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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Invitae To Lay Off 1,000+ Employees

The genetic testing company Invitae Corp. (San Francisco, CA) has announced plans to lay off more than 1,000 employees, or about one third of its total staff of 3,000, as part of a year-long restructuring plan. The company also intends to narrow the focus of its international operations to fewer than a dozen countries from more than 100 countries. The restructuring will cost Invitae up to $100 million—the hope is that it will lead to $326 million in annualized cash savings by 2023. "We're no longer chasing volume at all costs," said Ken Knight, CEO of Invitae, during a July 18 conference call with analysts. *Continued on page 8.*

Labcorp To Spin Off CRO Business

Labcorp has announced plans to spin off its Contract Research Organization (CRO) business to Labcorp shareholders through a tax-free transaction. The planned spin-off is expected to take place in the second half of 2023 and will result in two independent, publicly traded companies.

Labcorp originally entered the CRO business through the acquisition of Covance for $5.6 billion in 2015. Labcorp's CRO business provides Phase I-IV clinical trial management services to pharmaceutical and biotech companies. Over the 12 months ended June 30, 2022, the CRO business had revenue of $3 billion.
More details on page 9.

Monkeypox Cases May Be Vastly Undercounted

Based on CDC case counts, the current monkeypox outbreak in the U.S. doesn't look that bad. As of August 10, the CDC reports a total of 11,177 Monkeypox cases had been recorded since the initial case was identified in Massachusetts on May 18, 2022.

However, the official case count is misleading, according to Manoj Gandhi, MD, PhD, Senior Medical Director at Thermo Fisher Scientific. Gandhi thinks the number of unreported cases is bigger — probably much bigger — than the CDC case count suggests. "We're just seeing the tip of the iceberg," says Gandhi. The CDC is currently only reporting monkeypox cases on a weekly basis. The next case count will be announced on August 17.
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Monkeypox Cases May Be Vastly Undercounted (*cont'd from page 1*)

Thermo Fisher is manufacturing reagents that labs can use to develop their own laboratory-developed Monkeypox tests to run on QuantStudio 12K Flex PCR systems. LDT testing will augment the Monkeypox testing that is being performed by labs with access to CDC-developed kits, which are in limited supply.

Currently, the CDC-developed kits for Monkeypox testing are being used by 78 public health labs and five chosen commercial labs, including Aegis Sciences, Labcorp, Mayo Clinic Labs, Quest Diagnostics and Sonic Healthcare. Total combined capacity for public health and the five commercial labs is more than 60,000 Monkeypox tests per week.

In late July, the American Medical Association (AMA) issued a CPT code (87593) for molecular diagnostic testing that detects the monkeypox virus. A Medicare reimbursement rate has not been established yet for CPT 87593 and it is currently in the MolDx program for pricing, according to Lale White, Executive Chairman and CEO at XIFIN Inc. "Labs need to know Monkeypox tests are reimbursable, so they are encouraged to test," notes Thermo's Gandhi.

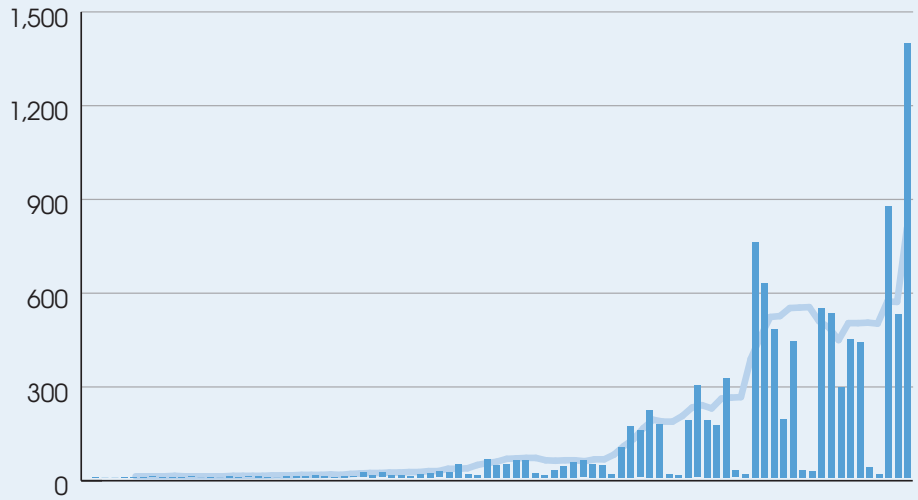
Test samples for Monkeypox are collected by swab from a patient's blister. People testing positive can be treated with the prescription drug tecovirimat, also called Tpoxx, which is in short supply. Most importantly, Gandhi says positive cases should isolate to prevent the spread. And family members and close contacts should get tested.

