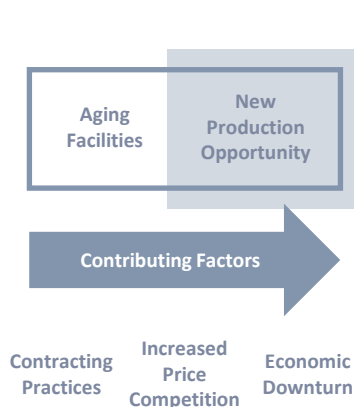
But for committed US players that do invest in the US market, the underinvestment by their peers may trim competitive intensity for the next three to five years.

Once the breaking point in pricing has been reached, drug shortages likely strengthen generic's pricing power in the US market due to a company's ability to bundle their other products with the ones in short supply, further adding to the overall market's upcycle.

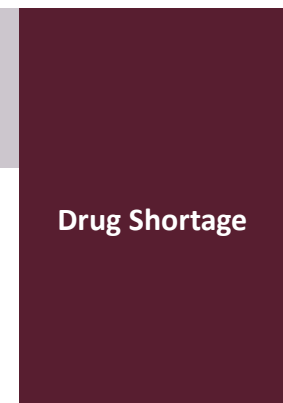
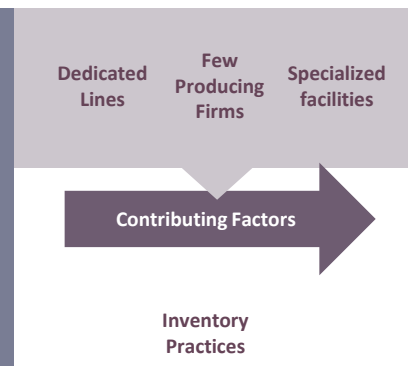
Therefore, large generic manufacturers who have the widest product basket should be expected to benefit the most in a potential upcycle. Although smaller players might benefit from better pricing and competitive dynamics later on.

Drivers of Drug Shortages

Economic Drivers



Supply Disruption



SOURCE: Nature.com/cpt⁽²¹⁾

Generic Sterile Injectables (GSIs) Shortages

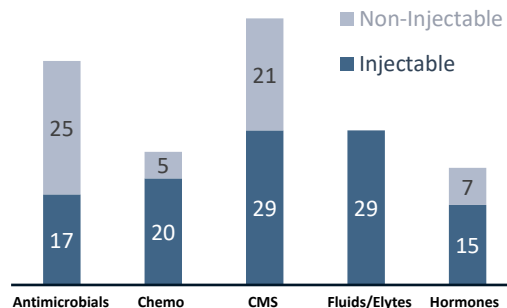
Disincentivizing Reliability

A key issue is that currently generic manufacturers compete solely on pricing. Hospitals view any two versions of the same generic drug as exactly equivalent substitutes, which exerts burdensome price pressures on manufacturers.

Reliability—both in the sense of a product's availability and in the sense of consistent, high quality—is not merely unimportant to manufacturers, it is actively discouraged. Both manufacturers and consumers are hurt in the long run by generics being differentiated solely through price competition.

Manufacturers are hurt because they must continuously compete with its competitors on prices, regardless of if that manufacturer's product is significantly more reliable than any of its peers. And patients are hurt because it leaves them exposed to drug shortages of essential medicines and to unsafe products due to poor manufacturing conditions.

Active Shortages Top 5 Classes



SOURCE: *ashp.org*⁽²²⁾

During a supply chain disruption, generic drug products lose 10.8% of their market share, unable to fully recover even after the supply chain is restored, with around 30% of products that experience a manufacturing disruption failing to regain their pre-disruption market within a year.

Constantly creeping price erosion can also reduce the viability of certain products and force specialized players into bankruptcy. The disjoint in the supply chain between what it needs to be reliable and what it incentivizes to be made, is the root cause of the instability in generic manufacturing companies' valuations and the availability/quality of the drugs they produce.

Disincentivizing Specialization

A Senate report found that critical generic drugs, particularly GSIs, were more than twice as likely to experience shortages compared to other dosage forms, such as oral tablets or topical products.

There are about 300-400 different FDA-approved, physician-administered GSI drugs—in contrast to more than 2,000 generic oral dose drugs sold in pharmacies—and the use of GSIs is much more specialized, meaning the markets are typically smaller than the markets for oral dose products, on the order of 200 times. GSI markets invite less entry than oral therapies and may end up highly concentrated—around 20% of GSIs have only one generic manufacturer. The January 2023 FDA drug shortage list included 77 GSIs, comprising 62% of all drugs then in shortage.⁽²³⁾

Of the over fifteen basic critical care drugs that have been in shortage over a decade, the majority are injectables. Meanwhile, new shortages are occurring in products where there are multiple manufacturers, but the product is still completely unavailable.

With low prices and margins, firms lack incentives to upgrade their facilities and may cut corners with respect to tight manufacturing and quality control processes.

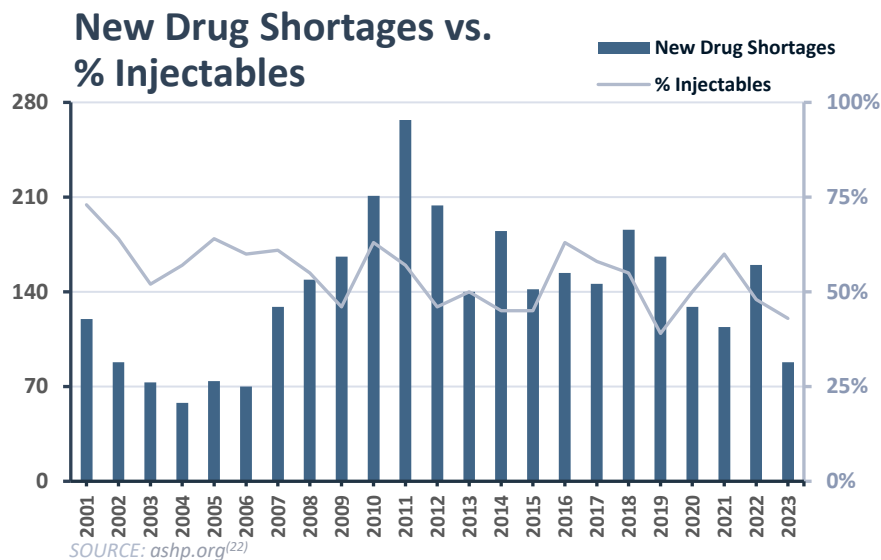
It is complex to produce GSIs because the lower margin for error in the final production stage requires that the fill-and-finish manufacturing stage be done in specialized facilities with well-defined manufacturing processes.

U.S. GSI manufacturing infrastructure is deteriorating due to limited external financing options since the returns on GSI investments are projected to be so low. Manufacturers may drop the less-profitable and generally older products from their portfolio if that portfolio is being transferred.

Oftentimes, generic drug manufacturers operate at full capacity and therefore are not able to adequately respond to manufacturing disruptions or increase in demand. They often rely on a single production line for multiple weeks to increase efficiency.

Many GSI production lines tend to repeatedly switch between products, raising the risk of contamination. Due to this, if a line is shut down to remedy a problem, it could take weeks to months to fix.

Generic Drug Shortages - Mitigating Impact



FDA Oversight

The FDA is forced to rely on manufacturers to report problems, meanwhile, manufacturers have strong incentives not to report any problems. The FDA does not have the authority to force companies to recall drugs in most instances.

Perhaps the most significant challenge the FDA faces is what might be referred to as “too-important-to-fail” products with GSI facilities that manufacture a large share of medically necessary products. There, the FDA must balance the short-term harm from creating a shortage with the potential impact of a manufacturing problem and often uses regulatory flexibility in the face of looming shortages. This allows a manufacturer to depart from requirements defined by current Good Manufacturing Practices (cGMPs).

But using regulatory flexibility to ensure product is flowing sends the wrong signal to manufacturers. The probability of being caught isn’t great, and the consequences likely not as high as they should be.

The FDA has repeatedly advocated for manufacturers to invest in systems that maintain consistent, reliable, and robust processes and go beyond the baseline manufacturing requirements to achieve a state of quality management maturity. This would help differentiate a generic drug product by a metric other than price.

Hospitals & Buffer Inventories

Annual spending on physician-administered GSI drugs in the US is about \$15B, with pharmacists suggesting that GSIs can often represent 70% of hospital pharmacy drug volume. Most hospital payment arrangements for GSI drugs encourage hospitals to minimize spending on inputs to treatments, like GSI drugs.⁽²³⁾

Holding buffer inventory is one way to improve continuity of supply. Normally a hospital might carry 30 days of product on hand, but with a buffer inventory, the government would pay wholesalers to carry 200 days of certain products. If there’s a supply disruption or demand increase, the buffer supply can start to be drawn down, so a shortage does not occur. Limiting contracts to reliable distributors is another way buyers can improve continuity of supply.

Drug Shortages’ Outlook Ahead

Overall, expect drug shortages to worsen, especially for sterile injectables, in the near-to-mid-term. Outside of the expected economic and quality pressures driving GSI shortages, Pfizer’s North Carolina manufacturing plant—which produces around 30% of sterile injectables used in US hospitals—was struck by a tornado on July 19th. While the production lines were reportedly spared the brunt of the damage, the warehouse, where Pfizer had its supply of sterile injectables stores, was heavily damaged. Sterile injectable shortages should be exacerbated until Pfizer can ramp-up production and recreate lost product.

Generic Drug Shortages - Root Causes

Economic Drivers

Market Consolidation in the pharmaceutical distribution market drives negotiation power for intermediaries, resulting in lower retail costs for final consumers, but also in lower margins for manufacturers.

Group Purchasing Organizations (GPOs) buy over \$100B of drugs in the U.S. each year, but only four GPOs account for 90% of the medical supply market. Limiting the number of suppliers for hospitals to choose from and for manufacturers to sell to, has led to race to the bottom pricing, squeezing manufacturers to the brink of bankruptcy and further fueling shortages.

Low Drug Costs correlate with shortages. In 2022, of the more than 400 drugs GPO Premier had under contract that cost \$3 or less per vial, 42% were actively in shortage, compared to only 6% of drugs that cost more than \$10 per vial. The average price of a generic drug product with a single manufacturer is 39% lower than the branded product, versus 95% lower for a generic drug product with six or more manufacturers.

Lack of Incentives and Market Exits caused by the economics of generic drug manufacturing, including the complex manufacturing process, has resulted in increased barriers for manufacturers to both enter and remain in the market. Between 2014-16, 40% of generic drug markets were supplied by one manufacturer. Lack of incentives to produce less profitable drugs is a key cause of shortages.

Lack of Investments in quality systems restrict supply chain resilience. Drug products manufactured at facilities with a greater number of manufacturing violations have a significantly higher likelihood of a shortage event. Between 2013-17, over 60% of drugs that experienced shortages were because of quality control issues.

Focused Geographic Reliance

By 2021, 87% of generic API manufacturing sites and 63% of generic finished dosage manufacturing sites were located overseas. US plants continue to close, while an increasing number of sites open in India and China, where issues of reliability have been much more prevalent. Anticompetitive pricing by China and others has also resulted in an overreliance on foreign sources.

Insufficient Supply Chain Visibility & Diversity

Manufacturers do not always know where their key starting materials are from and they generally do not know the API supplier's full capacity. Distributors have line of sight into suppliers but may not have visibility into raw material supply chain.

With a globalized supply chain, it's crucial to have diversity in sourcing and manufacturing to ensure unexpected disruptions do not lead to shortages. The lack of visibility makes it difficult to accurately assess supply chain vulnerabilities and often creates a false appearance of diversity in the market.

Increased Demand

According to GPO Premiere, a fill rate—defined as a pharmacy claim found within 90 days of the electronic medical records (EMR) prescription—above 90% indicates a supply chain is in good health, while below 80% is an early sign that shortages may be imminent due to demand outpacing supply.

Most generic manufacturers' flexibility to increase production when there is a spike in demand is limited due to just-in-time manufacturing, a limited number of manufacturers, and low cost of key generics.

Regulatory Challenges

Regulatory requirements can hinder manufacturer's ability to mitigate shortages by increasing the time and cost of responding to a supply disruption. More flexible regulatory approaches for API manufacturers could lower costs and make manufacturers more willing to pursue continual improvements, such as using a performance-based approach.

Natural & Biological Disasters

As the rate and severity of natural disasters and biological incidents continue to rise, concentrated geographic suppliers of critical drugs pose increased risks. Natural disasters and biological incidents, such as COVID19, have exposed the risks of relying on suppliers from a concentrated geographic location.



Generics & Generic Drug Shortages

Generic Manufacturers' Outlook Ahead

Nearly 80% of manufacturing facilities that produce active pharmaceutical ingredients (APIs) are located outside the US, and 90-95% of GSIs used for critical acute care in the US rely on key starting materials from China and India. Expect efforts to be made to incentivize domestic production in attempt to strengthen the durability and quality of the supply chain.⁽²³⁾

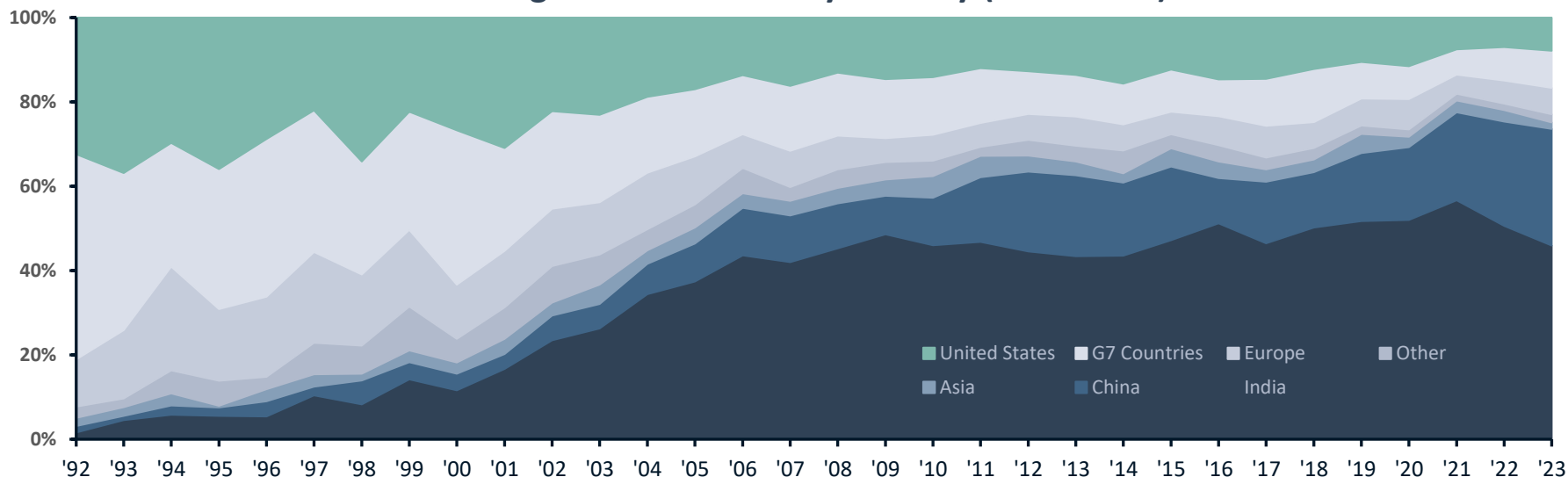
Modest generic deflation should be viewed positively by drug distributors, as the combination of the upcoming patent cliff, withdrawals of players from low-priced contracts and increased incidences of drug shortages, and also underinvestment by manufacturers in future US growth, should help ease the price erosion generics had been suffering to the point manufacturers might actually be empowered with a degree of pricing power.

