LIFE SCIENCES SNAPSHOT

A Quarterly Report on Financing Trends

EVOLVING ANTITRUST SCRUTINY OF LIFE SCIENCES M&A — WHAT'S IN THE PIPELINE? Q3 2022

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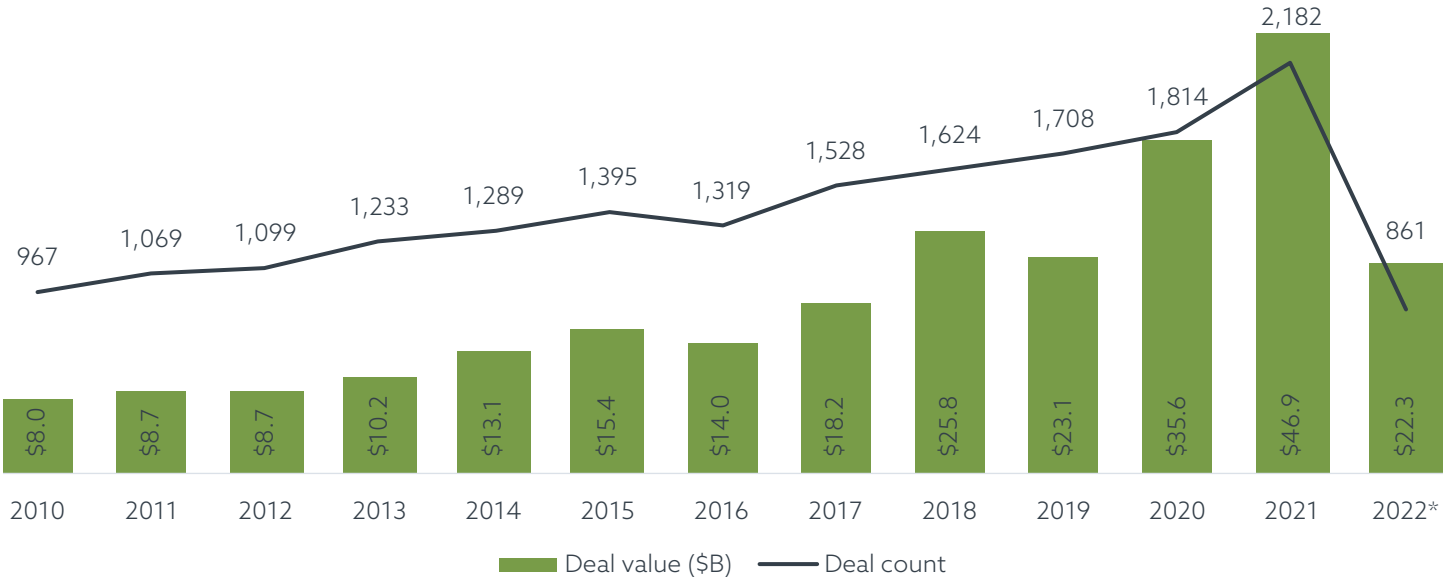
Data provided by

PitchBook

Key takeaways

Life sciences VC deal activity



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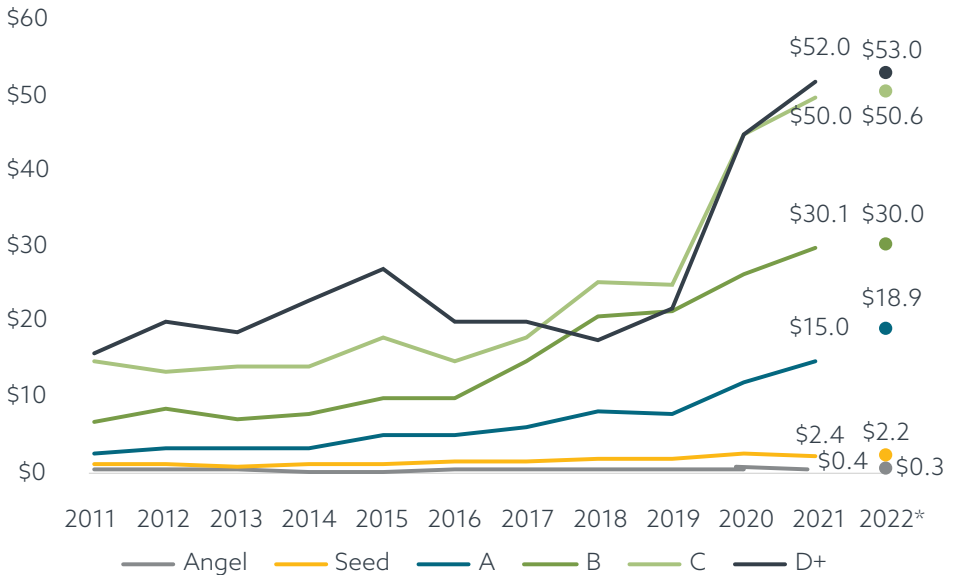
*As of June 30, 2022

This report series examines quarterly trends in life sciences venture investment. Key findings for Q2 2022 include:

- The industry generated $8.8 billion in deal value across 362 deals in Q2, a material decline from Q1, as the public market decline and macroeconomic pressures continued.
- Median deal sizes remained flat from 2021 for all stages except Series A. Median pre-money valuations rose across the board. A smaller population of deals may account for some of this increase.
- Public market turmoil continued to create ripple effects across the industry, particularly for exit activity. IPO conditions remain unfavorable, and acquisition activity was subdued.

