DECEMBER 2021 | Vol. 8, No. 11

MedTech STRATEGIST

Challenges Continue for Renal Denervation Trials

Mary Thompson

The Controversy Over Decompression vs Fusion: What Data Tells Us

Wendy Diller

Moon Surgical: Driving Robotics Into High-Volume Surgery

David Cassak

Minerva Surgical's IPO: Outlier or Sign of Things to Come?

Mary Stuart

Diagnostic Financings Are Robust, Fueled by COVID-19 and Precision Medicine

Private investors poured more than $8 billion into diagnostics companies between January 2020 and September 30, 2021, envisioning myriad opportunities for innovative COVID-19 testing technologies and precision medicine tests that help optimize individual treatment regimens.

▶ **Wendy Diller**

Private investors deployed roughly $8.4 billion in capital into diagnostics from January 2020 through the first nine months of 2021, with preferences for companies tied to innovative COVID-19 testing technologies and tech-enabled precision medicine strategies around optimizing individual treatment regimens. The 116 financings in 2020 and another 95 through the first nine months of 2021 raised a total of $3.93 billion and $4.45 billion, respectively, according to an analysis by Outcome Capital LLC (see *Figure 1*). By comparison, investors deployed a total of $2.47 billion in 95 financings in 2019.

"The diagnostic company financing environment has been healthy, as evident from the steady number of transactions, supported by double the combined investment from 2019 to 2020," says Craig Steger, SVP, life sciences, Outcome Capital. While larger financings during the period tended to favor companies with artificial intelligence or other computational components to their strategies, the lack of a big-data driver was not a deal-breaker, and outlier oversized transactions did not skew the numbers, he adds. Digital pathology has also been attractive to the venture community, and it continues to draw interest. Leaders in this field, such as **PathAI Inc.** and **Paige**, each scored significant funding raises during 2020-2021.

Paige, which sells AI-based diagnostic software for pathology, received the first ever FDA *de novo* approval for a clinical-grade software assistance program, in this case for *Paige Prostate* for prostate cancer detection, in September 2021, having raised more than $125 million in a Series C round in March 2021, and roughly $70 million in a Series B round that closed in July 2020.

PathAI, which develops and sells AI-based pathology biomarkers, raised $165 million earlier this year.

A mid-year 2021 report on healthcare financing trends by Silicon Valley Bank also notes positive trends for private company financings in diagnostics. The healthy financing environment was reflected in the first half of 2021, as seven diagnostics companies—**Cue Health Inc.**, **Inflammatix Inc.**, PathAI, **Truvian**, **Sera Prognostics Inc.**, **binx health**, and **Delphi Diagnostics**—each raised more than $100 million, the report states. The highest-valued diagnostics/tools companies so far this year had a median 2.1x step-up, the report says.

Nor did investors ignore earlier-stage opportunities. Based on the Outcome Capital data, of the 211 investments between January 2020 and the end of September 2021, 178 raised $70 million or less, for a total of $3.7 billion. Raises in this group skewed toward the higher range, as investments of less than $12 million accounted for only 5%, or $445 million of total invested capital in the entire sector. Much smaller amounts supported early-stage companies that need financing to advance their products from proof of concept to development or clinical trials. The types of diagnostics offered by these companies range from point-of-care platforms to direct-to-consumer (DTC) to digital diagnostics focusing on treatment decisions for cancer patients, Steger adds.

The diagnostics industry's ability to maintain this robust market is challenged, however, by the limited exit opportunities available to investors in young companies. For now, the IPO window remains open, as reflected by the 10-15 companies that went public during the 2020-2021 period, with stock of most of these continuing to perform well. The lack of M&A activity in the sector, however, is problematic, as the large companies that are likely buyers of innovation prefer to invest in players with successful track records. "The specific segment around precision medicine has attracted a lot of money and interest, both from private and public investors, but the large diagnostics companies that are positioned to scale and innovation prefer to wait to see which will be successful in the market before jumping into it," notes Steger.

This is true for companies like Cue Health, which is successfully capitalizing on interest in at-home and DTC testing, a market that due to COVID-19 is undergoing a transformation in the wake of a more welcoming regulatory environment brought on by the ultra-cautious FDA's relaxation of certain standards for at-home nonprescription tests and influx of interest in innovating in this subsector of the industry. (*See "How COVID-19 Is Changing the Diagnostics Industry,"* MedTech Strategist, *February 23, 2021 and "What the NIH RADx Program Means for Rapid, At-Home Testing Beyond COVID-19,"* MedTech Strategist, *April 14, 2021.*)

In early 2021, Cue received FDA authorization for at-home, nonprescription use of its COVID-19 diagnostic, the first nonprescription at-home use for a molecular test. (In June 2020 it received Emergency Use Authorization [EUA] for the test for use in clinical and point-of-care settings.) Since the start of the pandemic, the company has flourished, in part supported by hundreds of millions of dollars of government orders; further, it raised $100 million in June 2020 and another $235 million in May 2021 from private investors, before its initial public offering in September, which netted $213.9 million, after underwriting fees. Cue has ambitions to expand use of its platform beyond COVID-19 testing to address multiple point-of-care needs.