Bankruptcies, such as Akorn or Lannett, seem to point to prices having already hit unsustainable levels, meaning further downsides are potentially limited, and in FY23 the competitive environment in US generics has steadily improved.

Sentiments seem to have begun to shift among industry leaders as well. In a Q4FY23 earnings call, Lupin's CEO, Vinita D. Gupta, stated that "we are starting to see [improvement on the pricing erosion]... our customers have become, again, very, very focused on the reliability of supply.. which gives [Lupin] comfort that [customers] are prioritizing [Lupin's] reliability of supply over price."⁽²⁵⁾

Overall, the improvement in the US competitive environment appears sustainable in the medium term, with future improvements likely, and if the upcycle from 2011-2015 is anything to base off of, it seems likely that the long seven-to-eight-year downcycle that followed the peak of the upcycle in 2015 has bottomed out. The ground now is fertile for another upcycle in the US generic market in the near future.

Percent of API Manufacturing for U.S. Market by Country (1992-2023)



Off-Patent, Off-Exclusivity Drugs without an Approved Generic

FDA Drive Toward Pharmaceutical Competition

To improve transparency and encourage the submission of abbreviated new drug applications (ANDAs) in markets with little competition, the FDA maintains a list of off-patent, off-exclusivity drugs without an approved generic. These situations attract high political scrutiny since manufacturers of "single source" drugs can charge high prices, which are often subsidized by the public via Medicare and Medicaid.

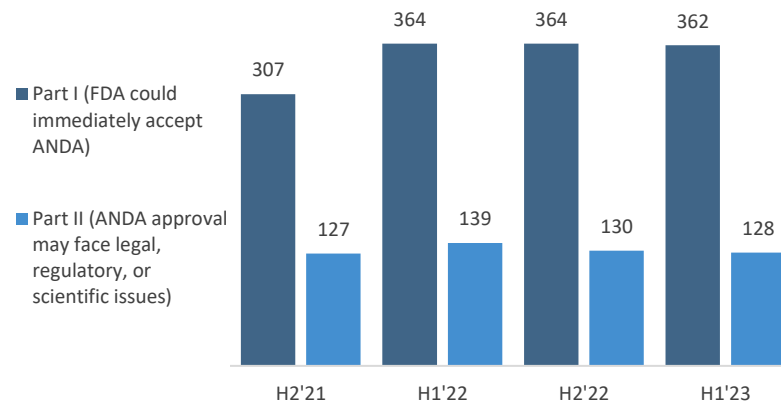
The FDA's June 2023 update lists 362 prescription NDA products for which the FDA could immediately accept an ANDA, which is only slightly below the tally of 364 from six and twelve months ago. Drugs with a single approved supplier are more vulnerable to supply shortages so the entry of additional competitors may reduce the frequency of such disruptions.

Competitive Generic Therapy Approvals

In 2017, the FDA Reauthorization Act of 2017 (FDARA) introduced the Competitive Generic Therapeutic (CGT) pathway which incentivizes manufacturers to develop drugs that address markets with inadequate generic competition. For drugs approved via the CGT pathway, the sponsor benefits from a 180-day period of marketing exclusivity, during which no other generics will be marketed. This upside is conditional on the new drug hitting the market within 75 days of the ANDA approval.

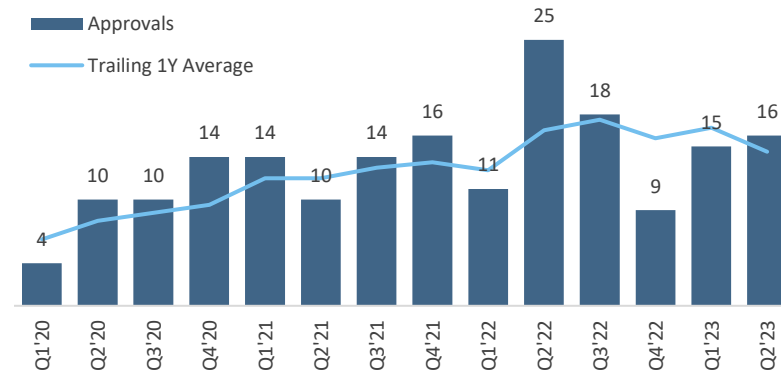
As of June 30, a total of 215 CGT approvals have been granted since inception of the program and the steady upward trend indicates that the program is working as intended by the FDA. The trend is also visible when reviewing SEC filings of publicly traded US generics companies; just two 2018 filings made reference to CGT, compared to eleven in 2022 and eight thru the first half of 2023 alone. Amneal is leading the race to develop CGT generics with 22 approvals to date.

List of possible CGT development targets remains lengthy



SOURCE: FDA List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic, Updated 6.13.2023⁽²⁷⁾

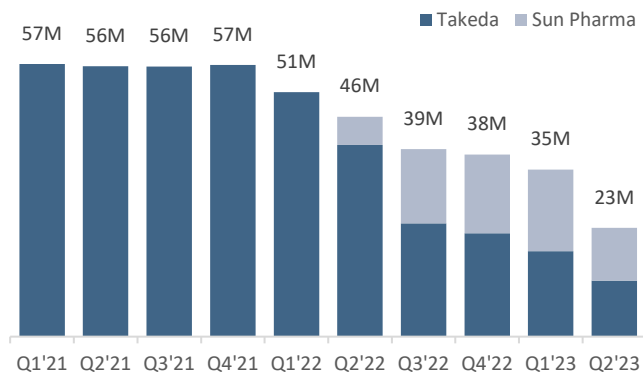
CGT approvals by FDA are increasing in frequency



SOURCE: FDA List of Competitive Generic Therapy Approvals, Updated 6.29.2023⁽²⁸⁾

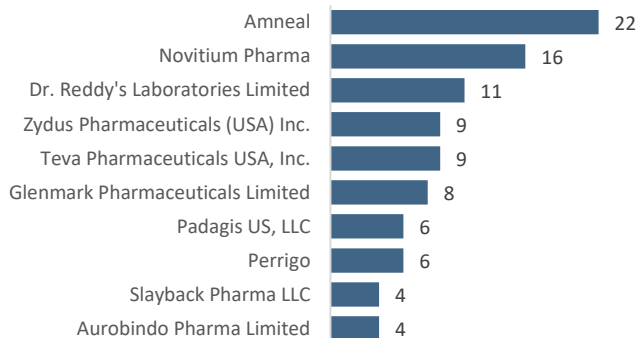
Off-Patent, Off-Exclusivity Drugs without an Approved Generic (Cont.)

Sun's Pentasa® generic launch exemplifies the success of the CGT program



SOURCE: Bloomberg Intelligence Accessed 7.23.2023⁽²⁹⁾

Amneal and Novitium share almost one fifth of the 215 CGT approvals to date



SOURCE: FDA List of Competitive Generic Therapy Approvals, Updated 6.29.2023⁽²⁸⁾

CGT Bolsters Generic Pharma and Cuts Federal Drug Spending

Increasing popularity of the CGT program is leading to positive outcomes for generic pharma. Glenmark saw a 5% increase to its share price following the FDA's CGT ANDA approval of its hydrocortisone valerate ointment in 2018. Revenues from the new generic contributed to an 11% increase in the company's US business for the 2018/2019 financial year. Takeda's ulcerative colitis drug Pentasa® (mesalamine sustained release capsules) - first approved in 1993 - had been on the FDA's watch list for several years since its patents and exclusivities expired, and no generics had entered the market. Sun Pharma finally launched the first CGT-designated generic in Q2 2022, and quickly picked up two-thirds of the volume by Q2 of 2023. Pentasa had previously been flagged as a leading contributor to federal spending across all off-patent drugs lacking generic competition, with an estimated \$68M billed to Medicare Part D and Medicaid after rebates in 2018. The introduction of Sun's lower cost generic halved the annual sales value of this market, thus reduced federal spending – as was the government's original objective of the initiative.

In 2018, total post-rebate federal spending on off-patent drugs lacking generic competition was estimated at \$1.6B. If the spending on these drugs could be reduced by between 20% and 80%, savings of between \$0.3B and \$1.3B could be achieved. These estimates do not consider the private sector market for pharmaceuticals which would also benefit greatly from increased generic competition.

Bourne Partners Takeaway

Bourne expects growing engagement with the CGT pathway by generic pharma companies, following the segment leaders Amneal and Novitium (a former Bourne portfolio company, exited in 2021 to ANI). Business development efforts may move to niche, specialized product development opportunities where regulatory support programs may expedite and risk-proof the approval process, while promising an attractive window of marketing exclusivity prior to the entry of additional generic competitors. Efforts by manufacturers to develop CGT-designated drugs will continue to be rewarded by the FDA, considering the political spotlight on drug pricing and drug shortages. The industry should also prepare for relaxation of rules surrounding drug imports from overseas, or even a decision to launch public-sector drug manufacturing.

An overhead view of three business professionals in a meeting. A man in a dark suit is at the top, looking at a document. A woman in a white blouse is on the right, pointing at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

iv. Emerging Markets

Obesity Therapies



Emerging Markets - Obesity

Novo Nordisk & Eli Lilly Race to See Who Can Win Pharma's Biggest Loser

As drugmakers race to carve out their slice of the weight-loss market—which is projected to reach \$150B by 2031—the fight for fractional increases in bodyweight reduction is turning into an arms race of innovation.

The current gold standard of efficacy is Eli Lilly's dual agonist tirzepatide, which targets GIP and GLP-1 and is already on the market for diabetes as Mounjaro.

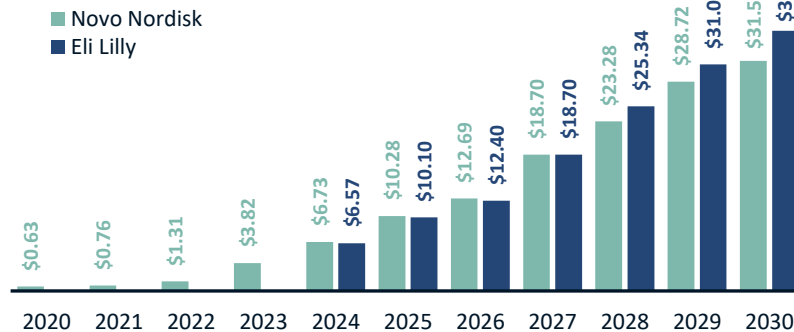
Tirzepatide saw a 22.5% bodyweight reduction in one study, crushing the 15% reduction expected by Novo's Wegovy over 68 weeks. US sales for it could top \$14B in 2030, given its higher projected weight loss and the fact that it would be launching into a more developed obesity market after its approval in 2024.

Novo Nordisk's response? CagriSema. Targeting 25% reduction at 68 weeks, CagriSema hitting that target is key to Novo sustaining long-term growth of their weight-loss franchise. Especially since Novo's diabetes version of Wegovy, Ozempic, loses exclusivity in 2032 and is a prime candidate for IRA price negotiations in 2027, which may affect Wegovy's sales.

However, Lilly may have an ace up its sleeve. Except for Novo's CagriSema, which targets GLP-1 and amylin, all known weight loss therapies on market or in development are agonists that target either one or two out of GLP-1, GIP, or glucagon.

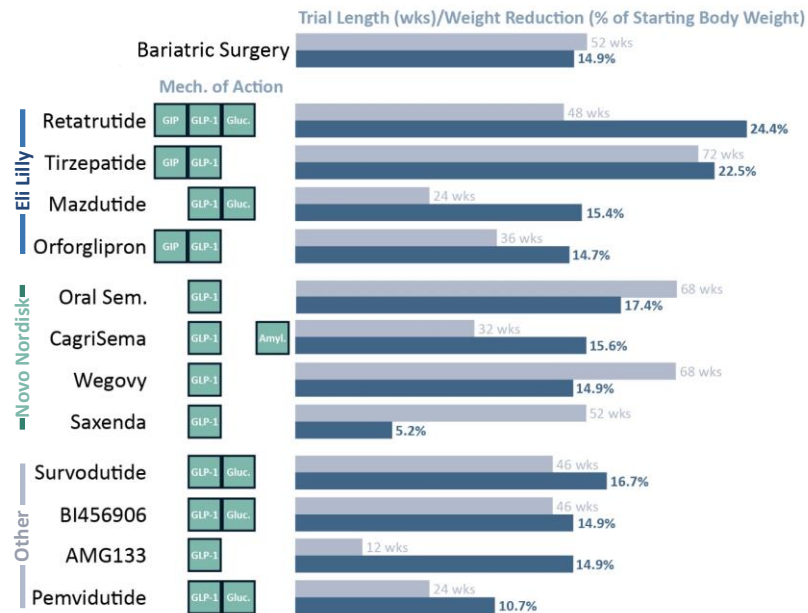
Lilly's Retatrutide is the only known triagonist in development, meaning it targets GIP, GLP-1, and glucagon. GLP-1 slows gastric emptying, increases satiety and reduces appetite, while GIP reduces food intake and body weight and increases energy expenditure; glucagon, meanwhile, is a hormone that modulates lipid metabolism and promotes appetite suppression and energy expenditure.

Novo Nordisk vs. Eli Lilly's Obesity Drugs Projected Revenue (\$B) US, 2020-2030



SOURCE: Bloomberg Intelligence⁽³⁰⁾

Efficacy of Obesity Therapies



SOURCE: Company Press Filings⁽³¹⁾



Emerging Markets - Obesity

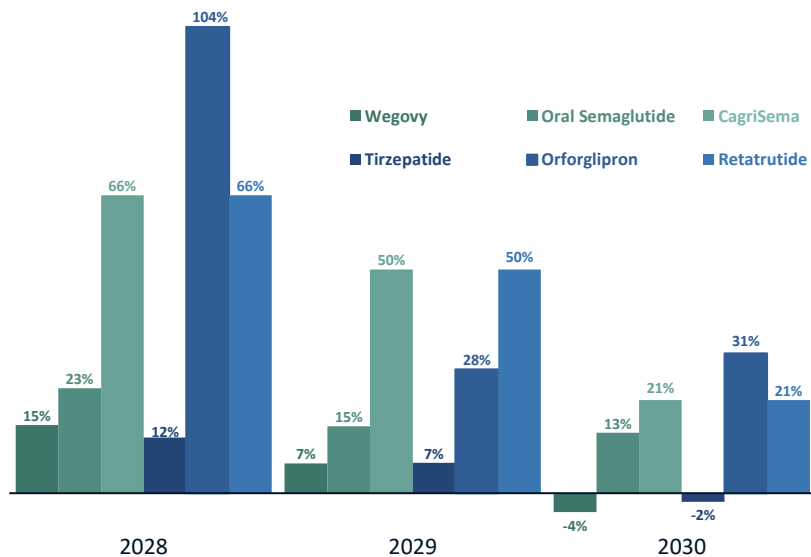
Tri-agonist, Retatrutide, Is Likely to Give Eli Lilly the Lead by the End of the Decade

Targeting all three might be the edge Lilly needs to outperform its competition. Retatrutide’s benefit already exceeds tirzepatide—the drug achieved a 24% weight reduction at 48 weeks in a P2 obesity trial and a 17% reduction at 36 weeks in a diabetes trial.