Monkeypox is usually a self-limited disease with the symptoms lasting from 2 to 4 weeks, according to the World Health Organization. However, severe cases can occur. There have been no reported deaths from Monkeypox to date in the United States.

Mako Medical Labs (Raleigh, NC) is one of the first independent labs to offer an LDT for Monkeypox. Mako went live with Monkeypox testing on July 18 on Thermo's QuantStudio, according to Matthew Tugwell, Director, Genomics at Mako.

Tugwell says Mako currently has the capacity to perform up to 30,000 Monkeypox tests per day. The majority of Mako's samples for monkeypox testing are coming from STD clinics. Patients getting tested for sexually transmitted diseases like herpes and syphilis are also being tested for Monkeypox. Positivity rates are currently averaging about 13%. So far, Tugwell says demand for Monkeypox testing has been low—probably because people are shying away from getting tested because of a perceived stigma associated with the disease.

Daily U.S. Monkeypox Cases (*May 18 throught August 10*)



Note: Chart shows cases of monkeypox confirmed by the CDC in the 50 states, Washington, DC, and Puerto Rico
Source: Centers for Disease Control and Prevention

So far, nearly all Monkeypox cases in the United States have been among gay and bisexual men. However, Tugwell notes, "We don't really know where this is going. It has the potential to infect anyone, regardless of gender, skin color or sexual preferences."

Spotlight Interview: OSU Wexner Medical Center's Anil Parwani

Anil Parwani, MD, PhD is Vice Chair and Director, Anatomic Pathology, Department of Pathology, The Ohio State University Wexner Medical Center (Columbus, OH). He joined OSU in 2015 and has led its transition to digital pathology for primary cancer diagnosis. Here's a summary of our interview:

Anil Parwani, MD, PhD

Can you describe OSU and its Pathology Department?
The OSU Pathology Department has a staff of 45 anatomic pathologists who serve seven OSU hospitals, including the flagship Wexner Medical Center (1,170 beds), as well as 100 affiliated clinics across Ohio. We also provide pathology services to three non-OSU hospitals. In total, we process approximately 95,000 patient cases per year.

When did OSU first start digitizing slides and what was the initial purpose?
We first started scanning in May 2017. Initially the focus was on scanning our archive of glass slides for education and research purposes. We now have about 12 years of slides scanned and manage one of the world's largest collections of whole slide images with 2.9 million digitized slides, representing almost 300,000 patients, and every imaginable tissue and disease type.

When did you start using digital pathology for primary cancer diagnosis?
We started in 2018 and within about one year, 50% of our glass slides for clinical diagnostics were being scanned and read digitally. Today, more than 90% of our primary diagnoses are read digitally. We are currently scanning an average of between 2,000 and 3,000 slides per day. The only exceptions are certain tissue samples that require high magnification, such as looking for micro-bacterial infections in lung biopsies and H. pylori in gastric biopsies. In addition, cytopathology smears are not scanned.

Which slide-scanners do you use?
We have a total of twelve high-speed scanners, including from Philips, Hamamatsu, Huron and Leica Aperio, at our histology lab and research lab. In addition, we are now scanning frozen sections in our hospital operating rooms using compact microscope scanners from Mikroscan and Grundium.

What are the biggest benefits your pathology department has received from going fully digital?
There are numerous benefits. One of the biggest is our pathologists don't have to travel to get to slides or wait for slides to get to them. Digital pathology has improved our average turnaround time by as much as 1-2 days.

It has also made consultations and second opinions easier. Our pathologists are more likely to seek out subspecialty expertise if it only requires a button click to send an image.

Our archive of digital images has also proven to be more valuable than we anticipated in terms of both teaching residents and industry partnerships.

