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Amid Broader Market Pressures, Dx M&A Deals See Downturn in First Half of 2022

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NEW YORK – After two years of increased attention led to more merger and acquisition activity in the *in vitro* diagnostics market, a lull has hit in 2022 thanks in part to widespread macroeconomic issues.

Rising federal interest rates and inflation, the fallout of the ongoing invasion of Ukraine by Russia, along with a slowdown in COVID-19 testing have contributed to the decrease in deals, according to industry experts.

In the first six months of 2021, there were 39 total M&A deals; so far this year, there have been 34. While not a significant decrease in volume, the size of the deals has changed – in the first half of 2021, two deals topped out at over $1 billion, whereas in 2022 no deal has reached $650 million. The largest acquisition in H1 2022 was the $623 million deal struck by Sema4 to acquire GeneDx, followed by BioMérieux's purchase of Specific Diagnostics for about $416.8 million. (Earlier this week, however, SD Biosensor announced it would acquire Meridian Bioscience for $1.53 billion.)

Rounding out the top five priciest deals in the first half 2022 are, Maravai LifeSciences' purchase of MyChem for at least $240 million, Exact Sciences' $190 million deal for PreventionGenetics, and Fulgent Genetics' acquisition of Inform Diagnostics for $170 million.

Although not a full acquisition, LabCorp also spent $400 million in a deal to manage health system Ascension's hospital-based lab system and acquire some of its outreach business.

Compared to the many massive deals in 2021, such as Illumina's $8 billion buy of Grail, Roche's $1.8 billion deal to acquire GenMark, and DiaSorin's $1.8 billion purchase of Luminex, the drop off is stunning.

According to industry experts, there are a multitude of reasons for the decline, but macro trends have taken a real toll in the past few months. Brandon Couillard, an analyst at Jefferies, said that the industry has "seen a big shift in risk appetite" due to the current interest rate cycle, leading to a decline in investor interest when it comes to earlier-stage companies that aren't yet profitable. In light of macroeconomic conditions, many companies have switched their focus from M&A to conserving cash, he said. Right now, there's a lack of clarity surrounding the interest rate cycle that has led to uncertainty and an unwillingness to take risks.

Changes in the diagnostic industry more specifically are also affecting deals, he said. As demand for SARS-CoV-2 testing has slowed, and the federal government has declined to fund further testing, there is "very little appetite" for COVID-19-centric companies. These companies need to pivot and be able to "articulate a menu pipeline" for their platforms beyond COVID-19, especially for companies that placed a lot of instruments during the pandemic – they have to prove they can stick around post-COVID, he said.

The downturn in M&A interest doesn't seem to be changing any time soon, Couillard said. Public companies that are forward-leaning on M&A are "few and far between," although he noted that traditional diagnostic players – such as Roche and Bio-Rad Laboratories – are always looking for potential acquisitions. Myriad Genetics could also be an acquirer after cleaning up its balance sheet by selling its Myriad RBM pharma research services business, its myPath Melanoma laboratory and test, and its autoimmune business last year, he said.

Meanwhile, other diagnostics platform vendors, such as Qiagen, PerkinElmer, and Thermo Fisher Scientific, all of which have been aggressive in the M&A market in recent years, were mostly quiet in the first half of 2022. And Quidel spent its COVID-19 test sales windfall on its $6 billion acquisition of Ortho Clinical Diagnostics late in 2021.

Diagnostic industry consultant Harry Glorikian seconded Couillard's assessment of the space, noting that "things have sort of cooled off" in the market. "I'm not seeing guns blazing," in terms of M&A, he said.

The uncertainty in the broader markets has led people to "take a step back and evaluate" before jumping into a deal. They "don't want to catch a falling knife," said Glorikian. As diagnostic companies' valuations continue to drop from the record highs seen in 2020 and 2021, investors and acquirers are being cautious about potential deals. "Why would you want to execute a deal today that you might be able to get a slightly better deal on tomorrow?"

Challenging macroeconomic factors don't mean deals aren't going to happen, but they likely won't be "happening at a fast and furious pace," he said.

Strategy is the "biggest motivator" for both acquirers and companies looking to get acquired – the deal has to move the needle for both firms in some way – but Glorikian said negotiating deal terms could be a sticking point, as some companies may feel they're worth more than an acquirer is willing to pay. "Not that long ago, everybody thought their company was worth a lot more than it is today," he said.

An ideal acquisition target in this climate is a company that has revenues rising or is profitable, has at least one product doing well, and is working with a robust pipeline of future products, Glorikian said. It must also broaden the acquirer's portfolio or provide some "strategic advantage," and those companies "don't fall off a log."