Both trials suggested more improvement was likely beyond the time frame.

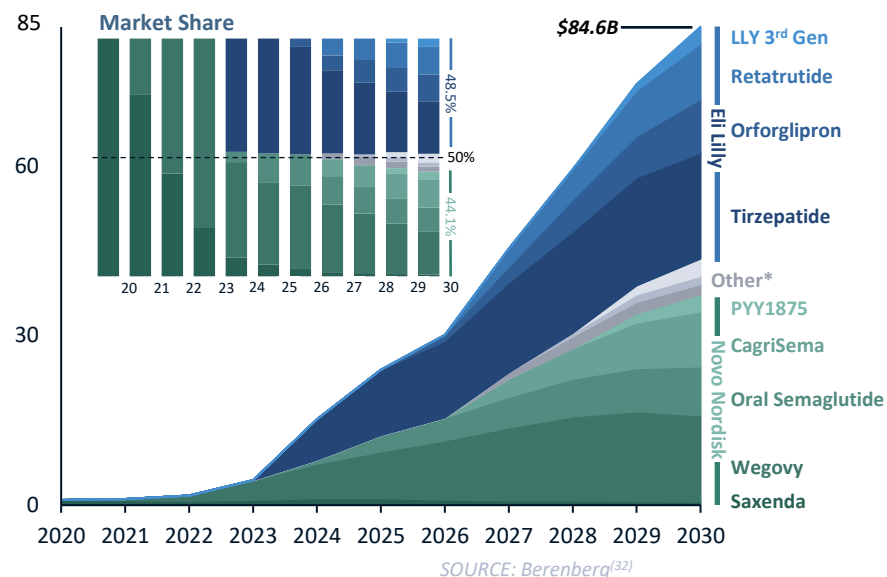
In retatrutide’s diabetes trial, 63% of patients lost 15% or more weight, which is a 23% improvement over the number of patients who met the threshold for diabetes reversal in tirzepatide’s trial.

Forecasted YOY Revenue Growth



SOURCE: Berenberg⁽³²⁾

Projected Revenue (\$B) Obesity Therapies Worldwide, 2020-30

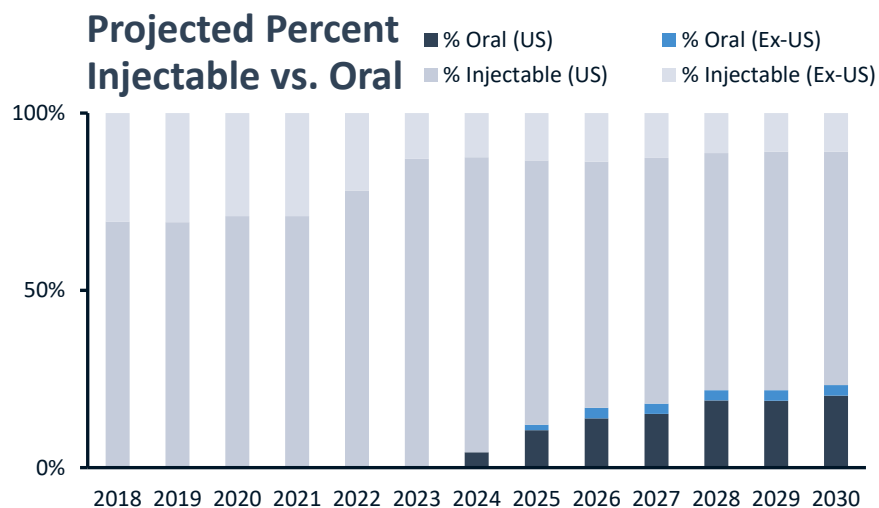


Retatrutide’s progress suggests a 2027 approval, after which sales in the US could hit \$2B in 2030.

And while there is even more potential competition in development—such as Altimmune’s pemvidutide—that may have competitive weight loss now, Novo and Lilly will likely have raised the efficacy bar further by the time they reach the market.

If rivals can’t compete on efficacy, they will likely have to compete on price instead.

Emerging Markets - Obesity; Oral Therapies



Oral Therapies Are Poised to Claim a Smaller but Meaningful Slice of the Weight Loss Market

Another differentiation may be application, with Pfizer claiming sales of oral GLP-1 drugs could reach \$16.5B in 2030, 30% of total GLP-1 drug sales (Pfizer may have missed their chance to claim the lion's share of that, however, after announcing in July they've scrapped lotiglipron for safety concerns, leaving only twice-daily danuglipron left in their pipeline—which had been seen as having far less potential than its once-daily counterpart, lotiglipron). Orals are thought to need at least a 15% bodyweight reduction in order to drive meaningful use.

Novo Nordisk's oral semaglutide appears on par with its injectable counterpart, Wegovy. It's projected to win approval in 2024, but its launch timing is less certain. With the pill version having 20x more active ingredients—25-50mg of semaglutide vs 2.4mg in the Wegovy injectable—used than in the injectable, expect an already tight supply to tighten further.

Large molecules, like Novo's oral semaglutide, are known for their difficulty to manufacture and often require specific temperatures to safely transport and store, typically cold ([contact us for Bourne Partners' 2023 Biostorage Services Report for more](#)), unlike the generally cheaper and easier to manufacture small molecules being developed by Pfizer and Eli Lilly.

Another issue facing Novo's oral semaglutide compared to its rivals is drug-food interaction, requiring it to be taken on an empty stomach, while Pfizer and Lilly's version do not.

What Novo's oral semaglutide does have working for it, however, is the at least two-year head start it will likely have over Lilly's orforglipron and Pfizer's danuglipron, if Novo's oral semaglutide meets its expected approval time of 2024. The timeline for orforglipron's approval suggests a 2026-27 launch and danuglipron is projected to launch at soonest in 2027. Novo's oral semaglutide's US sales could reach \$2.5B in 2030 and \$4B worldwide.

Ultimately, it is unclear if Novo's oral semaglutide's head start will be enough to edge out likely cheaper options. Wegovy has a gross annual cost of around \$17K per patient. While oral therapies are typically cheaper than injectables, if Novo's oral semaglutide is even more complex to manufacture than Wegovy and requires complex storage and transportation facilities, it's unlikely there will be much savings passed down to the consumer.

Section Three

BioPharma Spotlight

i. Therapeutic Market Performance

ii. BioPharma Outlook – Cautious & Creative Dealmaking

iii. FDA Incentives – Priority Review Vouchers & Accelerated Approval

An overhead view of three business professionals in a meeting. A man in a dark suit is at the top, looking at a document. A woman in a white blouse is on the right, pointing at a document. A man in a light blue shirt is at the bottom, typing on a laptop. The table is cluttered with papers, a laptop, a coffee cup, and a smartphone.

i. Market Comparison

NBI[®] Therapeutic Market Performance

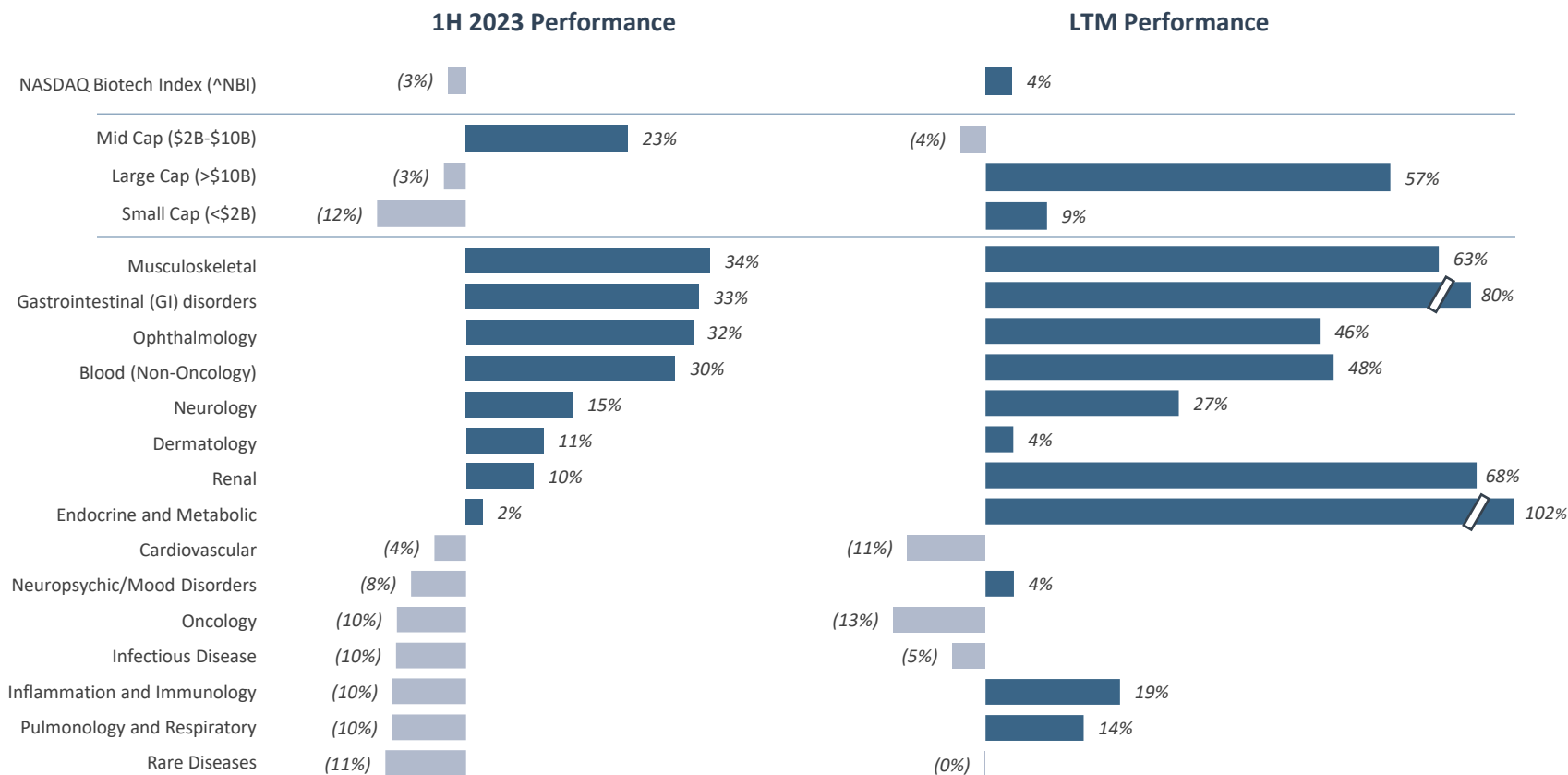


NBI® Therapeutic Market Performance

Consistent with the trend, the NBI has lagged the larger S&P 500 since late 2021. This trend has worsened YTD since NBI did not participate in the recent rally which saw the S&P gain 15%. The NBI is now trading at a 19% discount to the S&P 500.

Midcap Biotech's have been the exception, posting 23% returns, while Small and Large caps have been a drag on the index.

Renal and Endocrine focused companies, which outperformed other therapeutic categories through Q1, have now fallen precipitously but remain positive for the year. The most consistent winners remain GI, ophthalmology, and blood disease focused companies.



SOURCE: Bloomberg; CapIQ, and Bourne Partners' Internal Database; As of July 5th, 2023
 NOTE: All breakouts are equal weighted; LTM and 1H period as of July 5th, 2023

An overhead view of three business professionals in a meeting. A man in a dark suit is looking at a document. A woman in a white blouse is pointing at a document. A man in a light blue shirt is typing on a laptop. The table has a laptop, a coffee cup, and several documents.

ii. BioPharma Outlook

Cautious & Creative Dealmaking

Cautious & Creative Deal Making

BioPharma Financing Outlook

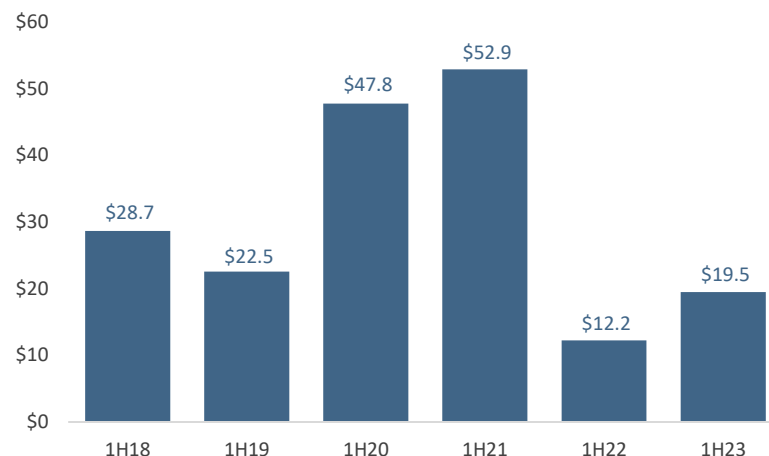
The stage is set for Large Cap Biopharma dealmaking. As mentioned, a historic LOE event putting more than \$390B of sale at risk is driving pharma's need to replenish pipelines.⁽²⁾ This coupled with healthy balance sheets provides the firepower to do deals. Further, on the supply side, there is no shortage of highly discounted companies as Biotech valuations have fallen significantly over the past two years. Biotech's are facing a dramatically different funding environment than two years ago when many were embraced by public markets and VCs.⁽¹¹⁾

Despite large cap pharma's demand, wiliness to pay, and ample supply of cash starved targets, the M&A market has defied basic economic principles. This of course is not the full picture. Uncertainty around regulatory scrutiny in the wake of Amgen/Horizon and Pfizer/Seagen deals, IRA complexities reshaping strategies, and broader macroeconomic issues have been the impeding factors keeping this market out of balance.

We believe these underlying factors are too strong to pin down deal making and Q2 started to see a pickup. However, big pharma is deploying a disciplined approach to M&A now more than ever. These acquisitions are focused on specific therapeutic areas and clinical success foremost, followed by valuations second. Immunology and oncology are two therapeutic areas that have seen significant breakthroughs in recent periods and have drawn interest from big pharma and biotech.

Even if a flurry of M&A ensues, this will limit the number of eligible biotech, leaving many to source funding elsewhere. Biotech funding increased in 1H 2023 compared YoY to 1H 2022, but still sits below 2019 levels and a far cry from 2021 highs. This has declined average cash balances to 5.4 quarters of runway left, compared to 8.6 in early 2021. Volatile capital markets make IPOs and Secondary offerings unattractive, and VC funding still lags. This has forced would-be-sellers to get creative with alternative financing strategies in order to bridge the company to its next inflection point and advance its top candidates.