Median life sciences VC deal value ($M) by series



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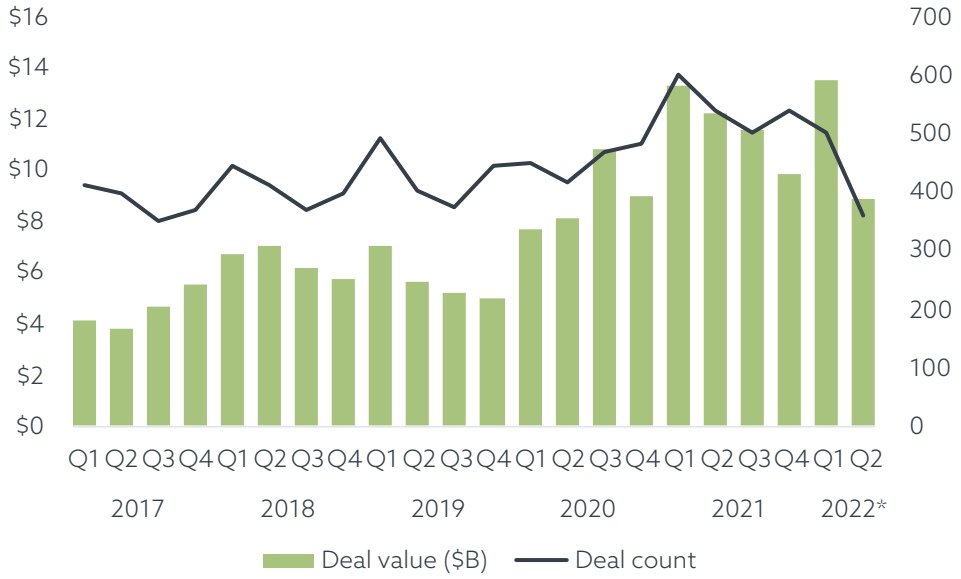
Market analysis

Despite various disruptions in the broader markets, life sciences venture deals were resilient in Q1 2022. Momentum slowed in Q2, however, presenting the lowest deal value for a quarter since Q2 2020 and a 34.5% decline from the previous quarter. Far fewer deals were closed in Q2 2022 as investors faced a longer than expected period of public market turbulence, with noticeable retractions for perceived higher-risk stocks, including biotechnology and pre-revenue therapeutics companies. Poor IPO conditions created particularly strong headwinds for the industry's capital-intensive population of companies. Investors are less open-handed now than in prior quarters, and this has caused many companies to downsize for runway extension.

However, on a historical basis, deal value remains steady. The aggregate deal value generated in H1 2022 represents more than half of total deal value in 2020 and is just shy of the total deal value closed in all of 2019. Venture capitalists (VCs) still have significant pools of capital to put to work, and companies continue to pursue exciting scientific developments.

Life sciences VC deal activity by quarter



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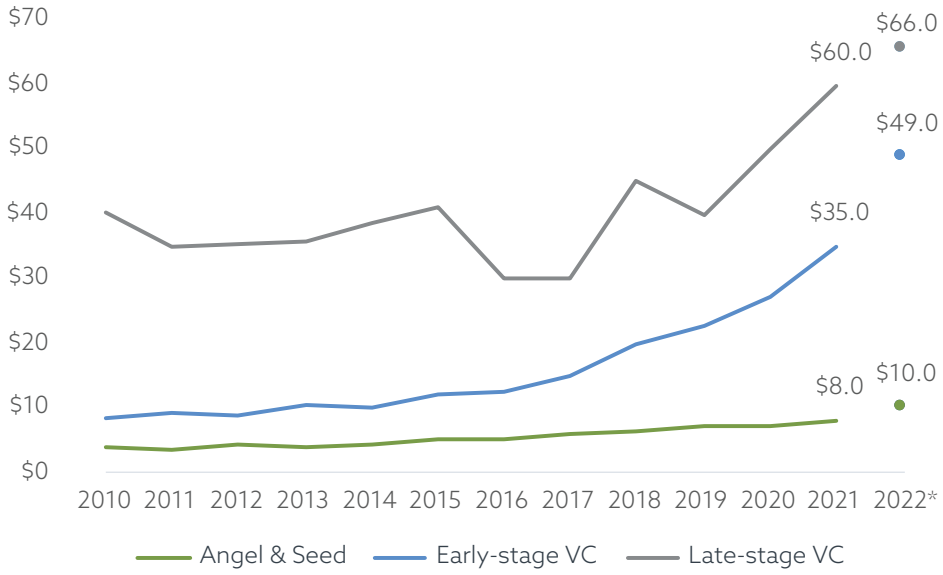
Median life sciences pre-money valuation ($M) by stage



