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Public, Private Dx Financing Wanes as Post-Pandemic Diagnostics Landscape Changes

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NEW YORK – After two years of basking in the spotlight and money flowing into the industry as a result of the COVID-19 pandemic, financing for diagnostics companies has largely withered in 2022.

Funding in the diagnostics industry has long lagged behind other areas of healthcare investment, such as vaccines and therapeutics development, but the COVID-19 pandemic changed the game – at least temporarily.

2020 and 2021 saw an influx of interest in the space, leading to a boom in initial public offerings and mergers and acquisitions, as well as significant funding rounds for companies big and small. But as COVID-19 testing has declined and general investor attention has returned to more traditional industries, the financing environment for diagnostics has stagnated in comparison.

In 2021, the window for IPOs in the diagnostics industry swung wide open with more than 19 companies going public or filing for an IPO throughout the year – in 2020, meantime, six firms went public. But in 2022, that number has declined significantly as only four firms have gone public or filed for an IPO, two of them – Lunit and Prenetics – outside the US. In addition, companies that went public during the IPO boom have faced challenges as stock prices have declined significantly and many are trading well below their IPO prices.

They include Talis Biomedical, LumiraDx, and Cue Health. Talis Biomedical went public in February 2021 with its stock priced at $16 per share, and as of Tuesday afternoon its stock price was $.49. LumiraDx, meantime, went public in September 2021 with stock priced at $9.94 – its shares were trading at $.97 on Tuesday afternoon. Cue Health also went public in September 2021 and its share price has dropped from $16 at the time of its IPO to $2.54.

The number of mergers and acquisitions have also decreased, although not quite to the same extent: in 2021, there were 70 M&A deals, compared to 54 in 2020, while this year there were 47 completed deals.

According to several experts there are several potential reasons the volume in deals volume has dried up: macroeconomic concerns such as rising interest rates and geopolitical uncertainty related to the war in Ukraine have had an impact, for example. They also cited hesitance on the part of investors due to changing valuations for many companies in light of the decline in COVID-19 testing.

Oded Ben-Joseph, managing director of Outcome Capital, noted that most investors are taking a defensive position as a result of "the systemic risk and high degree of uncertainty in the marketplace" right now and are pulling back on diagnostics, partially because of the changes in COVID-19 testing dynamics. "We have all these companies, particularly COVID-related companies that mushroomed during 2021," he said, but most of them are "sort of behind the curve."

The need for new COVID-19 technologies is "much diminished," compared to 2020, and while the virus is here to stay, the demand is much lower. As a result, many investors are "discounting pretty heavily any COVID-related companies or companies that generate revenues through COVID-19," he said.

A recent report from Silicon Valley Bank, bears out the reluctance that investors had in the healthtech industry, in general, in 2022. According to the report the number of investments greater than $100 million during the past year declined 40 percent year over year.

Craig Steger, a director at Outcome Capital, noted that 2020 and 2021 were outlier years and that the investment landscape is "reverting back to the normal of how investors are looking at diagnostics just as a whole to invest in." Compared to other healthcare investment areas, such as therapeutics, diagnostics have historically not had the same return on investments, making them the "ugly stepchild," he said, adding there's a "value difference" between treating a disease and diagnosing it, and insurers will pay more for a treatment than a diagnostic.

The lack of return for investors, combined with the other financial headwinds being felt, means that investors aren't putting new money into new companies, Steger said.

Ben-Joseph added that the diagnostics industry doesn't always support "sexy returns to investors" compared to a biotechnology company because clinical development is costly, there's a lot of competition within the space due to the low barrier to entry, and there's significant downward pricing pressure. According to his research, the average time for a molecular diagnostic company to exit is 18 years, so investors "probably are better off deploying capital elsewhere," he said.

The most important thing for an investor to see, particularly a venture capital investor, is how a company will make money – that often requires a lot of data and, in many cases, some type of regulatory clearance for the firm's technology, Ben-Joseph said. Regulatory clearance is "almost like a starting point" to garner investment for molecular diagnostic companies, he added.

One reason for that is because the molecular diagnostics marketplace is crowded and has relatively low barriers to entry, so companies have to be "fundamentally differentiated" to stand out from the crowd, he said, adding that differentiation should come in one of three areas: turnaround time, menu, or cost of goods.

Steger noted that early diagnostic companies, in particular, have to have a clear value proposition based on data that shows why the company is different and better than its peers, while regulatory clearances can provide some of that proof. Without a regulatory clearance, there has to be a high volume of data to back up the firm's claims.

By Outcome Capital's measure, about $5 billion went into diagnostic investments in 2019, a figure that number approximately doubled in 2021. Things have come full circle, however, and numbers are going back to pre-COVID levels, Ben-Joseph said. He foresees the entire industry pulling back – albeit with some exceptions – and many companies closing shop, as well as fewer new companies seeing the light of day.

Steger agreed and said he expects a lot of consolidation, with big diagnostics players waiting for prices to come down overall to consolidate multiple pieces of intellectual property and technologies.

Some areas of the industry may see more investment than others, Steger and Ben-Joseph said. Digital pathology, neurological and rare disorders, and "any place where technology can meet the lab work" will likely be of interest to investors even as overall funding declines, Steger said.

For Caroline Popper, founder of healthcare and life sciences consulting firm Popper and Company, there hasn't necessarily been a downturn in private financing, but rather an oversupply – there are so many opportunities to choose from that it's hard for a specific company to stand out to investors. That could lead to increasing interest in alternative funding sources, such as nonprofits, as companies that got started with COVID-19 search for their "second act."