1H Biotech Funding (\$B)



SOURCE: Bourne Analysis of CapIQ Data, Accessed 7.20.2023

Bourne has seen several solutions stem from licensing deals and reverse mergers, to more creative options like divestures, priority review voucher monetization, and synthetic royalties.

Divestures may seem unlikely for biopharma, but several companies have large drug pipelines that ballooned when capital was abundant, but they now have limited budgets to develop just a few products and need to monetize these assets. In the same vein, monetizing priority review vouchers awarded to rare disease successes can serve as another source of funding, as described further below. Additionally, synthetic royalties, also referred to as revenue interest financing ("RIF"), has seen a dramatic increase of late and provide non-dilutive, bespoke financing.

Cautious & Creative Deal Making - RIFs

Tailor-Made Financing Solutions

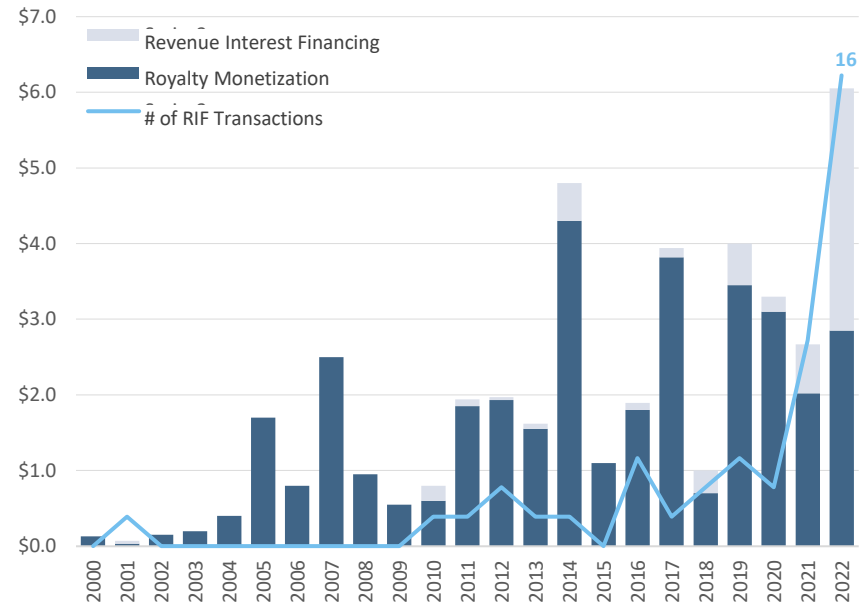
An example of creative deal making is synthetic royalties, often referred to as revenue interest financing ("RIF"). RIF transactions have grown in popularity as a viable financing option for the biopharma industry.

These transactions accounted for only 2% of overall Biopharma funding within the previous five years, but the market for such transactions more than tripled between 2021 and 2022, with \$3 billion (out of the ~\$4.5B total) in RIF deals executed in 2022 alone.⁽³³⁾ Sagard Healthcare, Royalty Pharma, and other key players in this niche believe the market for RIF transactions is still in its infancy and will grow significantly, surpassing 8% of the total funding market within the next five years, totaling \$36 billion.⁽³⁴⁾

Structure

- RIF transactions are a relatively new development in biopharma dealmaking. This arrangement incorporates elements of structured credit as well as traditional royalties.
- Traditional royalty-based transactions were limited to corporations who had previously acquired passive royalty rights through an out-licensing transaction and then chose to sell the royalty rights.
- A RIF, on the other hand, creates a new royalty on top-line product sales, preserving the marketers' right to pursue future royalty-based transactions.
- This hybrid structure allows fledgling biopharma companies with a new therapy in late development or early launch to 1) retain operational control of the clinical programs and commercial plan, 2) access non-dilutive capital at a lower cost than equity, and 3) avoid the restrictive covenants of a credit facility.
- These structures are also program and product specific, non-limiting to future M&A or licensing deals and provides third party validation of the opportunity.⁽³³⁾

RIF vs. Royalty Transactions (\$B)



SOURCE: Sagard Research

Cautious & Creative Deal Making - RIFs (cont.)

RIF deals provide Biopharma companies with a non-dilutive financing option and can be used to create a tailored financing solution with several levels:

- Flexible payments and structure: RIFs provide upfront capital and offer more flexibility than typical credit facilities. Payments are tied to the performance of the underlying product.
- Non-dilutive alternative: RIFs offer a less expensive and non-dilutive alternative to equity financing, helping biotechnology companies reduce financing overhangs and provide a more stable financial footing for long-term growth.
- Product validation: RIF transactions validate a product's commercial potential and signal to the market that specialized investors have confidence in the product's long-term success.
- Transaction favorability: RIFs are not prohibitive to other deal making and most all include a buyout option.
- Operational Control: RIFs allow the developer to maintain operational control of the clinical programs and commercial plan of the product.⁽³³⁾

| | Equity | Debt | Royalty | RIF |
|---------------------------------------|--------|------|---------|---|
| Payment & Structural Flexibility | | | | • Payments commensurate with product revenues |
| Non-Dilutive | | | | • No equity dilution |
| Product Validation and Exit Strategy | | | | • Structured for future acquisitions • Provides product validation |
| Low Cost of Capital | | | | • Lower CoC than equity • 10-15% CoC |
| Maintain Operational Control | | | | • Non-financial covenants • Partly collateralized |
| Risk Sharing / Alignment of Interests | | | | • Aligned on product revenue growth and development |
| Upside Retention | | | | • Structured to retain upside through caps, tiering, etc. |
| Ease of Transaction Process | | | | • Simple and standardized |

SOURCE: Sagard Research

Recent RIF Transactions

Sutro Inks \$390 Royalty Financing Deal with Blackstone

Sutro Biopharma received a fresh cash injection from Blackstone Life Sciences to advance its next-gen vaccine platform, Vaxcyte. Blackstone will get a 4% royalty, or revenue interest financing ("RIF"), on all future sales of Vaxcyte's products in exchange for \$140M upfront and \$250M in contingent consideration.

Vaxcyte's lead candidate, VAX-24, is a Phase 3-ready, 24-valent next-gen pneumococcal conjugate vaccine (PCV) with enhanced serotype coverage and immunogenicity. Sutro's XpressCF® cell-free protein synthesis technology powers Vaxcyte's PCV brands



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iii. FDA Incentives

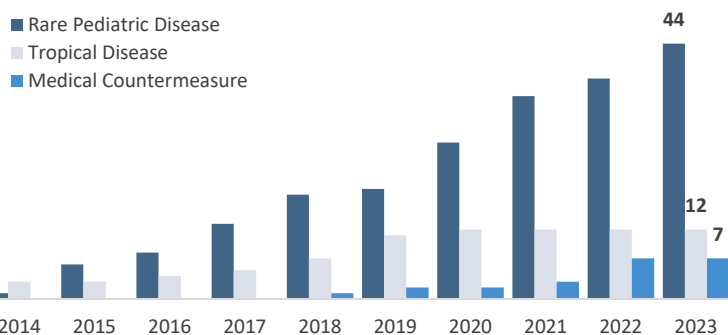
*Priority Review Vouchers &
Accelerated Approval Pathway*

Trading FDA Priority Review Vouchers: Savvy Dealmaking or Speculation?

The Market Price for PRVs Seems to Have Flattened since the First Sale in 2014, but Are They Worth the \$100M Price Tag?

Priority Review Vouchers (PRVs) are awarded by the FDA to incentivize the development of drugs for tropical diseases, rare pediatric diseases and for use as medical countermeasures. Typically granted to sponsors after their drug is approved for the treatment of a qualifying indication, the Priority Review Voucher (PRV) can be redeemed on a future date to expedite the review of new drug application - cutting the FDA's standard 10-month targeted review time down to just 6 months. The first PRV was awarded to Novartis in 2019 after an FDA nod for their malaria treatment Coartem, and a total of 63 PRVs have been issued since the program launched, according to Bourne estimates.⁽³⁵⁾ Though PRVs are only *issued* for a select list of diseases, there are no limitations on the drugs against which PRVs can be *redeemed*. Big Pharma has therefore leveraged the program to expedite the launches of potential blockbusters, and to gain advantage over rivals in more lucrative therapy areas such as respiratory and cardiology.

Rare pediatric disease dominates cumulative PRVs awards

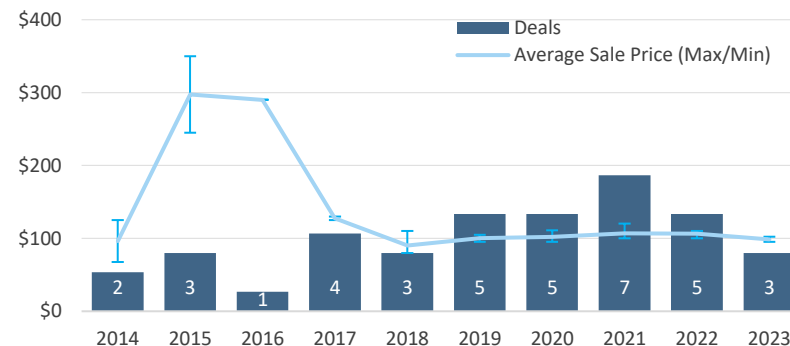


SOURCE: GAO-20-251 Priority Review Vouchers (September 30, 2019); Federal Register

Sponsors are not forced to redeem their vouchers against their own assets; a thriving secondary market has developed, starting in 2014 when Sanofi paid \$67.5m for BioMarin's voucher to get a head start against Amgen in the race for the first PCSK9 inhibitor. Bourne counts a total of 34 PRV transactions, with sale prices ranging from \$67.5m paid by Sanofi up to \$350m paid by AbbVie in 2015. Since 2019, however, the market value for PRVs has stabilized at \$100m which suggests a sustained equilibrium between their supply (stemming from biotech innovation in rare disease) and demand (driven by Big Pharma's bullishness in their own launch pipelines).

The flow of PRVs from biotech to Big Pharma, in exchange for cash, is representative of the broader pharma sector outlook. Auctioning of a PRV offers biotech companies immediate, non-dilutive funding where the public markets are unfavorable. This niche represents another creative deal structure that is growing in popularity in today's climate. Biotech Albireo Pharma raised \$105M in September 2021 from the sale of their PRV shortly after the approval of their rare disease drug Blyvay. One year later, they raised \$115 through a royalty monetization agreement – as described earlier in this report – before finally being acquired by Ipsen in a near-\$1B deal in early 2023.

Voucher pricing has stabilized at \$100M after turbulent start



SOURCE: Bourne Partners analysis of publicly available information and proprietary deal details

Trading FDA Priority Review Vouchers: Savvy Dealmaking or Speculation? (Cont.)



While the Rationale for Buying PRVs Is clear, Is Pharma Getting Value for Money?



Bourne performed an analysis of historic PRV acquisitions, comparing the prices paid against the success of the resultant product commercial launch. AbbVie's \$350M PRV purchase from United Therapeutics set a high-water mark in 2015 that has not yet been surpassed. The voucher was used to win approval for Rinvoq as a treatment for adults with moderately to severely active rheumatoid arthritis. The drug hit the market in 2019 - four years after the PRV was purchased - and pulled in an estimated \$302M in the first 12 months. Biohaven's \$105M PRV purchase helped bring its migraine drug Nurtec ODC to market just 2 months after AbbVie launched its direct competitor Ubrelvy. The drug brought in upwards of \$400M in its first year, which makes the fast-pass purchase seem like exceptional value at just \$105M. In a 2023 interview, BioHaven CEO Vlad Coric hailed the PRV acquisition and redemption as key to the success of the Nurtec ODC launch, which ultimately led to the biotech's \$12B buyout by Pfizer in 2022⁽³⁶⁾. In a final example, United Therapeutics expedited the review of its pulmonary hypertension drug Tyvaso DPI shortly after purchasing the PRV from Y-mAbs for \$105M. secure.



After a strong launch in June 2022, Tyvaso DPI brought in \$190M in its first 9 months, however sales appear to have ground to a halt according to Bloomberg Intelligence data. Bourne believes this due to supply challenges with its manufacturing partner MannKind.

It is clear from these examples that the value of a PRV depends greatly on its owner and the sales potential of its near-term pipeline. For drugs with blockbuster potential, a PRV is an excellent tool to expedite revenues and fend off rivals in competitive therapy areas. Buyers should be wary of lengthy delays between PRV purchase and redemption, which can tie up significant capital. Buyers should also assess potential supply limitations, since inability to fulfill market demand during the early launch phase erodes the value added by the expedited filing.

Bourne closely monitors the PRV market, which it views as an indicator of the equilibrium between biotech innovation – which provides supply or PRVs – and bullishness in Big Pharma pipelines – which represents the demand. It is interesting that the market PRV price has stabilized at \$100M since 2018, despite the excessive dry powder accumulated by Big Pharma, excessive inflationary pressure, and market uncertainty associated with the Inflation Reduction Act.

| | |
|--|---|
|  RINVOQ upadacitinib |  |
| Launch Date | August 2019 |
| Indication | Rheumatoid Arthritis |
| Year 1 Sales | \$302M |
| PRV Price | \$350M |

| | |
|---|---|
|  Nurtec ODT (rimegepant) orally disintegrating tablets 75 mg |  |
| Launch Date | March 2020 |
| Indication | Migraine |
| Year 1 Sales | \$401M |
| PRV Price | \$105M |

| | |
|---|---|
|  TYVASO DPI (treprostinil) tablets |  |
| Launch Date | June 2022 |
| Indication | Hypertension |
| Year 1 Sales | \$207M |
| PRV Price | \$105M |

SOURCE: Bloomberg Intelligence⁽³⁷⁾

Accelerated Approval Pathway in the Spotlight

Established in 1992, the Accelerated Approval pathway offers an expedited path to market for drugs that show promise in treating serious, incurable diseases for which there are no existing alternatives.⁽³⁸⁾ The program was initially a response to the HIV/AIDS epidemic of the 1980s, but today is more commonly used for approval of rare disease and oncology drugs. Pharma companies can request approval of their drug based on a surrogate or intermediate clinical endpoint which is reasonably likely to predict clinical benefit, rather than wait for more concrete endpoints such as overall survival. In exchange for authorizing the expedited approval, pharma companies must collect follow-up data to confirm the safety and efficacy of the drug in the broader population.

