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**Voice-over:** The *BioWorld Insider podcast*.

**Lynn Yoffee:** This is the *BioWorld Insider podcast*. I'm Lynn Yoffee, BioWorld's publisher. The average cost to bring a new drug from discovery to market is now north of $2 billion. That's why drug development firms are always focused on fundraising and partnering to support their programs, so far in the first half of '23, the financings environment is challenging. All the numbers are in, and the volume of M&As and biopharma deals are at their lowest levels in five years, so is the value of M&As. Deal values have declined by 8% compared to 2022.

On a brighter note, M&As seem to be picking up a little bit. Our guests today are both from Clarivate, BioWorld's parent company, and they're here to put the numbers from the first half of the year in perspective. Staff writer Lee Landenberger will lead the discussion. First up is Karen Carey, BioWorld's managing editor, and senior data analyst. We're also welcoming Mike Ward. He's the global head of thought leadership at Clarivate. A former journalist who has also been a BioWorld contributor, Mike has been deeply immersed in life sciences for more than three decades. After Karen's overview, Mike is going to focus on the post-Brexit impact on biopharmas in the UK relative to the current financings environment. Over to you, Lee.

**Lee Landenberger:** Thank you, Lynn, and welcome, everyone. We have guests. Karen is in Florida and Mike is in the UK, so we're pleased to have you with us. Karen, first off, you keep a pretty solid eye on what's going on with all of our data and all the first half of the year numbers are in. You've looked at them pretty closely. Can you give me a big-picture summary of what the landscape looks like compared to last year?

**Karen Carey:** Sure, Lee. Thanks for having me. I'll take it apart in three sections; biopharma deals, M&As, and financings. The biopharma deal values are much in line with the first halfs of all the years going back to 2020, but the number of deals has gone down in 2023. In fact, they're at the lowest level in five years, as Lynn had mentioned. What has not gone down is the number of mega deals, those worth $1 billion or more. We had 15 of those in the first quarter and 15 in the second quarter. All told there were 672 biopharma deals. Those are collaborations, licensing, joint ventures worth $87.8 billion in the first half of 2023.

Now, M&As are doing better than last year, both value and volume, but they still pale in comparison to the first halfs of 2020 and earlier. They also have the overhang from the FTCs antitrust challenge to the Amgen-Horizon deal. I've heard it said that big pharma is on hold with M&As waiting for an outcome on that challenge, but we honestly have been seeing more activity than last year despite the challenge. We had 58 completed M&As in the first half of 2023 worth $29.4 billion. That's up from last year. We also had six M&As with values above $1 billion in Q2.

That was double the numbers seen in Q1. Now, financings, like M&As, they are doing better than last year overall, and follow-on offerings and private placements are significantly up, but IPOs are scarce. Although venture capital rounds are higher than most years, 2019 and prior, they too are trending downward for the first time since the start of the pandemic. In total, the biopharma industry announced 584 transactions in the first half of 2023, raising $32.8 billion, which is 24% more than last year.

**Lee:** Let's drill down a little bit. Can you give me some insight into the biggest deals of the year so far?

**Karen:** Sure. In terms of deals, there were seven notable ones in the first half of this year, four of which occurred in the second quarter. There was a $2.6 billion deal in April between Novo Nordisk and Aspect Biosystems that was aimed at advancing 3D bioprinted tissue therapeutics for diabetes and obesity products. There was one worth $2.55 billion between Merck and Proxygen, focused on molecular glue degrader technology, was indication agnostic. Novartis had a $2.5 billion deal allowing Bausch + Lomb to take over rights to ocular therapies and quell $2 billion deal with AstraZeneca for rights to two autologous treg cell therapies for inflammatory bowel disease and Type 1 diabetes.

From the first quarter though, the top deal of the year was done in March. That was Evotec and Bristol Myers Squibb in a $4 billion pact for neurodegenerative disease therapies. Also notable are Immunome, AbbVie $2.8 billion for oncology antibody targets and Synaffix, and MacroGenics. $2.2 billion for next-generation antibody-drug conjugates.

**Lee:** Even though they're sluggish, the number of billion-dollar deals, or at least just having billion-dollar deals [chuckles] is, we're seeing a lot more of that than we used to.