Awards from organizations such as the Bill and Melinda Gates Foundation have long been a crucial source of funding for the healthcare sector, including newer, less established diagnostics developers. In an environment where other financing options may be available, the competition for such awards may become more heated. A recent report from FIND and Policy Cures Research noted that the Gates Foundation, for example, is one of the biggest funders of diagnostics R&D projects, along with the US NIH, the US Biomedical Advanced Research and Development Authority, and the European Commission. Among the projects the Gates Foundation has awarded in 2022 are $1.1 million to biocompatible semiconductor company Cardea Bio to develop infectious disease breath tests, $2 million to Sherlock Biosciences for a CRISPR-based instrument-free molecular diagnostics platform, which is on top of a prior grant of $5 million from 2020, and $14.2 million to LumiraDx to develop a point-of-care molecular tuberculosis test.

The Gates Foundation declined to comment citing scheduling constraints.

Meantime, the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) has also been busy this year, granting $1.7 million to Avails Medical to develop a rapid antibiotic susceptibility test device and $8.2 million to Day Zero Diagnostics for the firm's whole-genome sequencing and machine learning-based approach to antimicrobial resistance profiling.

Regardless of the source of funding, Popper also said that deal activity won't entirely go away – some companies that made a lot of money on the back of COVID-19 testing will be looking for acquisitions to fill the revenue gap now that COVID testing is declining. Private investors may also turn to areas with unmet needs that have nothing to do with COVID-19, such as oncology and brain diseases, where there are technologies available to generate new information.

Life sciences consultant Harry Glorikian also noted that funding hasn't died off completely but is "not necessarily happening in the same numbers" as investors are trying to be more selective. "Funding is down, but it's not down so much that … the floor has fallen out from under us, and the world is coming to an end."

Glorikian said that he "hasn't seen the downside" people have been predicting, noting that while the market has gotten leaner, things are getting funded and moving forward. He also said it'll take at least one more quarter to see if there's truly a downward trend in financing because we're at the point "right in between where things are changing." While "things are down," he said he has "a hard time seeing people sitting on the sidelines in the meantime."

Glorikian said that the key components any investor is looking for are technology and team – namely, whether the technology can make a big difference and whether the team can pull off its plan. Particularly for companies with a focus on at-home diagnostics, it's important to know what's next as COVID-19 declines – hopefully they've "loaded the gun with other bullets," he said.

Flush with government cash

The influx of government money during the pandemic has also played a role in shaping the current financing environment. For instance, in early 2020, the federal government announced the creation of the Rapid Acceleration of Diagnostics, or RADx, initiative, pouring $1.5 billion into the program and supporting more than 100 companies in their efforts to develop COVID-19 tests.

Popper said that the enormous amount of public funding that have gone into diagnostics development means that it has been harder for companies to make a case for private investment. If a firm already benefitted from millions of dollars of nondilutive government funding, no one is going to invest in its competitors who may not have the same leg up, she said.

That disproportionate injection of federal dollars, which provided a lifeline for some firms that previously had no or only marginal revenues, is likely to result in some companies falling away as the money recedes, she said.

Willo Brock, diagnostic nonprofit FIND's director of external affairs, said while there was an "enormous amount of money" that was fed into diagnostics from private and government sources during the height of the pandemic, that funding funnel has significantly dried up recently. The industry has "seen massive investment and interest" with everyone "understanding how essential the role of diagnostics is in the healthcare system much more than … before COVID-19," he said, but as COVID-19 rates have declined, governments are reprioritizing their funding.

That change is disheartening, Brock said. A year ago, he thought it was "almost impossible" to go back to the situation before the pandemic where investments were scarce, but some governments' healthcare R&D budgets have been cut to the levels of 2019 and before. Those cuts are widespread in the healthcare space, but for a diagnostics market that already sees such a small piece of the healthcare investment pie, the decrease can have a significant impact. When it comes to the government, "we see a situation that's not a whole lot better financially, investment speaking, than it was before."

Some governments are more proactive and willing to invest than others, but diagnostics are "often not the highest priority. Everyone hopes for the golden bullet of a vaccine," he added. Although the pandemic opened people's eyes to the role that diagnostics play in healthcare, there is still an overemphasis on vaccines. "If people get to choose … a vast majority of governments … will gamble on a vaccine."

Current strategies

Glorikian, the life sciences consultant, noted that the pandemic highlighted the importance of diagnostics and that there are opportunities available to invest, particularly from a federal perspective, but that on the private side, investment may have pulled back in recent months because "everybody wants to sort of understand where the economy is going" and investors can be more selective about where they put their money to work.

According to Mark Massaro, an analyst with BTIG, the IPO market is "pretty much shut" and the number of financings this year has materially declined. In the past year, almost every company in the space has pursued the "growth at any cost" strategy, but that mindset has "come to a screeching halt," he said. With rising interest rates, that strategy doesn't work, so companies are now "narrowing their focus on projects," initiating layoffs, minimizing acquisitions, and engaging in other cost cutting measures.

The new investor mandate is a focus on profitability, although most investors know that companies "cannot make that pivot overnight," he said. There is a "bit of a leash," but at the bare minimum investors are asking for profitability targets and goals. "It may not be feasible for a company to achieve profitability in 2023, but boy they better have a path and know how they're going to get there and roughly when they're going to get there," he said.

Despite the changes, Massaro said he's cautiously optimistic about 2023. In the second half of the year, depending on whether interest rates go down and inflation gets under control, he hopes to see a

pickup in investor sentiment in the space.

And in his view, many firms are better off now than when they started 2022, particularly in terms of reaching milestones, reimbursement decisions, and general momentum – that's just not being reflected in stock prices, he said, which is a stock market phenomenon rather than an industry one.

"The innovation we've seen in the diagnostics and life sciences tools space has continued to accelerate," he said.

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