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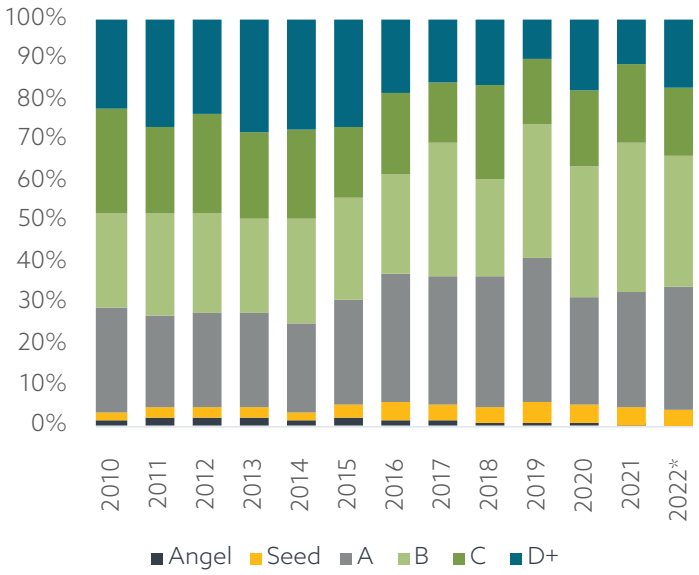
Share of life sciences VC deal value by series



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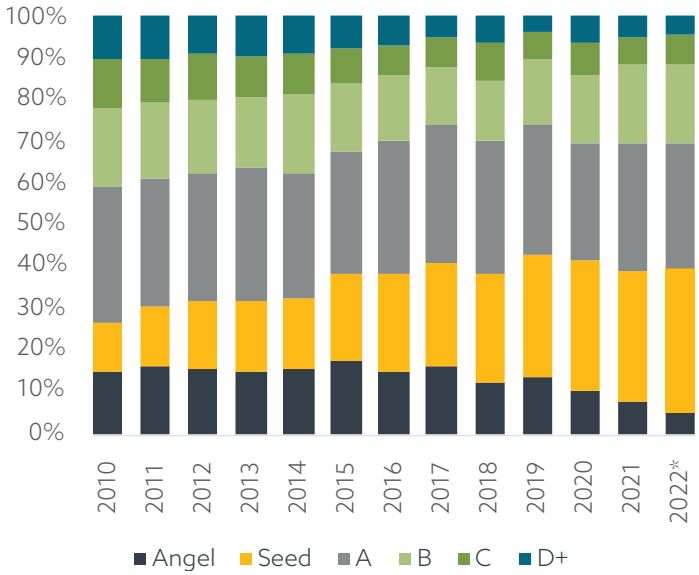
Share of life sciences VC deal count by series



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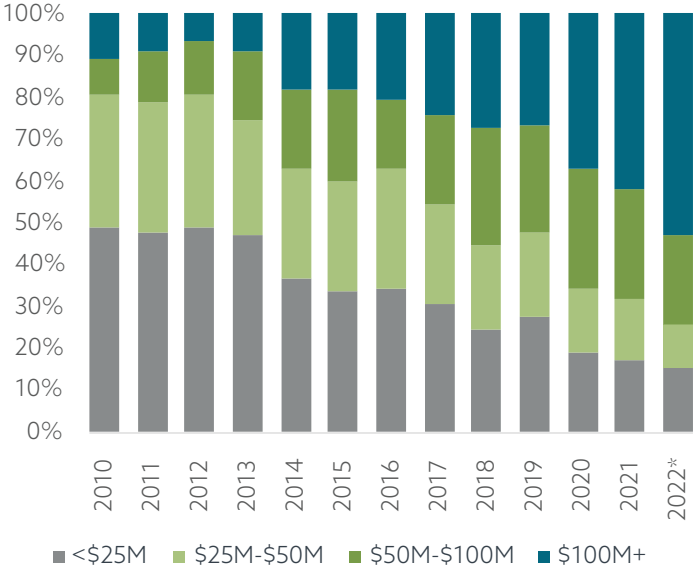
Share of life sciences VC deal value by size bucket



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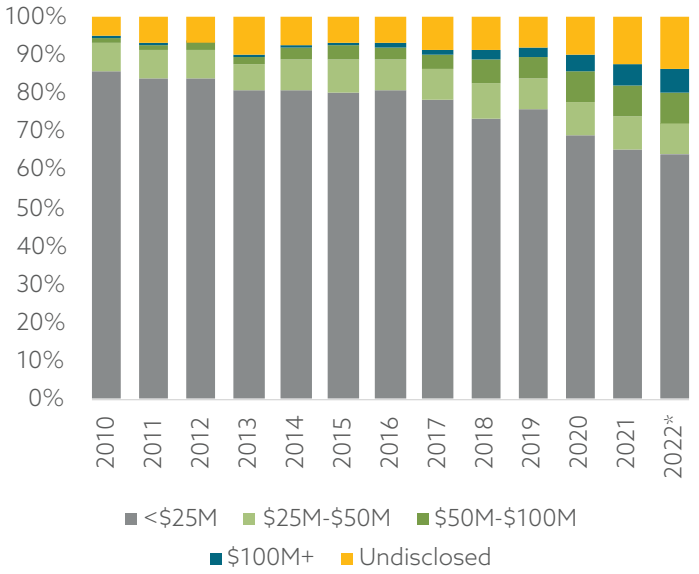
Share of life sciences VC deal count by size bucket