In March, the FDA published industry guidance which indicates that elevated scrutiny is on the way.⁽³⁹⁾ Several drugs have been approved through this pathway in recent years, only for confirmatory data to show a less favorable safety profile than it originally seemed from the trial.⁽⁴⁰⁾ The agency is paying specific attention to smaller, single-arm trials which are failing to identify safety concerns that are later observed in the real world. The PI3K inhibitor class of targeted oncology drugs has been in particular focus, with four accelerated approvals ultimately being withdrawn or facing review after confirmatory studies showed substantial toxicity in select hematologic malignancies.⁽⁴¹⁾

Fast-tracked P13K inhibitors face FDA scrutiny due to safety findings



SOURCE: *The Lancet*, April 2022

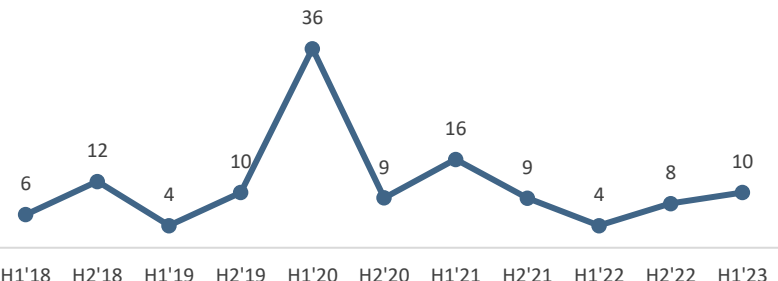
The accelerated approval pathway also caught widespread media attention in the context of Sarepta and its DMD gene therapy ELEVIDYS. It was ultimately approved by the FDA on June 22, albeit one month behind schedule and in a more limited patient population that originally

anticipated. The FDA committee voted to approve the drug by 8 votes to 6, reflecting concerns that the safety profile of the drug (13 serious side effects in 85 studied patients) may not outweigh the benefits.

Critics raised concerns that premature approval could harm ongoing clinical development of the drug – as patients switch from possible placebo arm to guaranteed commercial supply – and deprive patients of opportunities to try alternative investigational drugs which may be more effective. Others pointed to historic disobedience among pharma companies in meeting their post-marketing data collection commitments. Drugs that successfully convert their accelerated approval to full approval accomplish this within 4 months, whereas drugs that ultimately fail to meet the follow-up standard – and are removed from the market – don't reach the decision point for 10 months. Skeptics claim that pharma companies have dragged drag their heels to keep their ineffective drugs on the market for as long as possible.

The FDA hopes that by putting more up-front attention into the design of potentially pivotal trials, as well as confirmatory follow-up trials, they can reduce instances where patients are given unsafe or ineffective drugs. In parallel, they will continue to encourage innovation by expediting the development of potentially life-changing therapies for desperate patients.

Ten Accelerated Approvals Awarded in H1'23



SOURCE: CDER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint (June 30, 2023)

Section Four

M&A Transactions & Public Comps

i. M&A Activity – 1H Pharma Transactions

ii. Bourne Public Comps – Trading Multiples

iii. Bourne Public Comps – Trading Charts

iv. Bourne Public Comps – Operating Metrics

An overhead view of three business professionals in a meeting. A man in a dark suit is looking at a document on the table. A woman in a white blouse is writing on a document. A man in a light blue shirt is typing on a laptop. The table is cluttered with papers, a coffee cup, and a smartphone.

i. M&A Activity

1H Pharma Transactions

1H Pharmaceutical Transactions

To discuss pharmaceutical transactions, contact us at research@bourne-partners.com



To Acquire



To Acquire



Take private of



To Acquire



Take private of



February 2023



March 2023



April 2023



May 2023



June 2023

1H Pharmaceutical Products Transactions

To discuss pharmaceutical products transactions, contact us at research@bourne-partners.com



Sells DSUVIA to



Sells Zyprexa to



Sells BAQSIMI to



Sell Myoril to



Sell XIIDRA to



March 2023



April 2023



April 2023



May 2023



June 2023



1H Biopharmaceutical Transactions

To discuss biopharmaceutical transactions, contact us at research@bourne-partners.com

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ii. Bourne Public Comps

Trading Multiples



Bourne Comps - Large Cap Pharma

North America LC Pharma

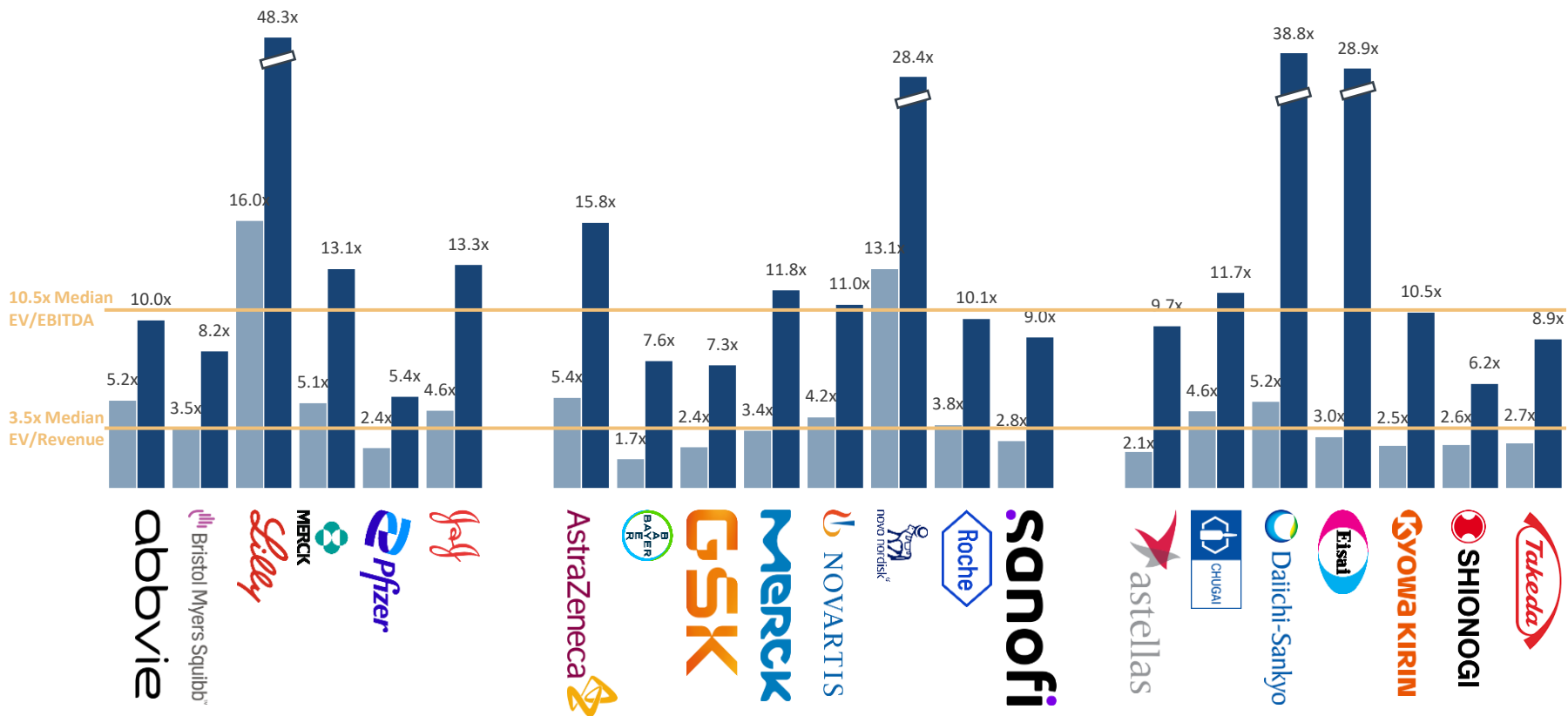
11.6x Median EV/EBITDA
4.8x Median EV/Revenue

Europe LC Pharma

10.6x Median EV/EBITDA
3.6x Median EV/Revenue

Rest of World LC Pharma

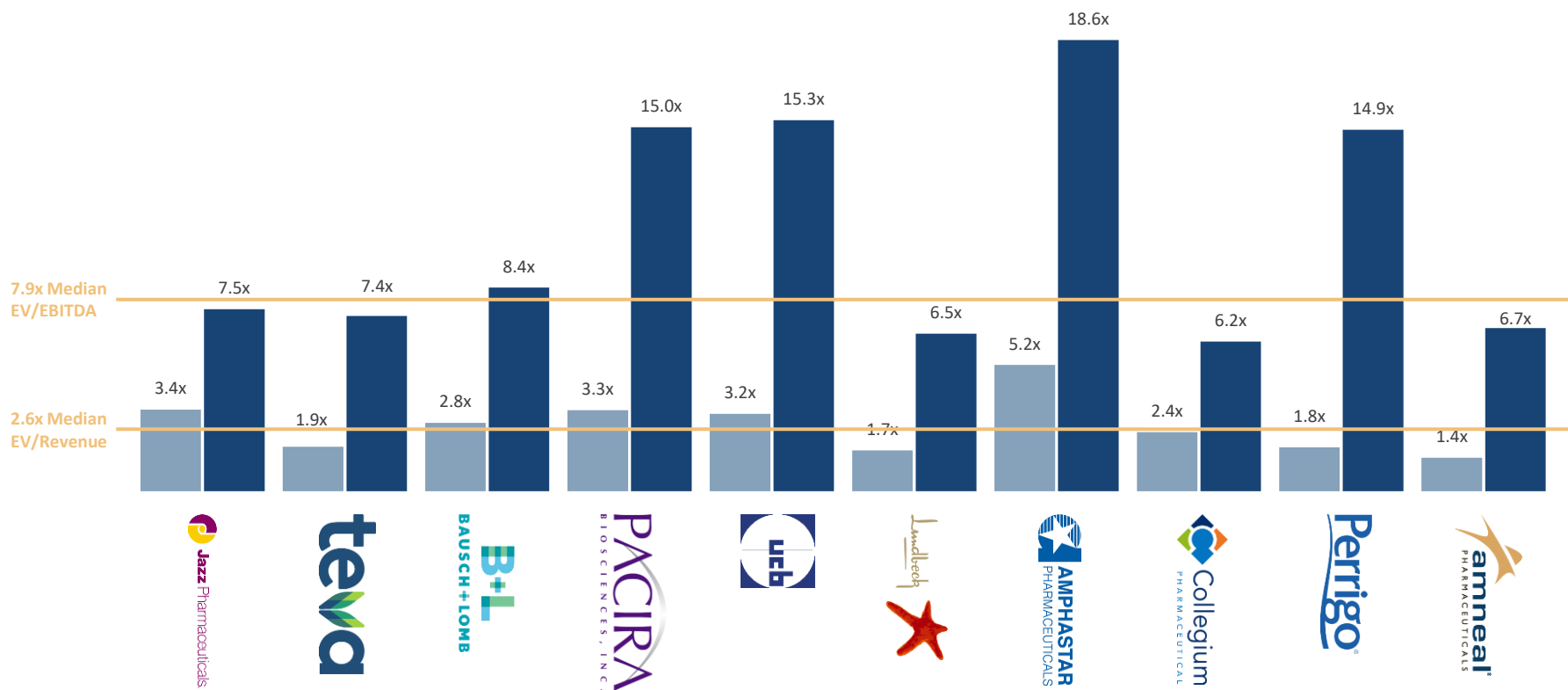
10.5x Median EV/EBITDA
2.7x Median EV/Revenue



SOURCE: CapIQ; Data as of 7/14/2023



Bourne Comps - Specialty Pharma



SOURCE: CapIQ; Data as of 7/14/2023

NOTE: Teva is currently being tracked in both Bourne Partners' Spec. pharma and Generic pharma indexes in light of CEO change and recent pivot to growth strategy