**Karen:** Yes, we definitely are. The volume is down, but the values, they're in line with a lot of the recent years. That just tells me that there's more billion-dollar deals, even if there's fewer deals overall.

**Lee:** How about the biggest M&A of the year so far?

**Karen:** The three top M&As all occurred in the second quarter, and the biggest one for the year $10.8 billion M&A between Prometheus Biosciences and Merck in June, that is the largest for the year and is the only one this year that makes BioWorld's top 20 list for acquisitions of biotech developers. It ranks at number 18 right now. Only one M&A in 2022 made that list. That was Pfizer's purchase of Biohaven for $11.6 billion in October. These are M&As that have been completed, not the ones on our pending list. Another big one, a $2.9 billion merger between Provention Bio and Sanofi in April. Also GSK $2 billion buyout of BELLUS Health in June. In the first quarter, $1.7 billion between Sobi and CTI BioPharma, and also AstraZeneca's purchase of SynCore Pharma for $1.8 billion.

**Lee:** You had mentioned earlier the Amgen-Horizon deal, and there's an FTC challenge to that. Can you give me a little insight into it?

**Karen:** Sure. The FTC challenging this merger has raised some red flags. Some analysts have said big pharma is holding back, waiting to see what happens. This deal, it would be number six on BioWorld's top 20 list if it completes. It's worth $27.8 billion. It was signed late last year, was originally expected to close in the third quarter of this year. Even though the FTC has acknowledged there is no commercial overlap, its concerns seem to be about the potential for Amgen to bundle formulary rebates that would essentially stifle future competition of Horizon's orphan drugs, Tepezza for thyroid eye disease, and Krystexxa for chronic gout.

It's not just the FTC, attorneys general from six states have also joined the lawsuit from California, Illinois, Minnesota, New York, Washington and Wisconsin. So far we haven't seen any other challenges to large pending M&As. Pfizer's purchase for Seagen for $43 billion, that was announced in March, for example, that's still expected to close later this year or early next. If it does, it will be Number 3 on our top 20 list. I do think this FTC challenge will have to be resolved before we see a true representation of M&A activity.

**Lee:** Do you have any idea how long that might take?

**Karen:** When you're dealing with the courts, it's so hard to say. I don't know, but I've definitely seen analysts saying that it's holding back M&A activity, and then other analysts saying they don't really anticipate it holding up certain M&As that are already in process. I'm not really sure.

**Lee:** How about the biggest financings? What have we seen so far in the first half of the year?

**Karen:** I said there was a pickup in follow-ons and public other financings. For the follow-ons, we had $575 million by Vaxcyte in June, $460 million Karuna Therapeutics in March. $402.5 million, Apellis Pharmaceuticals, February, and $400 million by Moonlight Therapeutics in June. That one followed promising Phase 2 data. If you look at the public other financings, these are private placements and other private financings of public companies. We had $2.49 billion senior notes offering by Teva. $500 million each for Ionis Pharmaceuticals through a royalty buyout, Summit Therapeutics, for a rights offering. There were some other royalty agreements as well, Uniqure, $375 million.

Legend Biotech raised $350 million through a registered direct offering. If we go to venture capital, all top private company financings happened in the second quarter. There was $1 billion by Galderma, $401 million in a Series D for ElevateBio. $350 million for Hasten Biopharmaceutical, $300 million for Renegade Therapeutics. That was a Series A. $270 million for Orbital Therapeutics was also a Series A. Just maybe one more, $273 million for ITM Isotope in Munich equity investment.

**Lee:** Last question for you. I want to talk about IPOs. How do we stand for the first half of the year and what are the biggest ones so far?

**Karen:** As for IPOs, like I said earlier, they are scarce. There were only seven biopharma companies that went public in the second quarter, but that was more than the previous quarter, which had six. Together, those 13 IPOs raised $1.46 billion. The lowest amount since 2016. The significant slowdown may be in response-- The sector was very overzealous in 2020 and 2021. Then there's other issues that are holding back IPOs across all industries, issues with the economy and geopolitical pressures. That may be what's happening there.