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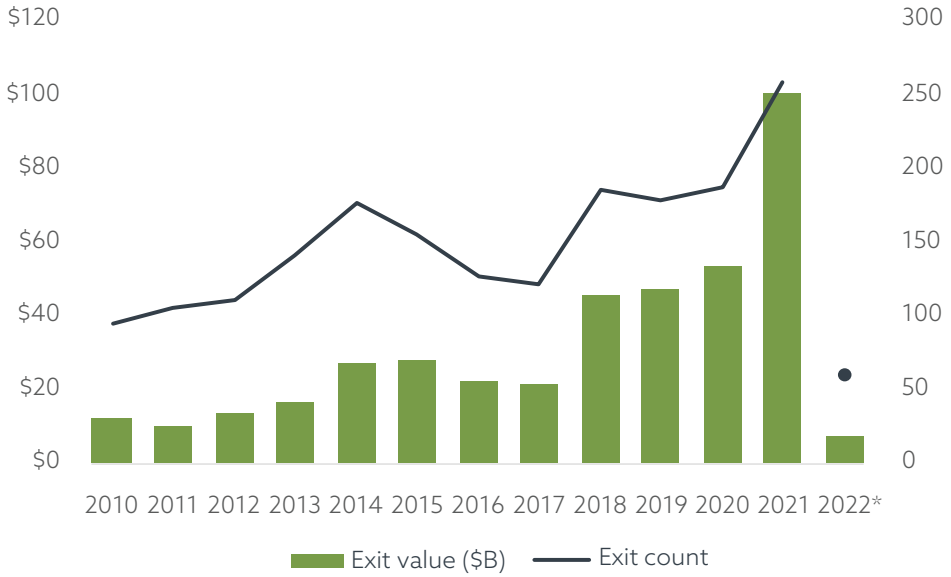
Market analysis

Median deal sizes have remained relatively flat since 2021, while pre-money valuations continued to rise across all company stages. Q2 2022 created a more difficult capital-raising environment for companies, but investors committed to their best early-stage players and continued to write checks for a more selective population. Over the past two years since the onset of the pandemic, deal flow has become more concentrated among deals over $100 million. At the same time, the proportion of deal value closed by early-stage VCs has increased.

Life sciences exits remain depressed, with a 72.8% decline in value since Q1 2022. Public market declines reduced IPO values and led many companies to put offerings on hold, with a 54.9% drop in the median IPO size since 2021. Inflation and rising interest rates contributed to a lag in other exit types as well, with just $2.3 billion in acquisitions closed in the first half of the year, compared with $26.2 billion in 2021 and $16.6 billion in 2020. (This excludes the $11.6 billion Pfizer/Biohaven acquisition, which was announced in Q2 but not yet closed, and so is expected to impact Q3 numbers.) M&A players are on the sidelines for now, but the 2025 patent cliff is approaching, with several large pharmaceuticals poised to lose exclusivity in the US and European markets. Pressure is mounting for companies to stock their pipelines with assets that may mitigate the expected loss in revenue.

Life sciences VC exit activity



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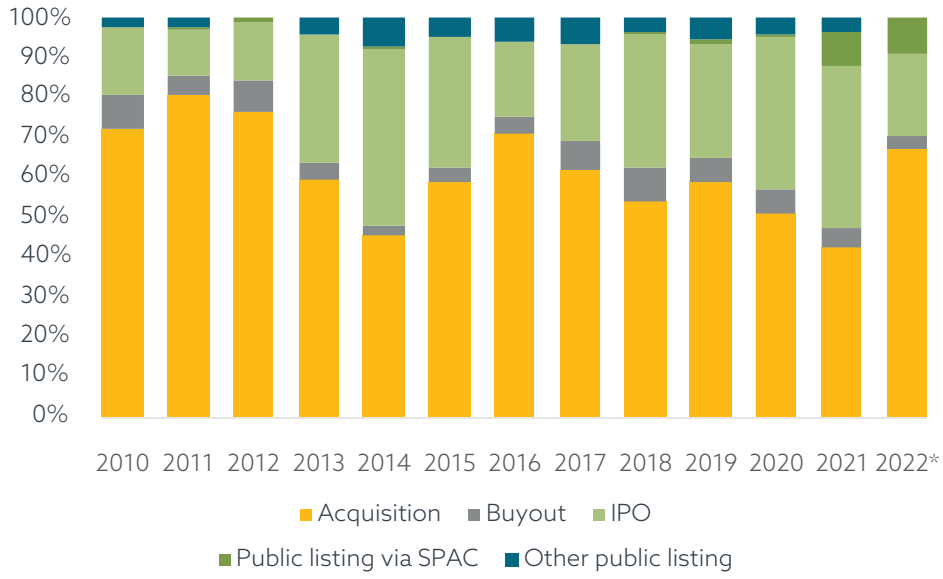
Share of life sciences VC exit count by type



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Roundtable

Participants

Anna Aryankalayil
Attorney Advisor to FTC Commissioner Noah Phillips

Dan Schneeberger
Founder/CEO of ADAR1 Capital Management

Michael Attar
SVP, Head, Business Development at Beam Therapeutics

Craig Falls
Partner, Orrick

David Schulman
Partner, Orrick

Stephen Thau
Partner, Orrick

Neel Lilani
Global Head of Tech Clients, Orrick

Craig: Antitrust policy is rapidly evolving with respect to how mergers are reviewed, so we are excited to hear from our panelists representing a variety of backgrounds on what is happening in antitrust enforcement and how it impacts life sciences dealmaking. Anna, what are antitrust enforcers concerned about right now in life sciences deals?