However, in the next six to nine months, M&A activity could see an uptick as more companies might need to make a deal to survive, leading acquirers to take the opportunity to snatch up a company and go through less "push and pull" in the negotiation process. Specifically, Glorikian cited Cue Health as a potential acquisition target. The firm has seen a swift drop in its share price since going public last September and recently laid off 170 staffers due to economic challenges and a decline in funding for COVID-19 testing. Upon its debut, the company opened on the Nasdaq at $16.00 per share and immediately climbed to $20 that day, valuing the firm at around $2.9 billion. At the close of the market on Thursday, the firm traded at $3.56 per share, giving it a market cap of around $525 million.

Cue Health, as well as many other companies that have gone public or gained prominence over the past two years, is focused on point-of-care and at-home technology. Glorikian, however, is hesitant about the long-term potential of testing "closer to the individual."

"I'm having a hard time seeing that really taking hold the way that people have said that it will," partly because a lot of questions have to be answered before a company can be successful in the space. Some of those questions include whether a platform or test will be cleared for home use by a regulatory body, how often the test or instrument will be used, whether there's an opportunity to put it in a retail setting, and what the platform's next test after SARS-CoV-2 will be.

As the COVID-19 pandemic wanes, the need to test for diseases at home "just isn't there on a regular basis, unless you're in a mini clinic or something where there's just a flow of people," he said. "I'm not saying that it doesn't make sense in some situations," but most people could go to a pharmacy or other retail setting to get tested instead of purchasing an at-home instrument, he added.

In contrast, Craig Steger, director of life sciences at investment bank Outcome Capital, said that COVID-19 has changed the diagnostic market and "how we will potentially practice some medicine," moving it closer to the patient and leading larger players to be more aggressive in the point-of-care testing space. They're looking for innovative technologies with turnaround times that mean you "never lose the patient" – someone can be diagnosed and treated all in the same visit.

But Steger emphasized that companies must prove themselves beyond COVID-19, particularly as the US Food and Drug Administration has slowed down on providing Emergency Use Authorizations for SARS-CoV-2 tests and government funding is drying up. Companies now have to be prepared to go through full clinical trials for regulatory approvals and "show that they can have multiple offerings on the same platform."

Inflated sales and revenues from COVID-19 will go away, so firms have to know "what's next to support all of that … infrastructure" and overhead accumulated during the pandemic to manufacture large volumes of tests. Diagnostic companies will need to show that they can commercialize their products and receive regulatory approval before investors and acquirers are willing to buy in, he said.

Beyond SARS-CoV-2

Outside of COVID-19, interest remains focused on sequencing, liquid biopsy, and early cancer detection, Jefferies' Couillard said. Liquid biopsy and its use in early cancer detection remains the most promising area and "could be by far the biggest diagnostics market ever." Many firms are still a few years away from being able to commercialize their tests, but if and when those assays come to fruition the market could expand significantly.

Julia Qin, an analyst at JP Morgan who covers the liquid biopsy and sequencing markets, also emphasized that there is expanding market potential for liquid biopsy – particularly for recurrence monitoring and cancer screening – but said that because of current market conditions, investors are being more selective within that space. There are already established players in the field, such as Guardant Health and Exact Sciences, so it's "tougher for new companies to join the party."

Certain liquid biopsy use cases may have an easier time cutting through the clutter, she noted. Many companies are already tackling large indications like lung and colorectal cancer, so it can be harder to make an impact in those diseases. Companies focusing on a less common cancer, such as pancreatic or ovarian cancer, may face less competition and be able to stand out from the crowd. "It's not about the size of the opportunity," she said. "It's about the unmet need."

Sequencing is also seeing a similar dynamic – 2022 has been a record year in terms of new instrument announcements and launches, so there's "a lot of competitive noise." Although there are new players bringing differentiated technologies and value propositions, it "will take some time to build market validation and traction."

Applying some of these technologies to other indications, such as autoimmune and neurological disorders, could also help companies stand out in a crowded market, Outcome Capital's Steger said. He specifically mentioned Synaps Dx, a company that has developed a test to differentiate between Alzheimer's disease and other forms of dementia, as a potential acquisition target in the next year because it is already marketing and launching its flagship test.

Regardless of when broader market pressures are resolved or which technologies see the most uptake in the coming months, Steger said "the whole idea of the promise of precision medicine is still there."

H1 2022 Top 5 M&A Deals in Diagnostics

Buyer	Seller	Price
Sema4	GeneDx	$623M
BioMérieux	Specific Diagnostics	$416.8M
Maravai LifeSciences	MyChem	$240M
Exact Sciences	PreventionGenetics	$190M
Fulgent Genetics	Inform Diagnostics	$170M

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