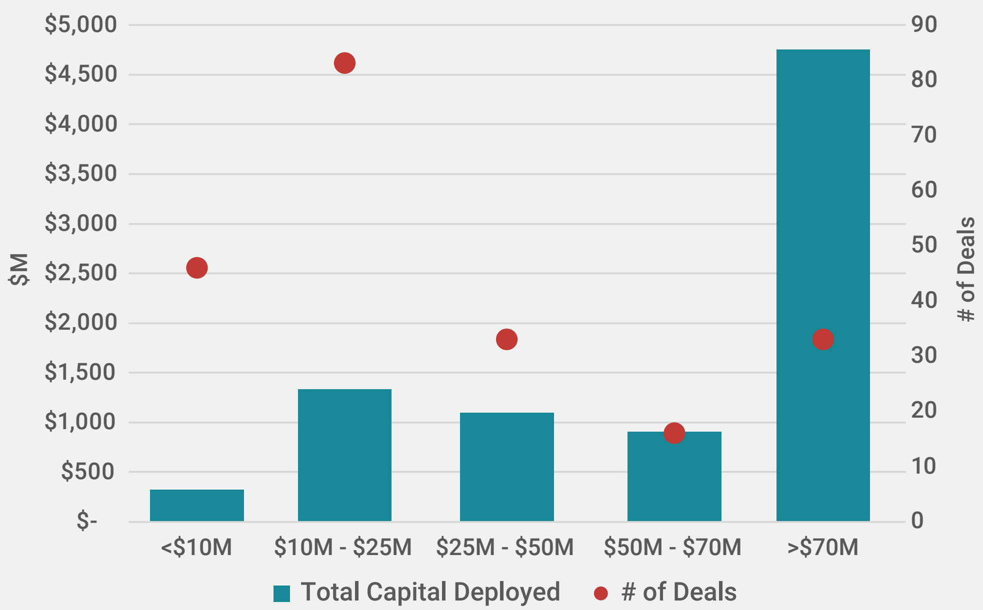
DTC testing remains on the edge of mainstream diagnostics testing for now, but the largest systems companies in the field are watching its evolution to learn which commercial models work best, says Steger. "The world has been changed by COVID-19, which is opening room for new players. For simple conditions, we may want to have the information DTC provides without going to a doctor's office, although

Figure 1

Diagnostics Financing Trends: Dollars Raised

Q1/2020-Q3/2021

Total Capital Deployed by Deal Range



Deal Range	# of Deals	Total Capital Deployed ($M)
<$10M	46	$321
$10M-$25M	83	$1,335
$25M-$50M	33	$1,101
$50M-$70M	16	$908
>$70M	33	$4,752

Source: Outcome Capital

we will need a doctor's prescription for medication."

Another COVID-19-related success is **Lumira Dx Ltd.**, which sells a point-of-care platform that runs a rapid COVID-19 test that has EUA for use in clinical and pharmacy retail settings. It went public via a special purpose acquisition company (SPAC) in April, listing on NASDAQ at a $3 billion valuation, after raising roughly $700 million in private funding from equity investors since its founding in 2014. The stock, however, was trading underwater as of mid-December. (*See "The FDA's Latest Initiative to Break the COVID-19 Rapid Diagnostics Bottleneck,"* Market Pathways, *April 2, 2021*.)

AI appeal also drove investors to **Sophia Genetics**, a developer of clinical decision support systems that enable more accurate diagnoses. The company completed an IPO in July that raised $234 million, in addition to a simultaneous $20 million private placement. The raise came after a $110 million private financing in October 2020.

Element Biosciences also raised significant sums, including a $276 million Series C in June 2021, which followed a $30 million Series B in June 2020. The company is developing a next-generation DNA sequencing platform that enhances the signal-to-noise ratio, which improves sequencing quality while lowering costs, innovations that will perhaps ultimately enable it to challenge market leader by far Illumina.

The seven-year-old developer of a multiomics liquid biopsy test for early cancer detection, **Freenome**, closed a $300 million Series D in December 2021 (this figure was not included in the cumulative totals mentioned in this article), which followed a $270 million raise in 2020, bringing the total value of its raises to date to more than $800 million. MTS

Posted on MyStrategist.com Dec. 15, 2021