Anna[1]**:** Antitrust enforcers have always been interested in life sciences, but recent factors have raised the level of scrutiny. The pandemic, healthcare costs, and high drug prices have received a lot of political attention. High-profile instances of bad behavior in this space, for example, 'Pharma Bro,' have drawn attention. Also, new leadership at the FTC and the Justice Department has taken an aggressive stance on M&A—which is clear in public comments from [FTC] Chair Kahn and [DOJ] AAG Kanter. This reflects how the agencies are approaching M&A overall, not only for life sciences.

About a month ago, the FTC held a pharma merger workshop. This was the first time we've heard from the FTC pharma task force, and while they didn't take any formal positions, the transcripts and videos from these workshops are available on the FTC website and contain a lot of signaling.

[1] Views expressed are Anna Aryankalayil's and do not reflect the views of the Commission or any Commissioner.

There is a lot of interest in nascent competition—the big worry is 'killer acquisitions,' where pharma companies acquire and then discontinue pipeline drugs that would have likely competed against the acquirer's products. While concerns about nascent competition is not a new issue (e.g., in 2019 FTC sued to block Illumina's acquisition of PacBio, an innovative, nascent competitor in gene sequencing), it is top of mind. We also may see a change in the burden of proof. Usually, the government, as the plaintiff, must prove that the merger will substantially lessen competition, but there are efforts, both through proposed legislation and proposed adoption of common law presumptions, to shift the burden to the parties to affirmatively prove that their merger is pro-competitive. The agency is also focused on cross-market effects, so if you have a blockbuster drug, there is concern that you could leverage that drug to get exclusivity or better positioning on formularies for newly acquired products when negotiating with payers or with PBMs.

The agency may also look to past conduct of firms engaging in M&A. For a long time, review was focused on the deal in front of the antitrust agencies. Now, enforcers may factor in prior anticompetitive conduct of the parties or proposed divestiture buyers into merger analysis. And this is not limited only to pharma—it's a consideration that's happening across the board. We've heard it most in the tech space, and there are also bills pending in Congress that go in this direction.

Stephen: Regarding nascent competition, if you're reviewing an acquisition of a company whose drug is in phase two clinical trials—so maybe it's three to seven years away from approval—is that still considered potentially nascent competition in the analysis?

Anna: The agency looks at products on the market and in the pipeline. What you described sounds like an earlier 'research pipeline.' The Pharma Taskforce has emphasized the need to look more closely at innovation competition and that we may miss the big picture if we're very focused on 'classic pipeline' products—therefore, yes, there's interest in looking at that.

Craig: The way we think about the goals of antitrust is changing across the board. We used to be focused on economic efficiencies, or "Is allowing this deal better economically than blocking it?" Now we're more concerned about, "Are we permitting growth of very large private interests in our society?" This is not an economic analysis, but a pro-democracy approach to antitrust. Separately, health care is always going to be a focus because the cost of failure is so high—if new products are killed off, then it can affect people's health and lives. And if prices go up as a result of a deal, then health care can become unaffordable to large portions of our population.

There are two competing narratives. For years, the rationale for a big pharma company buying a small biotech was that the emerging company has no ability to commercialize the product, so the big company could help bring the product to the market, which benefits everyone. But now, academic literature is questioning whether this story about accelerated outcomes is true. There's this idea among enforcers that in life sciences, and especially in big pharma, the companies have incentives to maximize and lengthen regulatory exclusivities, and not to innovate or compete and bring new and better products to the market. To Anna's point, enforcers are concerned that companies with track records of trying to exclude competition are going to be buying a company that otherwise would be hungry to compete on the merits. Traditionally, the buyer's incentives and past behavior have not been a focus of interest in antitrust reviews, but now that's applying across a lot of industries. Enforcers are going to be asking, "Are we putting companies in the hands of bad actors?"

And regarding the new cross-market issues, these make it difficult for parties because every deal is potentially a problem if white space deals can also raise concerns. For deals in which there's zero product or pipeline overlaps, we still have to prepare companies for scrutiny under the cross-market theory—that a company with a popular product will use its power in that product to force payers to accept some other product that the company is acquiring.

Neel: With scrutiny becoming more rigorous, Daniel, has your thinking about pricing changed for evaluating investment opportunities?

Daniel: Historically, big pharma has invested heavily in R&D and has achieved good returns. But over the last three decades, the ROI has declined. As a result, we've seen externalization, where smaller, more nimble companies take on this early-stage R&D, financed by private investors and then get acquired at a later stage. Personally, I have not seen the type of deal where large companies acquire smaller companies just for the sake of extending regulatory exclusivities on other products or with the intention to kill the acquired pipeline projects. A lot of pipeline projects get shelved, but that's not necessarily in bad faith. This is just a very risky field, and a lot of deals don't live up to the hope in terms of safety, efficacy, or commercial potential.