In terms of the biggest IPO so far this year, that would be the Acelyrin IPO in May, $621 million. It's the largest for the year and really the second largest to date behind Sana Biotechnology's IPO in February 2021. A number of the IPOs being completed now are fairly small, anywhere from $7 million to $20 million. Just to make note, we did just have one bigger one in July, Apogee's $345 million IPO.

**Lee:** Great. Thanks, Karen. Karen writes regularly about deals in BioWorld, and there's tons of detail in those stories. Thank you for doing that, and thanks for joining us today. We also have Mike Ward with us. Mike is in the UK, and I want to ask him about the UK and Brexit. It's been a while. A little bit of time has passed. We have a little better idea of how things are shaking out. Before we get to that, I wanted to ask you, Mike, why do you think there's been a rise in these billion-dollar mega deals?

**Mike Ward:** I think that one of the issues is that pharmaceutical companies, quite a lot of them are facing patent cliffs of some of their blockbuster drugs. Therefore, they have to grow. They've grown very big in recent years, so there's a lot of revenue that needs to replace. You're seeing companies either trying to get access to late-stage assets that are going to feed that revenue pipeline as quickly as possible. Unfortunately, there aren't that many of those late-stage assets around, they've basically been dealed out. The other thing we're also seeing, and some of the big deals that Karen mentioned around accessing key technologies that are going to be the platform or the launchpad for the big blockbuster drugs in the next decade or so, so, around antibody-drug conjugates or RNA technologies, or cell and gene therapy.

We're seeing that what's actually happened is that you're getting companies who think, "Oh wait, we need a piece of that action." Or it might be in areas where actually they don't know very much, so, around artificial intelligence and machine learning, where the skills required aren't necessarily ones that would have been expected within pharmaceutical companies. We've seen some deals around that space as well where these companies are looking to ensure that they've got access to these key technologies.

**Lee:** Yes, AI is a huge subject, and I wonder just how much of an impact is it that you're seeing?

**Mike:** I think the issue is that people are actually trying to work out exactly what artificial intelligence, machine learning, how it's actually going to deliver. We've seen some molecules, some candidates now in clinical trials. I think in silicon medicine is probably one of the ones that's in the lead. It's one of those issues that there's almost a fear of missing out, so that people want to make sure that they've at least got some skin in the game. Exactly how it's all going to pan out, I think we're going to find out over the next few years.

**Lee:** FOMO in biotech, I guess that's a thing now.

**Mike:** Yes. I think it's always been there, certainly was with the venture capitalists.

**Lee:** Talk to me a little bit about the UK post-Brexit, how things are happening. It's been a while now, and the landscape does seem a little bit clearer, but I'd like to have your take.

**Mike:** Yes. It's, prior to the Brexit referendum, there was a lot of concern within the life sciences sector that if the UK was to leave the European Union, it would suffer, it wouldn't prosper. That was around access to talent, access to capital, participation in things like the European Commission research programs like Horizon Europe. Some of those things haven't quite been resolved. Some of them, the UK has actually managed to pivot to put itself into a reasonably better position. For instance, there has been a problem with talent. A lot of the biotech companies here in the UK, actually they did have people from all over the globe, and particularly, for Europe, it was a lot easier for them to come in.

Many of them have gone back to their home countries. It is difficult for companies to encourage people to come to the UK in the way it'd been before. There's also the issue around financing. Now, the UK has always taken the lion's share or one of the biggest shares of the European investment cut. British companies would do pretty well getting financed by European venture capitalists. Many of these European venture capitalists are that their funds were cornerstoned by the European Investment Fund, which is a European Commission vehicle, which is there to encourage entrepreneurial activity but actually has, as a key objective, to grow business and the economies in the European Union.

Once you're outside the European Union, then you won't qualify for that. Therefore, that has been a bit of an issue because all of a sudden there are a lot of companies, a lot of venture capitalists who, in the past, would've been bankrolling. UK-based companies are unable to do so. We have seen, obviously, the creation of some British funds, and also we've seen American investors coming in, and actually now, or we're seeing British companies going and pitching much more to the US venture capitalists. That's obviously a big challenge because there's a lot more talent, a lot more interesting opportunities for those venture capitalists to invest in, in the US, than it would be necessarily in Europe.