Have you begun integrating AI algorithms into your process?
We have started to evaluate it with the goal of launching several AI algorithms and software solutions into practice later this year or early next year.

What advice would you give other pathology labs that are thinking about going fully digital?
Don't be put off by sticker shock. You will be surprised at how fast you recover your costs. In terms of direct costs, we reached breakeven in less than three years. And don't underestimate the benefits of a quicker more accurate diagnosis. When you over-diagnose, your practice winds up paying in some way, shape or form.

What's the biggest pitfall to avoid when implementing digital pathology?
For us, it was the need for better workflow planning. When we first started, our histology lab was small, at full capacity, and in a bad location. We couldn't place scanners there and this caused workflow problems.

However, in December 2019, we built our new histology lab with space to install high-speed scanners adjacent to the histology staining machines and cover slipping. Now our slides get scanned ASAP and entered into the database. We didn't start right, but we learned and became efficient.

How long before you think the majority of pathology slides in the U.S. will be digitized and read by computer monitor?
I've been too optimistic in the past, but I think we'll reach a majority within 5 to 10 years. The introduction of the new temporary add-on CPT codes for slide scanning are a great step forward. If reimbursement for slide scanning is established, then it's a no-brainer.

Theranos Whistleblowers Speak Out at AACC Meeting

Erika Cheung and Tyler Shultz—two of the key whistleblowers who helped expose Theranos—were interviewed by AACC President Stephen Master, MD, PhD, in a special fireside chat at the 2022 AACC Annual Scientific Meeting in Chicago on July 26.

After graduating from UC Berkeley with a B.S. degree in molecular and cell biology, Cheung went to work in the Theranos laboratory from October 2013 to April 2014. Stanford biology graduate Shultz was a research engineer at Theranos from September 2013 to April 2014. Both had hands-on experience with Theranos's Edison miniature analyzer, which was touted as a revolutionary invention capable of testing hundreds of analytes from a fingerstick blood sample.

Theranos's technology was ultimately found to be completely unreliable and the company was dissolved in 2018. Founder and former CEO, Elizabeth Holmes, was recently found guilty of four of 11 charges of fraud by a California jury. In addition, former Theranos President and Chief Operating Officer Sunny Balwani was found guilty on all 12 criminal-fraud charges. Sentencing is expected later this year.

Below we highlight insights provided by Cheung and Shultz.

The First Indication that Something was Wrong
Cheung was involved with validating LDT tests run on Theranos's Edison analyzer for launch into clinical settings. "I think about a month in of working for the company, I started to notice things that were wrong….Theranos was trying to construct all the validation studies for these Edison devices, and I think the most concerning thing for me especially was there was a lot of cherry picking of data." For example, Cheung said that if the accuracy of a PSA test was not up to par, outlier test results would be deleted until the correct reference range was met.

After Theranos started patient testing using Edison analyzers, quality controls were sometimes failing twice a day, between morning shift and night shift, according to Cheung. When she brought her concerns to Balwani, she was told "You need to do the job I pay you to do, which is to process patient samples without question."

Shultz said that he was on the team validating a syphilis test. "We recruited our colleagues and landlords to give blood and well over 20% of us tested positive for syphilis….We had known positive samples that tested negative, and negative samples that tested positive….We sent this data to the statistics team, and miraculously, it came back [as validated]….And Theranos started testing for syphilis on

real patients…. That moment, I felt like I'd been punched in the stomach because I knew that patients were going to get hurt by this test."

Why didn't more Theranos Employees Raise Red Flags?
Cheung said there was an "extreme culture of fear and secrecy" at Theranos. The company made all its employees sign non-disclosure agreements (NDAs). They used the threat of enforcing NDAs to silence employees, "not because they were scared of competitors, but because they were scared of their employees talking to other employees. A big red flag. That's not what an NDA is for."

Cheung said that Theranos employees who were disturbed by the company's practices would quit and keep their mouths closed. "There was extremely high turnover. The HR people were like, 'I don't even know what to do, every time I hire 10 people, 10 people leave.' So, there was no continuity in terms of people even understanding the whole situation."