Also, we shouldn't overlook how critically important exits are for the ecosystem. There needs to be a credible path to an M&A exit because it does not make economic sense for many smaller companies to launch their own product. Sector evaluations are reliant on exits. Otherwise, cost of capital will increase to a point where it will no longer be able to sustain

the biotech industry. From the FTC workshop that Anna mentioned, I came away with the conclusion that we wouldn't see increased scrutiny on smaller deals but instead an increased focus on large- and mid-sized deals.

Anna, for deals we're considering now, how quickly should we expect to see policy change? And how much more scrutiny will we see in practice?

Anna: The agencies are undergoing a review of our broader merger guidelines. I don't expect the pharma task force to come out with pharma- or life sciences-specific guidelines. Regarding cross-market effects, there is talk of codifying the theory that a firm being able to increase its bargaining leverage via M&A should be classified as an anticompetitive arm. Another concern is labor market issues. People have asked, "What happens when a pipeline product is shut down? Where do those scientists go?" Most of these pharma deals are resolved by consent agreements, so these theories of harm have not been tested in the courts. Another idea is maybe we need more tailored remedies that go directly to preserving certain pipelines so that the acquiring firm doesn't just shut something down. That could mean an independent monitor overseeing the development of that research pipeline, monitoring patent outputs, or requiring the buyer to keep a nascent competitor as an autonomous division and let them continue work on the existing pipeline.

Craig: Anna's point about consents and remedies raises a separate issue: What do the courts really think of the FTC's new theories? Even though the FTC requires divestiture of pipeline products to clear deals with consent, it's uncertain they would win on these cases if they ever went to court because the standard for potential competition under the case law is much higher than the likelihood that a phase two product gets approved. In fact, the FTC is a bit inconsistent in their cases. They will argue that the acquired company's pipeline product is a potential new competitor, but everyone else's pipeline product is so unlikely to make it to the market that there will never be any new entry in this industry. The practical problem for merging parties, however, is who has 18 months to go litigate against the FTC and put them to their proof and challenge some of these theories?

Parties should prepare now for the new scrutiny as this is already being seen in investigations even if not codified yet in Merger Guidelines. Buyers need to gather evidence to demonstrate that they did accelerate product launches in prior deals and show their track record of making substantial investments in acquired pipeline products. Biotechs must be prepared to tell their side of the story, "What is the future of this product if we don't do this deal?" The antitrust enforcers have a view that if they block these deals, the small companies will grow and challenge the incumbents, and as Daniel pointed out, that's just not how it works. Biotechs should show what the next six to twelve months could look like if they don't do this deal.

Anna: And with the enforcers' general skepticism of benefits of M&A, telling that pro-competitive story right from the outset is even more important—even if there is no formal shifting of the burden.

Neel: Craig, would you say that there's an increased politicization in how deals are scrutinized?

Craig: Yes. When you have two big companies merge, even if there's no product overlap, there's a concern that these companies are just becoming too powerful. With big buying small, you're less likely to get congressional scrutiny, though academics and the FTC are concerned about putting innovation on the shelf and creating the wrong incentives. Ultimately, you need to understand your deal, who the audience is, and what the likely concerns are upfront—so that you're telling the right story to the right audience.

In this environment, Daniel, do you think it's realistic that a party can stick around for a 12- or 18-month antitrust investigation and potential litigation to give itself the best chances of certainty?

Daniel: I don't believe long deal timelines are an issue if your company is financed well enough to bridge the gap. However, there may be value-creating milestones within the time line which could make it more difficult to agree on price. Mitigating that with a contract is one of the challenges that could emerge in merger discussions.

David: We've seen public biotechs in 2022 that have recently completed significant dilutive financings in these depressed equity markets, but they can only do so many of these dilutive financings. Now, a lot of biotechs are going to have to combine or engage in other M&A or licensing transactions—or in some way, they'll come to an end. They might sell off, engage in unfavorable M&A or licensing transactions, or go into liquidation if they can afford it. They're looking for a path forward, but trying to navigate these M&A and licensing deals in the midst of the antitrust rules changing is generating considerable confusion.

Daniel: I agree. Financing in the public markets has become more challenging for many companies and some could benefit from consolidation. It could be problematic if there is review uncertainty, but they can be bridged if there's willingness on both sides to pursue a transaction. We've seen some examples where buyers essentially provided bridge financing to consummate a transaction.

David: Depending on how the new antitrust review approaches shake out, I am concerned over how some typical scenarios could face deadlock and outcomes could contradict the overall goals of the FTC. Say you have two biotechs that both have drugs in phase two but no hope of getting data for another year. They have 13

months of cash but no new cash coming in. They approach the likely pharma acquirors and discover at best one or two interested acquirors, who in this climate know they're likely the only one or two bidders, so the exit price suffers. This is not a good place to be for the biotechs. So perhaps the biotechs turn to the antitrust lawyers and ask, "Can we put these two biotechs together?" The answer used to be that the absence of overlap meant combinations were possible. But now we're not sure, because it might be viewed as "squelching innovation."