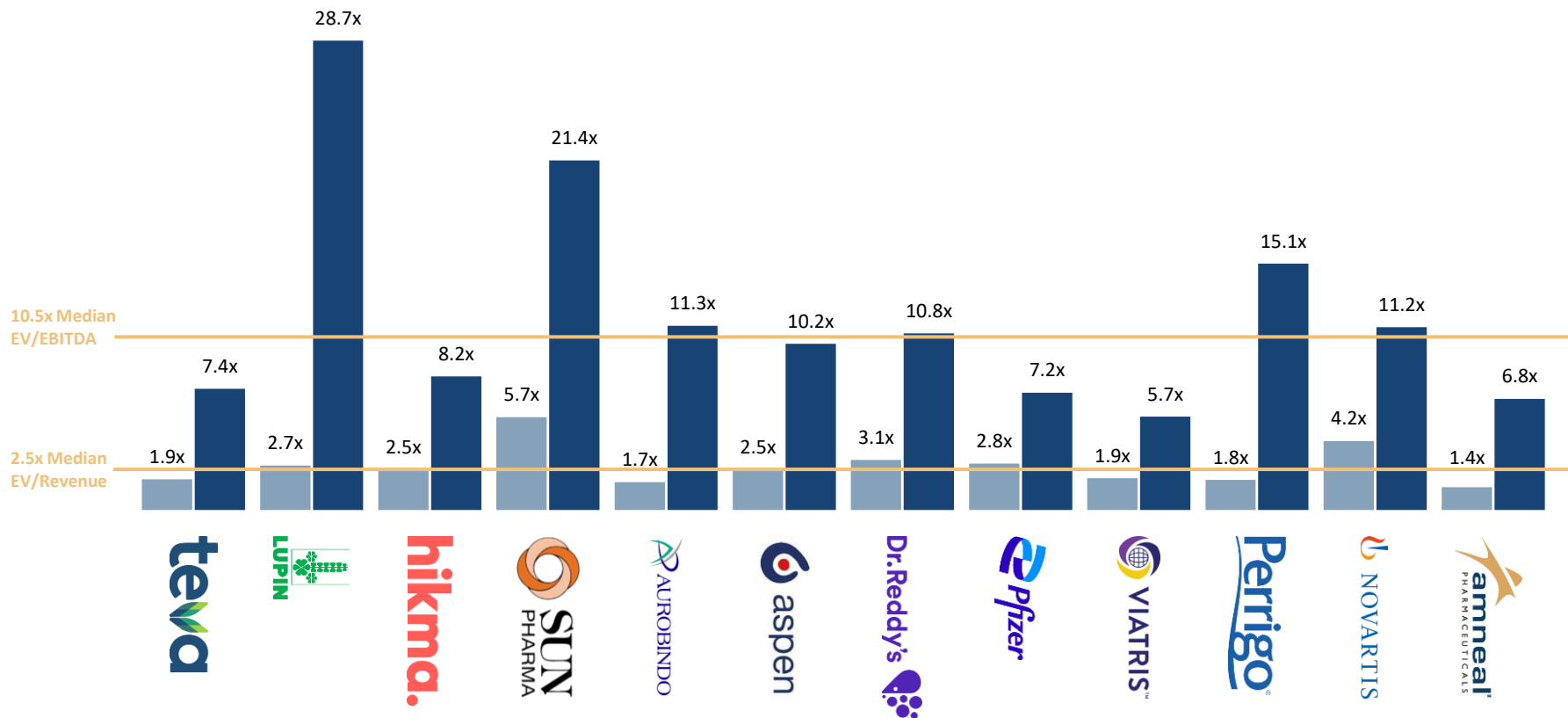
Bourne Comps - Generic Pharma

ROW Generic

10.8x Median EV/EBITDA
2.5x Median EV/Revenue

North America Generic

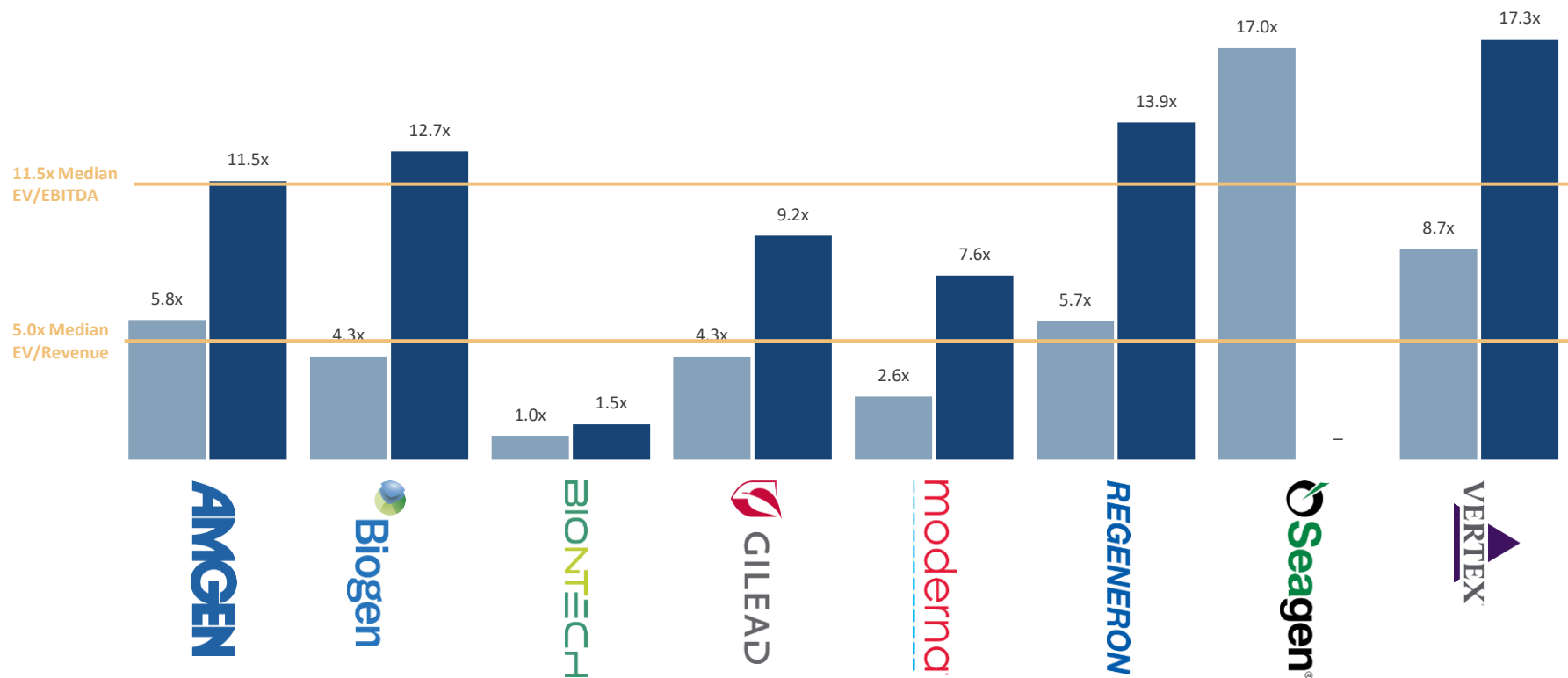
7.2x Median EV/EBITDA
1.9x Median EV/Revenue



SOURCE: CapIQ; Data as of 7/14/2023

NOTE: Teva is currently being tracked in both Bourne Partners' Spec. pharma and Generic pharma indexes in light of CEO change and recent pivot to growth strategy