Interestingly, if we actually look at the numbers, the UK is actually sourced at the venture capital front, has actually been pretty rock steady, has still maintained its preeminent position in terms of all the other European countries, and in global terms, is at the third or fourth-largest cluster when it comes to raising venture capital. What we've seen is there was a drop-off straight after Brexit, but actually it's beginning to pick up. Whether it's statistically significant in that pickup, we'll have to wait and see. I'm obviously discounting '21 and '22 because those years, it was just for the whole global biotech sector, that was a phenomenal amount of money that was raised.

Taking those two out, the pandemic years out, we actually looked at the UK, the investment at the venture capital front is steady. The challenge, though, is IPOs and also follow-on activity. What we're seeing is that the UK companies are looking further afield. They're looking to NASDAQ if they want to raise money. UK companies have struggled to access the capital you need to grow critical mass but the future actually might improve on that front.

**Lee:** Some companies have had to reinvent themselves and adapt to the new landscape and how Complement Therapeutics is one of them. Can you speak to me a little bit about that and what they've done?

**Mike:** Yes, what's happened is that to access these funds associated with the European Union, biotech companies in the UK have got to have a real active subsidiary. In fact, what happens is someone like Complement Therapeutics, which originally was underpinned by science from the University of Manchester in the UK, it actually upstakes the investment. The Series A, it was a €72 million investment, Series A earlier this year. It was, I think Gimv which is a Belgian VC, they were the lead investors. Complement, what they did was they actually reestablished themselves as a German company in Munich.

Now, one of the things that I've been using BioWorld data, I've been working with the UK Bioindustry Association just to benchmark how's the UK doing against all these various other clusters. It breaks their heart when they see that a company that was a UK company has now switched to Germany. Therefore, now Germany has got a €72 million Series A and the UK doesn't.

**Lee:** Mike, thank you for your insight. I greatly appreciate you joining us. I want to ask you, did you have any questions you wanted to ask Karen before we hand back to Lynn.

**Mike:** There was a recent announcement where pension funds in the UK will actually almost be forced to assign at least 5% of their funds to unlisted investments, all of which biotechs would obviously be a really, really great place to do it. The question I actually had for Karen, and it's one of the things that I noticed around this for the financings is that in recent years, we've seen a lot of activity in Asia Pacific, particularly in mainland China, but this year that's almost seems to have evaporated. I just wondered whether the geopolitical tensions that she mentioned earlier on, whether that was it, or there was something else going on.

**Karen:** I just really have noticed it overall globally. I've not noticed it specific to the Asian region. IPOs, for instance, we had three companies that went public. Remember I said there were only seven IPOs in the second quarter. Three of them went public on the Hong Kong Stock Exchange.

**Mike:** Yes, they were tiny though, weren't they? I know one was quite big.

**Karen:** I was going to say the largest was Laekna. That was $101 million. Yes, they're not $500 million and up like they were a few years ago. That's for sure.

**Mike:** No, but it's just VC stuff, and also, the other thing is though, and I don't think we've necessarily seen it yet, but conversations I've had with people like Zai Lab, other Chinese companies, what they've said is that they're now looking at Europe to do the deal. They've set up headquarters in Basel, which is obviously no surprise there, given it's probably one of the biggest hotspots for life sciences in Europe. I wonder whether, again, because of the geopolitical issues, that the focus is going to be elsewhere. That was all I was thinking.

**Karen:** Yes, I wouldn't be surprised if it is. If I really dug into it, I'd probably see a big difference compared to 10 years ago when there was so much investment coming out of China for biopharma, but yes, absolutely. Maybe I've not seen it with the IPO markets, but maybe in other investments, there is a downslide.

**Lee:** Great. Thank you. Mike, thank you for joining us. Thanks for your insight. Karen, you also, thank you both for not only this podcast but for your contributions to BioWorld. I look forward to seeing how the rest of the year goes. Lynn, back to you.

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**Lynn:** Thank you, everyone. That's our show for today. As always, BioWorld will continue to keep you informed of all the most important scientific, clinical, and business updates. if you need to track the development of drugs, turn to bioworld.com. Follow us on Twitter, or email us directly@newsdeskatbioworld.com. Also, if you're enjoying this podcast, don't forget to subscribe. Thanks for joining us.

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