Michael: For biotechs who are not capitalized well enough to get to the next inflection point, it's going to be hard to secure any financing. As a potential buyer or collaborator, why would I act today? As time passes and the value on their balance sheet goes down, the company will be more amenable to my terms. Unless there are other bidders—and in this scenario that we're positing, there aren't—I'm going to wait.

Craig: How could two small biotechs getting together help to solve the problem?

Michael: Maybe there's enough capital between the two–though they'd need to rationalize the workforce. Or perhaps there's some synergy, scientifically or operationally, where they'd benefit by having these two entities work together. More likely, if you're a seller, you'd try to sell yourself to a big pharma that has the capital to help you survive.

Anna: One of the things I worry about is: By taking an overly aggressive enforcement posture, are we discouraging innovation? But we heard during the FTC pharma workshop that the agency is worried about underenforcement. For example, not catching a small, nonreportable deal that might turn out to a be a killer acquisition. To address this, the agency now regularly includes prior approval and prior notice provisions in merger consents.

Craig: I think the problem here is that we're up against an imagined parade of horribles and speculation about the worst-case scenarios, and the current administration is willing to be wrong and block even beneficial deals if that makes merger enforcement easier and it helps them to avoid missing the cases that they have been criticized for missing in the past. They're willing to err on the side of over-enforcement and simplified analyses based on theory and speculation instead of evidence. Ultimately, however, antitrust requires cases to be decided on a case-by-case basis, so merging parties need to have the evidence available to show that the merger is better than the alternative of the company going alone and the product never making it to the market. You need to come in on day one of the FTC's investigation and show the staff that this is not the deal that they want to make an example of because it would be a hard case for them. Now, the challenge is, as we've discussed with the deal terms, if you only have 90 days in your purchase agreement to do all this, you don't have enough time. It's one thing to say to the FTC "You're not going to win this case if you bring it to court." It's another thing to say to the FTC, "Don't even investigate this case; Let us close in 60 days," when the FTC has a mandate to leave no stone unturned in healthcare deals.

Neel: What practical advice would you share with companies that are looking to make acquisitions or to be acquired themselves, given this potentially increased scrutiny?

Craig: If you're on the acquisition side, gather evidence on your prior deals to show that you have a good track record of promoting innovation when you've acquired companies. It's not just about what this deal does but, rather, are you a good buyer? And you need to show good antitrust compliance generally. It's important to get counseling on your lifecycle management activity and everything else you're doing, because, if you have a record of being scrutinized over your conduct, it's going to make your merger activity difficult.

Neel: What are criteria that could demonstrate a company has encouraged innovation after an acquisition and therefore is a "good acquirer" from the perspective of regulators?

Craig: If you've advanced other products you've acquired to a later clinical stage and you've obtained approvals. That you didn't put things on the shelves, or if you did that, you have a good-faith story as to why that happened—it was unexpected, or there was something that went wrong, and it wasn't because you were just taking out something you perceived as a future threat.

Daniel: Would it help the industry longer term if companies communicated more openly about failures and explained the rationale for discontinuing a program?

Craig: In individual investigations, if there's scrutiny over what happened in a prior deal, then, yes, it's prudent to be upfront and tell that story to enforcers. Sharing your failures publicly maybe is not necessary! However, if there are industry groups or trade associations that can tell this story [behind why things fail], that could have the potential to change the narrative that academia is promoting—that biotechs are being bought up and put on the shelf—and that could be worthwhile. Especially now, while the FTC is still considering how they should analyze pharma deals.

David: As an example of some of the challenges I anticipate we may see: Craig and I are working on a sale of a product that happens to have an overlap with one bidder's pipeline, but the acquiror has not initiated any clinical trial work on the alleged overlap in three years—which is a pretty good indication that it failed. In this market, a bidder could say, "I'm not sure what's going to happen with the antitrust rules, so we're

not going to move forward with the deal." Normally, we'd assume they'd have the option of selling the overlap product—but in this climate, no one would buy it. Even if someone was willing to pay for this parked asset, I've seen similar scenarios where the FTC has responded, "Having a buyer is not sufficient. You need a buyer who's going to develop it." So there's no remedy, other than being prepared to fight the FTC on this. And clients are saying that because the rules are unclear; they want to avoid getting stuck in a big fight.

Craig: Divestitures are more difficult than before. Now, we are still seeing consents being done in pharma. The FTC is still approving deals with divestitures, but the statements out of the DOJ and the FTC on all mergers is, "It's not our job to fix your deal." Parties could fix it themselves, by making a divestiture without going through the whole process of getting a buyer approved by the government—but you can't do that unless you can litigate the fix—because you don't have a consent, the FTC can still challenge and you have to defend the merger "as fixed." And you can't do that if you only have nine months, because that process typically takes a year and a half to two years.

Neel: Given the current climate, are you applying any sort of valuation modification with regard to M&A activity?

Daniel: Most of the smaller therapeutics deals we've seen have closed quickly, and we haven't seen many second requests. So I don't believe that public market valuations are discounting FTC concerns. We didn't see many acquisitions in the last year, but that's probably because valuations were too high, so there was a significant bid-ask spread between what smaller companies thought they were worth and what potential acquirers were willing to pay.