Bourne Comps - Large Cap Biotech



SOURCE: CapIQ; Data as of 7/14/2023

iii. Bourne Public Comps

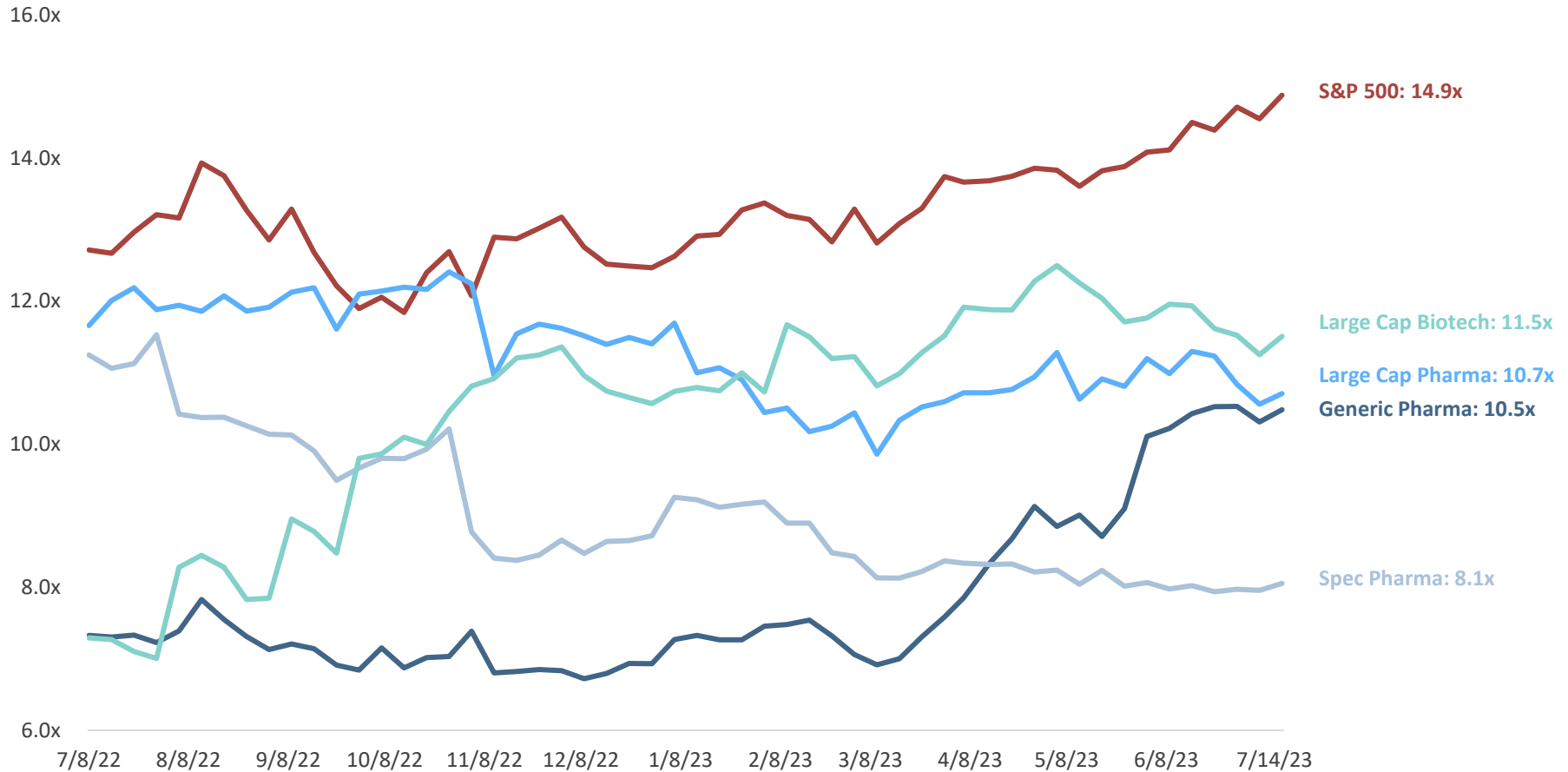
Trading Charts





Bourne Partner's Pharma Indices

Last Twelve Months, EV/EBITDA Multiples, Weekly

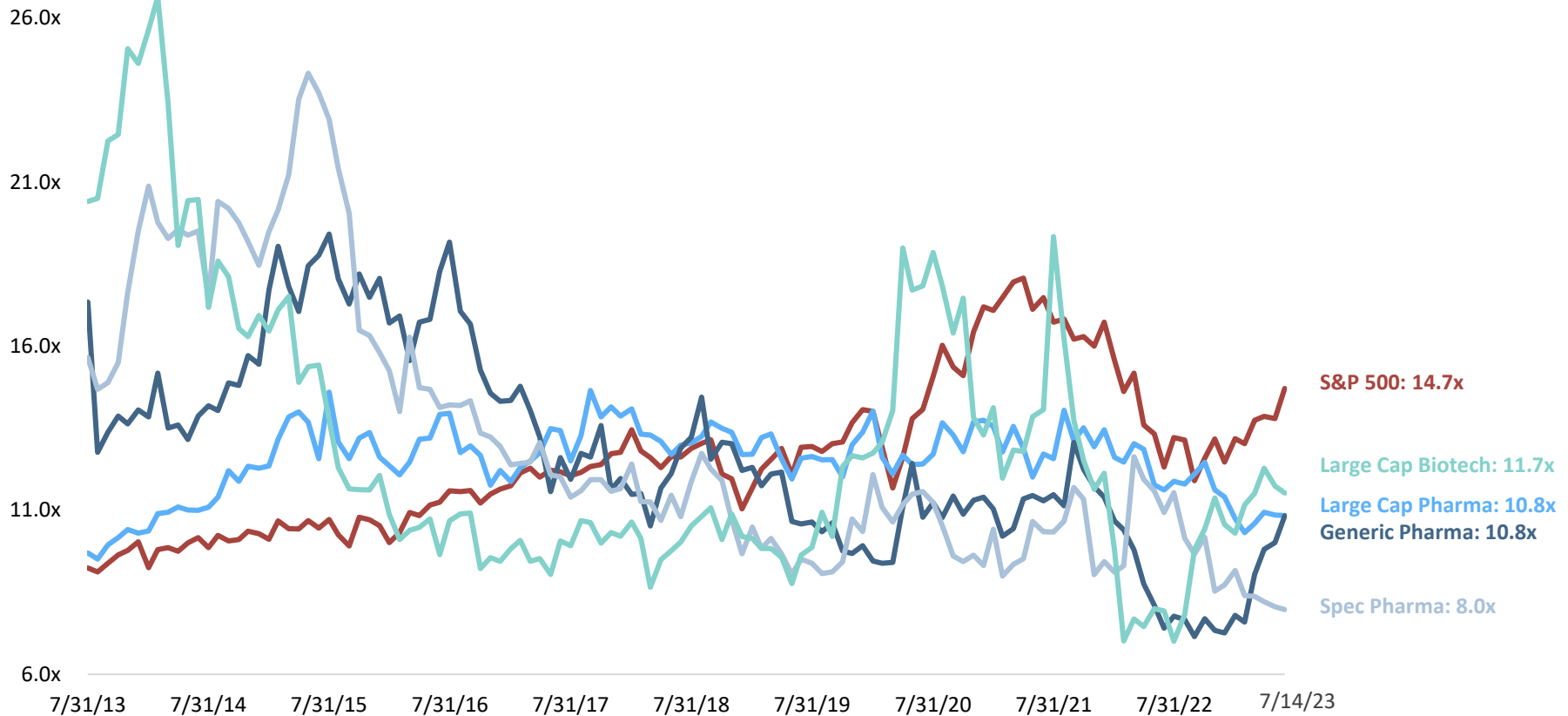


SOURCE: CapIQ; Data as of 7/14/2023, See Appendix for index constituents



Bourne Partner's Pharma Indices

Last 10-years, EV/EBITDA Multiples, Monthly

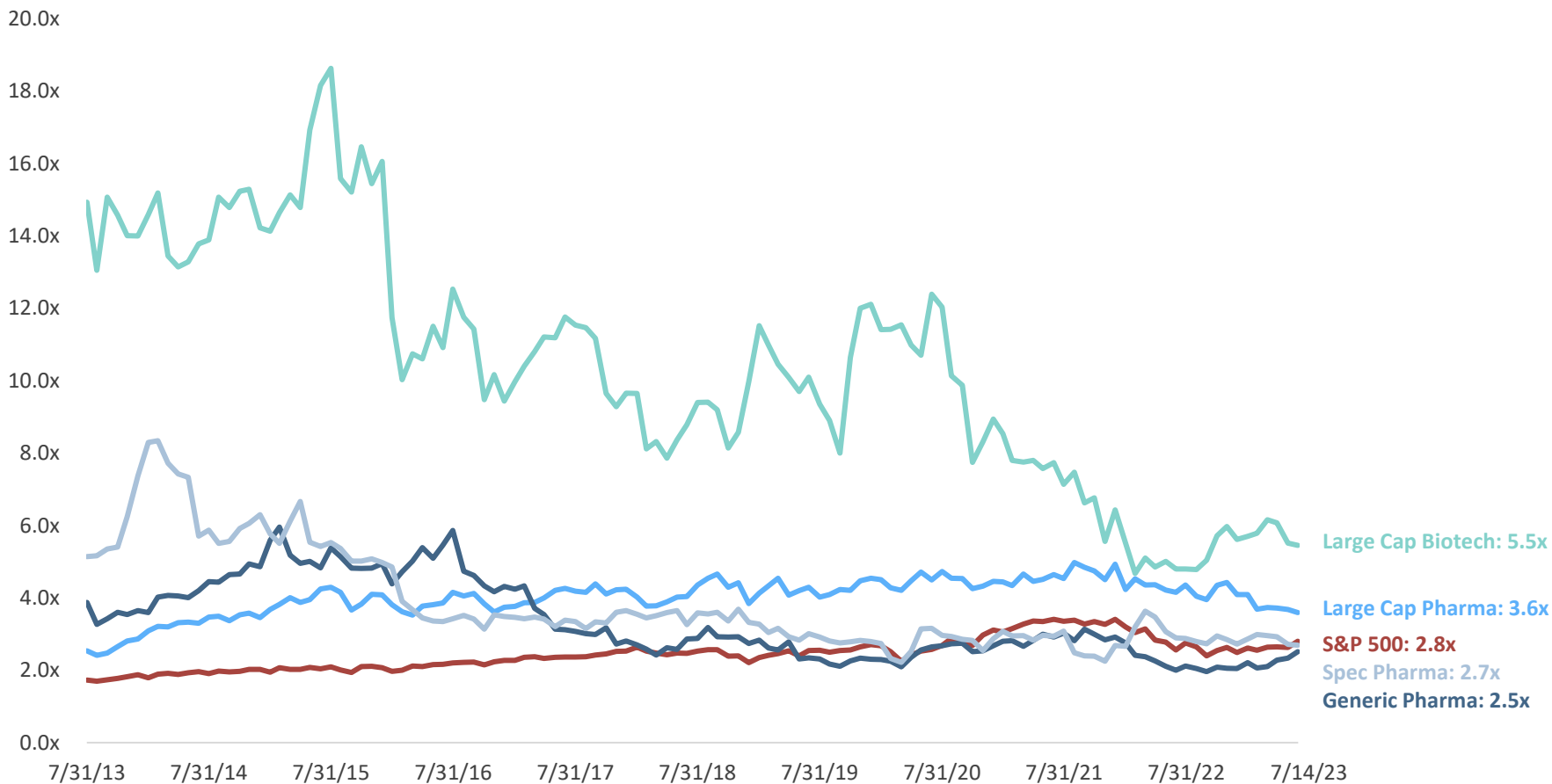


SOURCE: CapIQ; Data as of 7/14/2023, See Appendix for index constituents



Bourne Partner's Pharma Indices

Last 10-years, EV/Revenue Multiples, Monthly

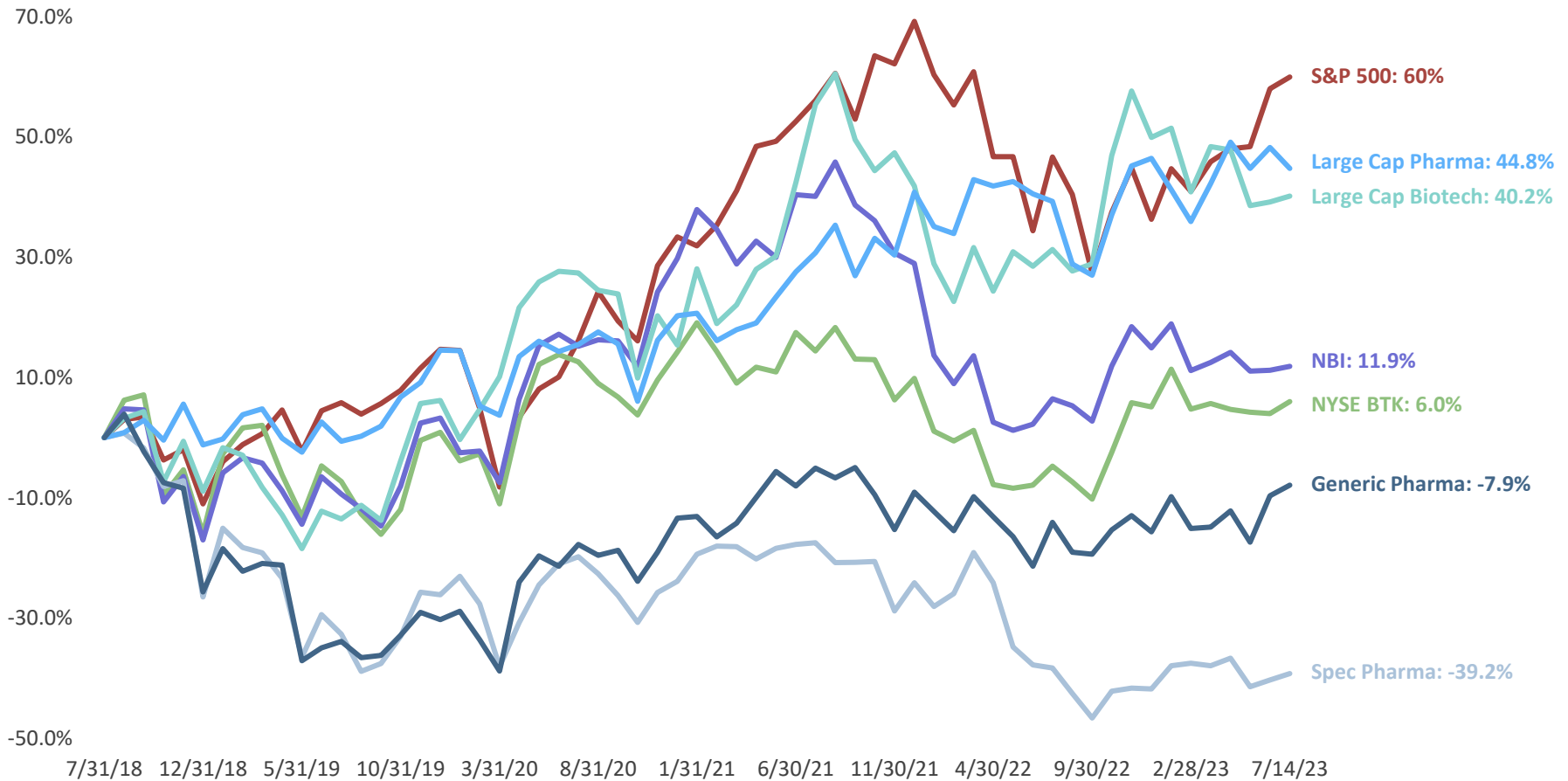


SOURCE: CapIQ; Data as of 7/14/2023, See Appendix for index constituents



Bourne Partner's Pharma Indices

5-year, Total Return Index, Monthly



SOURCE: CapIQ; Data as of 7/14/2023, See Appendix for index constituents

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iv. Bourne Public Comps

Operating Metrics

Bourne Comps Operating Metrics

Large Cap Pharma

| Company Name | HQ | Market Cap (\$B) | Total Debt (\$B) | Cash & Cash Eqv (\$B) | Enterprise Value (\$B) | LTM Revenue (\$B) | LTM EBITDA (\$B) | EV / LTM Revenue | EV / LTM EBITDA | DEBT / LTM EBITDA | NET DEBT / LTM EBITDA | EV / DEBT | Credit Rating |
|-------------------------|-----|------------------|------------------|-----------------------|------------------------|-------------------|------------------|------------------|-----------------|-------------------|-----------------------|-----------|---------------|
| Large Cap Pharma | | | | | | | | | | | | | |
| AbbVie | US | \$240.0 | \$62.5 | \$6.7 | \$295.7 | \$56.7 | \$29.5 | 5.2x | 10.0x | 2.1x | 1.9x | 4.7x | BBB+ |
| Bristol-Myers Squibb | US | 130.1 | 39.4 | 9.3 | 160.2 | 45.8 | 19.6 | 3.5x | 8.2x | 2.0x | 1.5x | 4.1x | A+ |
| Eli Lilly | US | 426.7 | 19.0 | 3.7 | 441.9 | 27.7 | 9.2 | 16.0x | 48.3x | 2.1x | 1.7x | 23.3x | A+ |
| Merck & Co. | US | 272.4 | 30.7 | 10.4 | 292.7 | 57.9 | 22.4 | 5.1x | 13.1x | 1.4x | 0.9x | 9.5x | A+ |
| Pfizer | US | 205.0 | 36.2 | 20.0 | 221.2 | 93.0 | 40.6 | 2.4x | 5.4x | 0.9x | 0.4x | 6.1x | A+ |
| Johnson & Johnson | US | 415.5 | 52.9 | 24.6 | 443.8 | 97.8 | 33.9 | 4.5x | 13.1x | 1.6x | 0.8x | 8.4x | AAA |
| AstraZeneca | EU | \$209.9 | \$32.5 | \$6.5 | \$235.9 | \$43.8 | \$14.9 | 5.4x | 15.8x | 2.2x | 1.7x | 7.3x | A |
| Bayer | EU | 55.5 | 47.0 | 8.7 | 93.9 | 54.9 | 12.4 | 1.7x | 7.6x | 3.8x | 3.1x | 2.0x | BBB |
| GSK | EU | 70.2 | 25.9 | 8.6 | 87.4 | 36.0 | 11.9 | 2.4x | 7.3x | 2.2x | 1.4x | 3.4x | A |
| Merck & Co. | EU | 73.0 | 11.6 | 1.9 | 82.7 | 24.3 | 7.0 | 3.4x | 11.8x | 1.7x | 1.4x | 7.2x | A |
| Novartis | EU | 206.8 | 28.3 | 11.1 | 224.0 | 53.1 | 20.0 | 4.2x | 11.2x | 1.4x | 0.9x | 7.9x | AA- |
| Novo Nordisk | EU | 359.5 | 3.7 | 4.1 | 359.1 | 27.5 | 12.7 | 13.1x | 28.4x | 0.3x | (0.0x) | 96.5x | AA- |
| Roche | EU | 251.5 | 28.9 | 10.6 | 269.8 | 71.8 | 26.7 | 3.8x | 10.1x | 1.1x | 0.7x | 9.3x | AA |
| Sanofi | EU | 131.5 | 23.0 | 13.8 | 140.7 | 50.2 | 15.6 | 2.8x | 9.0x | 1.5x | 0.6x | 6.1x | AA |
| Astellas Pharma | ROW | \$26.0 | \$1.5 | \$3.0 | \$24.5 | \$11.4 | \$2.5 | 2.1x | 9.7x | 0.6x | (0.6x) | 16.0x | NM |
| Chugai Pharmaceutical | ROW | 45.9 | - | 4.2 | 41.8 | 9.1 | 3.6 | 4.6x | 11.7x | - | (1.2x) | - | NR |
| Daiichi Sankyo | ROW | 54.3 | 1.5 | 6.2 | 49.6 | 9.6 | 1.3 | 5.2x | 38.8x | 1.1x | (3.7x) | 34.2x | NR |
| Eisai | ROW | 18.1 | 0.9 | 2.0 | 17.0 | 5.6 | 0.6 | 3.0x | 28.9x | 1.6x | (1.8x) | 18.0x | NR |
| Kyowa Kirin | ROW | 10.3 | - | 2.6 | 7.7 | 3.0 | 0.7 | 2.5x | 10.5x | - | (3.6x) | - | NR |
| Shionogi | ROW | 12.4 | 0.1 | 4.2 | 8.2 | 3.2 | 1.3 | 2.6x | 6.2x | 0.1x | (3.1x) | 116.4x | NM |
| Takeda Pharmaceutical | ROW | 48.3 | 36.6 | 4.0 | 80.8 | 30.3 | 9.1 | 2.7x | 8.9x | 4.0x | 3.6x | 2.2x | BBB+ |

| | | | | | |
|----------------------------|-------|-------|------|--------|--------|
| Mean (Equal Weighted) | 4.6x | 14.9x | 1.5x | 0.3x | 20.1x |
| Median (Equal Weighted) | 3.5x | 10.5x | 1.5x | 0.8x | 7.9x |
| Mean (Market Cap Weighted) | 6.6x | 18.3x | 1.5x | 0.9x | 19.9x |
| Min | 1.7x | 5.4x | - | (3.7x) | 2.0x |
| Max | 16.0x | 48.3x | 4.0x | 3.6x | 116.4x |

| | | | | | |
|------------|------|-------|------|--------|-------|
| US Median | 4.8x | 11.6x | 1.8x | 1.2x | 7.3x |
| EU Median | 3.6x | 10.6x | 1.6x | 1.1x | 7.2x |
| ROW Median | 2.7x | 10.5x | 0.6x | (1.8x) | 18.0x |

Bourne Comps Operating Metrics

Specialty and Generic Pharma

| Company Name | HQ | Market Cap (\$B) | Total Debt (\$B) | Cash & Cash Eqv (\$B) | Enterprise Value (\$B) | LTM Revenue (\$B) | LTM EBITDA (\$B) | EV / LTM Revenue | EV / LTM EBITDA | DEBT / LTM EBITDA | NET DEBT / LTM EBITDA | EV / DEBT | Credit Rating |
|--------------------------|----|------------------|------------------|-----------------------|------------------------|-------------------|------------------|------------------|-----------------|-------------------|-----------------------|-----------|---------------|
| Specialty Pharma | | | | | | | | | | | | | |
| Jazz Pharmaceutical | | \$8.1 | \$5.8 | \$1.2 | \$12.8 | \$3.7 | \$1.7 | 3.4x | 7.6x | 3.5x | 2.8x | 2.2x | BB- |
| Teva Pharmaceutical | | 9.2 | 21.0 | 2.1 | 28.1 | 14.9 | 3.8 | 1.9x | 7.4x | 5.6x | 5.0x | 1.3x | BB- |
| Bausch Health | | 3.1 | 20.7 | 0.5 | 23.2 | 8.2 | 2.7 | 2.8x | 8.5x | 7.5x | 7.3x | 1.1x | CCC |
| Pacira BioSciences | | 1.7 | 0.6 | 0.2 | 2.2 | 0.7 | 0.1 | 3.2x | 14.5x | 4.2x | 3.0x | 3.5x | NM |
| UCB | | 16.9 | 3.1 | 1.0 | 19.0 | 5.8 | 1.2 | 3.3x | 15.6x | 2.5x | 1.7x | 6.1x | NM |
| H. Lundbeck | | 4.4 | 0.8 | 0.4 | 4.7 | 2.8 | 0.7 | 1.7x | 6.6x | 1.1x | 0.5x | 6.2x | BBB- |
| Amphastar Pharmaceutical | | 2.7 | 0.1 | 0.2 | 2.6 | 0.5 | 0.1 | 5.0x | 18.0x | 0.7x | (0.6x) | 25.5x | NM |
| Collegium Pharmaceutical | | 0.7 | 0.8 | 0.3 | 1.3 | 0.5 | 0.2 | 2.4x | 6.2x | 3.9x | 2.6x | 1.6x | NM |
| Perrigo | | 4.6 | 4.3 | 0.6 | 8.4 | 4.6 | 0.6 | 1.8x | 15.1x | 7.8x | 6.8x | 1.9x | BB |
| Amneal Pharmaceutical | | 0.5 | 2.9 | 0.1 | 3.2 | 2.3 | 0.5 | 1.4x | 6.8x | 6.1x | 5.8x | 1.1x | B |

| | | | | | |
|----------------------------|------|-------|------|--------|-------|
| Mean (Equal Weighted) | 2.7x | 10.6x | 4.3x | 3.5x | 5.1x |
| Median (Equal Weighted) | 2.6x | 8.0x | 4.0x | 2.9x | 2.1x |
| Mean (Market Cap Weighted) | 2.8x | 11.5x | 3.9x | 3.1x | 4.8x |
| Min | 1.4x | 6.2x | 0.7x | (0.6x) | 1.1x |
| Max | 5.0x | 18.0x | 7.8x | 7.3x | 25.5x |

| Company Name | HQ | Market Cap (\$B) | Total Debt (\$B) | Cash & Cash Eqv (\$B) | Enterprise Value (\$B) | LTM Revenue (\$B) | LTM EBITDA (\$B) | EV / LTM Revenue | EV / LTM EBITDA | DEBT / LTM EBITDA | NET DEBT / LTM EBITDA | EV / DEBT | Credit Rating |
|-----------------------|----|------------------|------------------|-----------------------|------------------------|-------------------|------------------|------------------|-----------------|-------------------|-----------------------|-----------|---------------|
| Generic Pharma | | | | | | | | | | | | | |
| Teva Pharmaceutical | | \$9.2 | \$21.0 | \$2.1 | \$28.1 | \$14.9 | \$3.8 | 1.9x | 7.4x | 5.6x | 5.0x | 1.3x | BB- |
| Lupin | | 5.2 | 0.6 | 0.2 | 5.5 | 2.0 | 0.2 | 2.7x | 28.7x | 2.9x | 1.8x | 10.0x | NM |
| Hikma Pharmaceutical | | 5.2 | 1.3 | 0.3 | 6.2 | 2.5 | 0.8 | 2.5x | 8.2x | 1.7x | 1.3x | 4.9x | BBB- |
| Sun Pharma | | 31.4 | 0.8 | 1.8 | 30.4 | 5.3 | 1.4 | 5.7x | 21.4x | 0.6x | (0.7x) | 36.2x | NM |
| Aurobindo | | 5.3 | 0.6 | 0.8 | 5.2 | 3.0 | 0.5 | 1.7x | 11.3x | 1.4x | (0.3x) | 8.0x | NM |
| Aspen | | 4.5 | 1.6 | 0.5 | 5.6 | 2.3 | 0.6 | 2.5x | 10.2x | 2.9x | 2.0x | 3.6x | NM |
| Dr. Reddy's | | 10.3 | 0.2 | 0.7 | 9.7 | 3.2 | 0.9 | 3.1x | 10.8x | 0.2x | (0.6x) | 63.7x | NM |
| Pfizer | | 205.0 | 36.2 | 20.0 | 221.2 | 77.9 | 30.8 | 2.8x | 7.2x | 1.2x | 0.5x | 6.1x | A+ |
| Viartis | | 12.2 | 19.0 | 0.6 | 30.6 | 15.8 | 5.4 | 1.9x | 5.7x | 3.6x | 3.4x | 1.6x | BBB- |
| Perrigo | | 4.6 | 4.3 | 0.6 | 8.4 | 4.6 | 0.6 | 1.8x | 15.1x | 7.8x | 6.8x | 1.9x | BB |
| Novartis | | 206.8 | 28.3 | 11.1 | 224.0 | 53.1 | 20.0 | 4.2x | 11.2x | 1.4x | 0.9x | 7.9x | AA- |
| Amneal | | 0.5 | 2.9 | 0.1 | 3.2 | 2.3 | 0.5 | 1.4x | 6.8x | 6.1x | 5.8x | 1.1x | B |

| | | | | | |
|----------------------------|------|-------|------|--------|-------|
| Mean (Equal Weighted) | 2.7x | 12.0x | 2.9x | 2.2x | 12.2x |
| Median (Equal Weighted) | 2.5x | 10.5x | 2.3x | 1.5x | 5.5x |
| Mean (Market Cap Weighted) | 3.5x | 10.1x | 1.5x | 0.8x | 9.7x |
| Min | 1.4x | 5.7x | 0.2x | (0.7x) | 1.1x |
| Max | 5.7x | 28.7x | 7.8x | 6.8x | 63.7x |

