

Dx M&A Market Remains Stagnant in H1 2024

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MultiplAI for \$340 million.





NEW YORK - Macroeconomic uncertainty, confusion surrounding the diagnostic regulatory landscape, and the continuing post-COVID-19 pandemic hangover have all contributed to a stagnant, quiet period for mergers and acquisitions in the in vitro diagnostics space in the first half of 2024.



The next highest deal was South Korean firm Lunit's A\$292 million (US\$194 million) acquisition of Volpara Health Technologies, which was announced in December but completed in May. Rounding out the deals that topped \$100 million is Quest Diagnostics' purchase of Brooklyn-based Lenco Diagnostics Laboratories for \$111 million. While there were other large deals that took place, such as Laboratory Corporation of America's purchases of BioReference Laboratories' and Invitae's assets for \$237.5 million and \$239 million, respectively, those were not full-company acquisitions and haven't been included in 360Dx's final tally.

The size of the deals also reflects the general hesitance permeating the diagnostics industry's M&A market, as investors remain risk-averse and await more certainty on macroeconomic considerations like the US presidential election and the impact of the US Food and Drug Administration's final rule to regulate laboratory-developed tests.

According to Kyle Mikson, an analyst at Canaccord Genuity, the general uncertainty surrounding the diagnostics space has resulted in a limited number of buyers willing to "pay a premium for growth markets," such as spatial biology or proteomics. There simply hasn't been "a lot of heroic, aggressive M&A in the first half of the year," he said.

Some large companies, such as Thermo Fisher Scientific and Danaher, may be looking to "dip their toe" into markets they don't already have a presence in, like spatial biology, but overall Mikson said he believes the market is in a lull right now in terms of acquisition interest.

Companies that were once potentially seen as high growth and sexy are not as attractive to public investors or big acquirers as before, Mikson noted, and firms looking to make acquisitions are likely seeking profitable companies that have stable businesses already and aren't as much of a risk, such as



Luke Sergott, an analyst at Barclays, noted that for big acquirers, it is cheaper to buy new technology that comes out in smaller deals, a strategy that likely hasn't changed.

The "massive" initial public offering boom in 2020 and 2021 caused many companies to go public whereas in other years they might have been acquisition targets. There were a lot of earlier-stage companies that "needed time to mature," Sergott said, but instead went public, and those companies have faced difficulties since their IPOs, with some — like Cue Health — going bankrupt.

Consolidators are now taking a step back and being more opportunistic, monitoring the space but not pulling the trigger yet. Meanwhile, the largest players in the IVD space are likely waiting to see which companies are most profitable and successful before making a purchase.

One technology space that has attracted interest in the diagnostics space is liquid biopsy, and the recent FDA advisory committee's <u>endorsement</u> of Guardant Health's blood-based early detection test for colorectal cancer could increase interest in that market and make the space more "legitimate" to investors, Mikson said.

Sergott added that there will always be demand for anything using liquid biopsy, particularly for therapy selection. One driver of growth will be more therapeutics receiving regulatory approval with companion diagnostics, and as the space grows, more companies that offer liquid biopsy solutions may become acquisition targets.

In terms of disease indications, cancer, rare diseases, and neurology are areas of particular interest, he noted.

Sergott also emphasized the importance of the upcoming US presidential election and its impact on deal-making in the diagnostics industry. There has been "increased scrutiny" on large M&A deals from the US Federal Trade Commission, and many acquirers may prefer to wait to see how the election will turn out — and the potential impact it will have on the FTC — before pulling the trigger.

For example, heavy scrutiny from regulators led to the dissolution of one of the biggest deals of the past few years in the diagnostics industry: Illumina's <u>\$8 billion purchase</u> of Grail, which was first announced in 2020. After nearly four years of debate and legal battles with <u>the FTC</u> and the <u>European Commission</u>, Illumina officially completed its divestment of Grail last week.

Sergott added that he expects the industry will continue to see bolt-on deals throughout the year, but that he'd be relatively surprised if any bigger deals come through.

Beyond the macroeconomic concerns, there are also industry-specific concerns, namely, the recent LDT ruling from the FDA. Oded Ben-Joseph, managing partner at Outcome Capital, said the LDT regulations have caused a "level of angst in the industry" as stakeholders are concerned that the ruling will delay patient access to new and innovative diagnostics.

In addition, the impact of the COVID-19 pandemic continues to be felt in the industry. The "irrational exuberance" for diagnostic technology firms that pervaded the pandemic as valuations skyrocketed and deals flew off the shelf has come to a standstill, he said.

Even before the pandemic, smaller deals, such as asset purchases and licensing agreements were trending up in the diagnostics market. Since COVID-19 became a household word, said Craig Steger, managing director of life sciences at Outcome Capital, the "junk in the system" that was left over as the pandemic waned, such as small companies that weren't ready to go public, has helped encourage the larger trend of asset sales instead of full-company deals.

Some of those asset sales are the result of bankruptcy: Labcorp purchased Invitae's assets after the firm went bankrupt, and in January, Roche <u>purchased</u> LumiraDx's assets in a bankruptcy auction. Other firms, such as <u>Cue Health</u> and <u>DermTech</u>, have recently gone bankrupt and put their assets up for sale, as well.

Asset sales make sense for a large company because many large companies don't want to take on the responsibility and liability for an entire firm, Steger said.

However, as the "noise starts settling," he added, there is still an opportunity for well-managed companies to get acquired in a deal that makes sense financially and technologically, and some deals may get done if companies have solid regulatory and marketing strategies.

One key area of interest that Steger and Ben-Joseph mentioned is precision medicine beyond cancer, such as in the autoimmune and neurology spaces. The market is realizing the value of therapy selection assays and seeking out companies that offer those tests, Steger said. Platform companies, in contrast, often aren't differentiated enough and need to prove they have stable, consistent revenue before seeing interest.

That does not include COVID-19 test development firms. Even if a company does have solid revenue, if that cash flow comes from COVID-19 it may not be worth much, Ben-Joseph said. Many firms that once capitalized and flourished on testing for the SARS-CoV-2 virus have <u>since struggled</u> as the COVID wave subsided.

Many investors now are discounting or ignoring COVID-19 revenue when looking at certain companies because it is not sustainable and is inconsistent, Steger said.

The general consensus is that, at least for the rest of 2024, the deal volume and cadence seen in the first half of the year will remain the same. Asset deals will continue as companies remain defensive and unwilling to go out on the ledge on unproven or uncertain firms, but larger mergers or acquisitions will likely fall by the wayside until there is more clarity around the macroeconomic environment.

"Nobody's going to do anything until we have a clear sense of what normalized growth looks like and what the recovery looks like in all the key end markets," Sergott said. "There's just no visibility right now."

Top 3 Dx M&A Deals in H1 2024

| Buyer | Seller | Price |
|-------------------|--------------------------------|---------|
| OmnigenicsAl | MultiplAl | \$340M |
| Lunit | Volpara Health Technologies | A\$292M |
| Quest Diagnostics | Lenco Diagnostics Laboratories | \$111M |

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