Michael: For my company, we're not making big M&A transactions. We're doing collaborations and trying to get our editing technology to select other partners. Regarding a value modification, if we were buyers, I think that would depend not on the FTC considerations but rather on a case-by-case basis of the fair value of the asset. The FTC risk, especially for relatively cheap and smaller biotech, would be lower down on our list of concerns. If you see significant value, then you'd factor it in, but it wouldn't be a key driver of the decision.

With this nuclear winter we're in, with how frothy the markets were before, and because there are still a large number of companies that are not going to be able to finance in the public markets, isn't there still a lot of M&A activity to be done? For example, a lot of the companies that recently went public perhaps wouldn't have gone public in a more rational market, so doesn't that signal that there will be a lot more M&A or bankruptcy that will occur before a lot of these companies are cleared out?

David: Personally, yes, I do think there's going to be more M&A. The reality is that it's a buyer's market now. If you're a seller, you might try to negotiate, but it's unlikely they'll find any financing and licensing alternatives worth considering. And even though it seems there'd be more M&A, it hasn't really unfolded that way—yet. For strategic acquirors, there is incentive to wait for further data and downward adjustment in shareholder recognition of value. But for those biotechs with less than 12 months of cash on the balance sheet, time is not a friend. For those biotechs, lawyers and bankers are going to tell them, "You have 11 months of cash on the balance sheet now. For every month you don't finish this out, your leverage gets exponentially worse."

Michael: Agreed. Even for bankruptcy, you need a certain amount of cash to get yourself through that process and wind things down in an orderly fashion. Having eight months of cash doesn't mean you can continue to run the company and then also do a bankruptcy filing–that's just not how it works.

David: This has also come up in divestitures of parked candidates at large pharmas. We were working for a biotech in talks with a large pharma who typically demands cash up front as a condition to any divestiture. The biotech communicated in its final offer that it would only offer its equity up front. In response, the pharma agreed to waive the rule of having to put cash up front. For me, that was a wake-up call: cash is scarcer now, and the old rules don't apply. I think there will be a lot of pharma divestiture deals but at lower valuations.

Something else we're hearing public biotechs talk about, especially from those where the share price has plummeted since last year is, "I have more than enough cash for a couple of years. We'll get more cash by doing collaboration deals. And we won't license out our lead candidate, but we'll license out a part—maybe Europe." And if that hundred million up-front milestone is ascribed to the United States for a U.S.-centric deal, the biotech will need to consider the changed antitrust approval issues we have been discussing. This may even force ex-U.S.-centric deals. Ultimately, I think the uncertainty around the antitrust rules may cause deal structure distortion.

Craig: Anna, what might we see out of the FTC and the rest of this administration that could give us clarity on these analytical frameworks? And, separately, what would you expect to see if we have a change in the administration at the White House?

Anna: The agencies are saying that life sciences deals and pharma deals should anticipate stricter scrutiny. I would say: believe them. But agencies cannot challenge every deal. That's a function of resource constraints: *e.g.*, number of people/money. So, merger consents aren't going away. I expect that most of these deals under scrutiny will continue to be resolved by consent. But there is a lot of public pressure and desire from agency leadership to outright block certain pharma deals. I think size matters, and the biggest firms are going to see this play out. Also, the agencies have said that we are going to issue broader second request investigations that look at things like bargaining power with PBMs and other payers, cross-market effects, and labor questions. If you are negotiating remedies with the agencies, you should expect to get pushback on the proposed divestiture assets. Maybe it's not just the product on the shelf or pipeline products that you have to divest, or maybe you have to accept an independent monitor who's going to watch what's happening with your research pipeline. You also have to look out for prior notice and prior approval provisions in your consent agreement.

I think the big takeaway is that large or small, companies should plan for uncertainty, and plan for longer investigations. This goes back to Craig's point in the beginning: You want to prepare to clearly articulate pro-competitive factors that are driving the acquisition decisions.

Craig: You have to both articulate and ***substantiate***, and that requires more work up front. My personal view is that this new environment is not going to go away, even if we have a change in administration. The push for more antitrust scrutiny is bipartisan. Different concerns motivate the Republicans than the Democrats, but they both want more scrutiny of powerful companies, so this new environment is going to stick around. Therefore, I think the takeaway is: Don't wait two years to do your deal, because I don't think it's going to get significantly easier.

Anna: I'll add that vertical deals haven't had a lot of attention because people used to think of those as more insulated from antitrust scrutiny. The agencies have signaled that that's not the case anymore. The vertical merger guidelines were rescinded on a partisan basis, and in life sciences, as in other industries, a vertical deal might face more scrutiny than before.

Michael: I haven't seen vertical integration as a huge trend, but given the number of manufacturing issues that have plagued companies, especially in gene therapy and gene editing, there is security in being able to control the manufacturing side. I think we will see more of this over time, potentially through M&A.

Neel: It's going to be interesting to see how the shifting political and economic climate may impact regulatory scrutiny. Thank you, everybody, for joining today's discussion and sharing your insights.

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