Bourne Comps Operating Metrics

Large Cap Biotech

| Company Name | HQ | Market Cap (\$B) | Total Debt (\$B) | Cash & Cash Eqv (\$B) | Enterprise Value (\$B) | LTM Revenue (\$B) | LTM EBITDA (\$B) | EV / LTM Revenue | EV / LTM EBITDA | DEBT / LTM EBITDA | NET DEBT / LTM EBITDA | EV / DEBT | Credit Rating |
|--------------------------|----|---------------------|---------------------|--------------------------|---------------------------|----------------------|---------------------|---------------------|--------------------|----------------------|--------------------------|-----------|---------------|
| Large Cap Biotech | | | | | | | | | | | | | |
| Alnylam Pharmaceutical | | \$24.5 | \$1.3 | \$2.1 | \$23.8 | \$1.1 | (\$0.7) | 20.8x | (32.2x) | (1.8x) | 1.0x | 18.0x | NM |
| Amgen | | 121.5 | 61.6 | 31.6 | 151.6 | 26.2 | 13.1 | 5.8x | 11.5x | 4.7x | 2.3x | 2.5x | BBB+ |
| Biogen | | 40.4 | 6.6 | 5.0 | 41.9 | 10.1 | 3.4 | 4.2x | 12.4x | 2.0x | 0.5x | 6.3x | BBB+ |
| BioMarin Pharmaceutical | | 16.1 | 1.1 | 1.2 | 16.1 | 2.2 | 0.2 | 7.4x | 90.7x | 6.2x | (0.3x) | 14.7x | NR |
| BioNTech | | 26.1 | 0.2 | 13.6 | 12.7 | 13.3 | 8.8 | 1.0x | 1.4x | 0.0x | (1.5x) | 55.8x | NM |
| Gilead Sciences | | 96.3 | 25.2 | 6.5 | 115.0 | 27.0 | 12.5 | 4.3x | 9.2x | 2.0x | 1.5x | 4.6x | BBB+ |
| Moderna | | 46.3 | 1.1 | 8.9 | 38.4 | 15.1 | 5.2 | 2.6x | 7.4x | 0.2x | (1.5x) | 34.7x | NM |
| Regeneron Pharmaceutical | | 77.0 | 2.7 | 9.0 | 70.7 | 12.4 | 5.1 | 5.7x | 13.9x | 0.5x | (1.2x) | 26.2x | BBB+ |
| Seagen | | 37.1 | 0.1 | 1.5 | 35.7 | 2.1 | (0.6) | 17.4x | (60.2x) | (0.2x) | 2.3x | 340.7x | NM |
| Vertex Pharmaceutical | | 90.8 | 0.8 | 10.4 | 81.2 | 9.2 | 4.6 | 8.8x | 17.6x | 0.2x | (2.1x) | 102.9x | NM |

| | | | | | |
|-----------------------------------|-------|---------|--------|--------|--------|
| Mean (Equal Weighted) | 7.8x | 7.2x | 1.4x | 0.1x | 60.6x |
| Median (Equal Weighted) | 5.8x | 10.4x | 0.4x | 0.1x | 22.1x |
| Mean (Market Cap Weighted) | 6.8x | 7.4x | 1.7x | 0.3x | 49.9x |
| Min | 1.0x | (60.2x) | (1.8x) | (2.1x) | 2.5x |
| Max | 20.8x | 90.7x | 6.2x | 2.3x | 340.7x |

Section Five

Bourne Spotlight

i. Thought Leadership

ii. Bourne Partners Overview





Thought Leadership

Bourne Perspective

After 20+ years of exclusive industry and capital markets coverage, we know the space and we are committed to providing actionable insights to our clients. We provide cutting-edge thought leadership on all things Pharma, Pharma Services, and Consumer Health.

Though leveraging resources and insights of both Bourne Partners Strategic Capital and Investment Banking divisions, **we provide differentiated perspectives to our clients from our unique vantage point.** Our goal is to deliver heavy-hitting, timely reports in an easy-to-read format tailored specifically for executives within our industry coverage.

Deal Profiles

DEAL PROFILE
Amgen | Horizon Therapeutics

AMGEN Inc. (NASDAQ:AMGN)
Biopharmaceutical, pharmaceutical, and biotechnology company. Amgen is a leading biotechnology company focused on developing innovative medicines to improve the lives of people with chronic and acute diseases.

HORIZON THERAPEUTICS PLC (NASDAQ:HZNP)
Horizon Therapeutics is a publicly traded pharmaceutical manufacturing company. The company is focused on the discovery, development, and commercialization of medicines that address critical needs for people impacted by rare, autoimmune, and cancer performance issues.

VALUES
 \$28.3bn Enterprise Value | \$34.9x LTM EV/EBITDA Multiple | *21.0x LTM Revenue (23-24)

Market Conference Commentary

BIO BRIEFING
Xan Smith

BOURNE PARTNERS

Industry Update Posts

INSIGHT
Industry Update
Recent Trends & Transactions

Bar chart showing Deal Transactions, M&A Pipeline, and Strategic Capital. Y-axis: Deal Transactions (Millions). X-axis: Week Ending (2022-01-01, 2022-03-01, 2022-05-01, 2022-07-01).

Weekly Newsletter

Week of July 18, 2023 | Vol. 12, Issue 28

INSIGHT
Newsletter
Recent Trends & Transactions

In This Issue
 Upcoming Events
 Industry M&A Activity
 Recent Transactions
 Trading Comps
 Market Reports
 M&A Pipeline
 Featured Headlines
 Tamer Updates

Quick Links
 Who We Are
 Investment Banking
 Strategic Capital
 Research

Contact Information
 Xan Smith
 Managing Director
 Business Development
 xsmith@bourne-partners.com

Industry Snapshot
 Bar chart showing Deal Transactions (Millions) and Aggregate Reported Deal (Millions) by week ending (2023-07-01, 2023-06-24, 2023-06-17, 2023-06-10).

Above is an overview of recent industry M&A activity. Click on the chart to view complete transaction tables broken out by industry sub-sectors. For additional information, see the Industry M&A Activity section below.

Market Reports

BOURNE PARTNERS

Biostorage Services
Market Insight

2023

Strategic Divestitures Interview

MARKET INSIGHT: USING DIVESTITURES TO DELIVER EXCESS RETURNS

READ

INSIGHT
Industry Update
FDA Draft Guidance

Bourne Partners Overview

Our Service Offering

For over twenty years, Bourne Partners has focused exclusively on providing investment banking advisory services and making direct investments in the Pharmaceutical, Pharma Services, and Consumer Health and Wellness industries. Since 2015, we have successfully executed on **over \$10B** in transactions, having worked with many leading companies and private equity investors in these core focus areas.

Investment Banking

Mergers and Acquisitions

Sell-side and buy-side assignments

Transaction Experience: \$10mm - \$3.5b

Capital Sourcing

Debt / Equity / Hybrid

\$10 - \$500 million raises

Business Development Support

Development stage and approved products

Local and international

Strategic Capital

Investment Focus

Direct investments in private companies

Selective approach in vital focus areas

Other Criteria

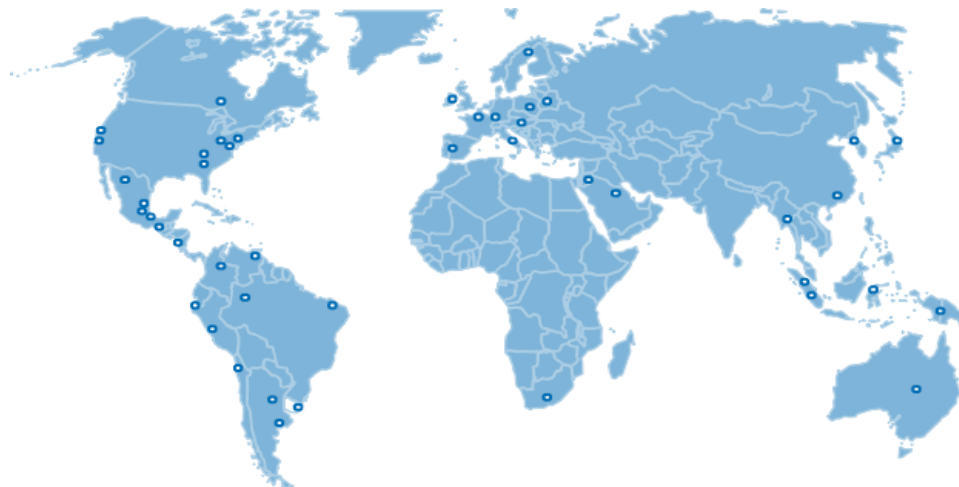
Cash flow positive opportunities

Complex situations with creative structures

Actionable growth stage or middle market business

Flexible investment targets with established private equity relationships

Geographic Coverage



Sector Expertise

Pharmaceuticals

Pharma Services

Consumer Healthcare

Investment Banking Overview

Bourne Partners Investment Banking provides investment banking services within the healthcare and life sciences sector for external clients as well as our portfolio companies.

Value Beyond the Deal

Total Perspective

Experience advising, investing in, building, operating, buying, and selling companies
Unmatched 360° perspective for every project

Uncompromised Service

Direct involvement of senior management throughout process
High level of attention regardless of transaction value

Global Reach

Experience working with companies around the globe
Extensive network of potential international buyers

Focus Areas



Select Tombstones



Partners, Sponsors, and Lenders



Recent Clients & Counterparties



Strategic Capital Overview

Bourne Partners Strategic Capital partners with/invests in opportunities in our focus sectors where we can invest a significant amount of our own capital, add value, and align incentives/partner with management

10

direct or co-investment platforms

15+

Investments in PE funds since inception

\$20+

billion in transaction experience

>11x

realized MOIC (average)

What We're Looking For



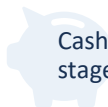
Proven and experienced management teams



Companies or platforms that align with incentives



Highly flexible companies - equity checks up to and > \$1B



Cash flow positive, commercial stage transactions



Companies where BPSC's value add can create a significant return on our personal capital

Current Portfolio Companies



Private Equity Partners & Co-Investors



Exited Portfolio Companies (Active Role)



Appendix



Bourne Partners' Life Sciences Indices

Large Cap Pharma Index:

US: AbbVie Inc. (NYSE:ABBV), Bristol-Myers Squibb Company (NYSE:BMJ), Eli Lilly and Company (NYSE:LLY), Merck & Co., Inc. (NYSE:MRK), Pfizer Inc. (NYSE:PFE), Johnson & Johnson (NYSE:JNJ)

EU: AstraZeneca PLC (LSE:AZN), Bayer Aktiengesellschaft (XTRA:BAYN), GSK plc (LSE:GSK), Merck KGaA (XTRA:MRK), Novartis AG (SWX:NOVN), Novo Nordisk A/S (CPSE:NOVO B), Roche Holding AG (SWX:ROG), Sanofi (ENXTPA:SAN)

ROW: Astellas Pharma Inc. (TSE:4503), Chugai Pharmaceutical Co., Ltd. (TSE:4519), Daiichi Sankyo Company, Limited (TSE:4568), Eisai Co., Ltd. (TSE:4523), Kyowa Kirin Co., Ltd. (TSE:4151), Shionogi & Co., Ltd. (TSE:4507), Takeda Pharmaceutical Company Limited (TSE:4502)

Specialty Pharma Index:

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), Teva Pharmaceutical Industries Limited (NYSE:TEVA), Bausch Health Companies Inc. (NYSE:BHC), Pacira BioSciences, Inc. (Nasdaq: PCRX), UCB SA (ENXTBR:UCB), H. Lundbeck A/S (CPSE:HLUN A), Amphastar Pharmaceuticals, Inc. (NasdaqGS:AMPH), Collegium Pharmaceutical, Inc. (Nasdaq: COLL), Perrigo Company plc (NYSE:PRGO), Amneal Pharmaceuticals, Inc. (NYSE:AMRX)

Generic Pharma Index:

ROW: Teva Pharmaceutical Industries Limited (NYSE:TEVA), Lupin Limited (BSE:500257), Hikma Pharmaceuticals PLC (LSE:HIK), Sun Pharmaceutical Industries Limited (NSEI:SUNPHARMA), Aurobindo Pharma Limited (NSEI:AUROPHARMA), Aspen Pharmacare Holdings Limited (JSE:APN), Dr. Reddy's Laboratories Limited (BSE:500124)

US/EU: Pfizer Inc. (NYSE:PFE), Viatris Inc. (NasdaqGS:VTRS), Perrigo Company plc (NYSE:PRGO), Novartis AG (SWX:NOVN), Amneal Pharmaceuticals, Inc. (NYSE:AMRX)

Large Cap Biotech Index:

Alnylam Pharmaceuticals, Inc. (NasdaqGS:ALNY), Amgen Inc. (NasdaqGS:AMGN), Biogen Inc. (NasdaqGS:BIIB), BioMarin Pharmaceutical Inc. (NasdaqGS:BMRN), BioNTech SE (NasdaqGS:BNTX), Gilead Sciences, Inc. (NasdaqGS:GILD), Moderna, Inc. (NasdaqGS:MRNA), Regeneron Pharmaceuticals, Inc. (NasdaqGS:REGN), Seagen Inc. (NasdaqGS:SGEN), Vertex Pharmaceuticals Incorporated (NasdaqGS:VRTX)

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