Followed by Private Investigators
Theranos hired private investigators to follow Cheung and Tyler 24-7 after they resigned. "The scary thing about being followed is that they didn't actually care who I was having lunch with, where I was going to work out, or whatever. They just wanted me to know I was being followed. They followed us as a fear tactic to show they had power over us," said Shultz.

The Theranos Board
The Theranos board was packed with retired generals and politicians, including former Secretary of State Henry Kissinger, former Defense Secretary William Perry, former Senator Sam Nunn and former U.S. Secretary of State George Shultz (grandfather of Tyler Shultz). "The board was full of these old men who just fawned over her [Holmes], who treated her like the prettiest girl on the playground more than a CEO," said Tyler Shultz.

Lack of Due Diligence from Private Investors
Theranos was valued at $9 billion at its peak in June 2014.

"One of the most astounding things about this story is that she [Holmes] was able to raise almost a billion dollars in capital without an investor ever seeing an audited financial statement. She just preyed on people who would not ask those types of questions," said Shultz.

The Walton family, heirs of Walmart founder Sam Walton, lost a total of $150 million on Theranos. Other big investors included Rupert Murdoch, Executive Chairman of 21st Century Fox, who lost $100 million, and Betsy DeVos, former U.S. Education Secretary, who also lost $100 million. In addition, the Cox family, which controls Cox Enterprises, a media, telecom, and automotive conglomerate, lost $100 million.

The need for LDT regulation?
"I do think that the laboratory developed LDT loophole that Theranos exploited should be closed. And I don't really see a reason to test for vitamin D or B12 or HIV on a laboratory-developed test, an unproven device like Theranos's, when there are readily available FDA-cleared products that do exactly that," said Shultz.

Cheung said that FDA regulation might have stopped Theranos. "But Theranos was a very, very special case. You're dealing with people who are going to lie to basically win at all costs. It doesn't matter what rules you have or what laws you have. They were going to break them."

DOJ Crackdown on Genetic Testing Telefraud

In a continuing effort targeting fraudulent telemedicine arrangements, the U.S. Department of Justice has charged two lab owners with schemes to defraud Medicare by billing unnecessary tests, including cardiovascular and cancer genetic tests. The charges are part of a nationwide enforcement action in which dozens are being charged with $1.2 billion in Medicare fraud.

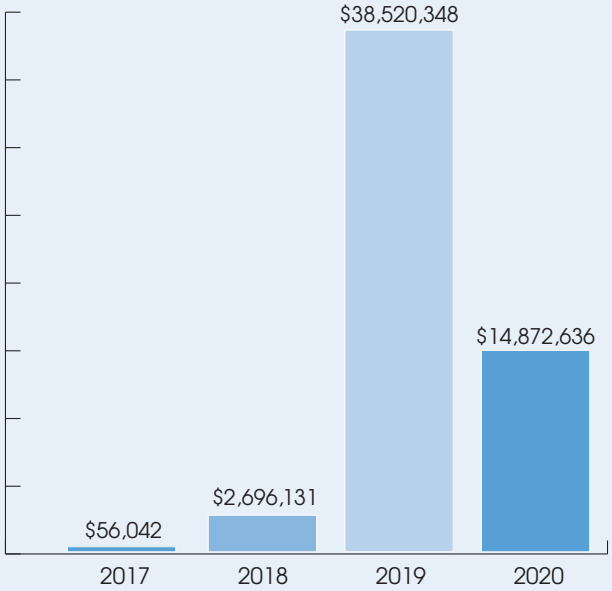
The federal investigations, announced July 20, 2022, targeted schemes involving the payment of illegal kickbacks and bribes by lab owners in exchange for the referral of patients by fraudulent telemedicine companies. Basically, the labs would contract with telemarketing call centers that would call Medicare beneficiaries, sometime multiple times per day, with the promise of "no-cost" genetic screening tests to determine risk of cancer or heart disease. The telemarketers would obtain beneficiary medical information and then pay telemedicine doctors to electronically sign off on lab test orders.

These charges include some of the first prosecutions in the nation related to fraudulent cardiovascular genetic testing, a burgeoning scheme, according to DOJ. The DOJ says that cardiovascular genetic testing is not approved by Medicare for use as a general screening test for determining increased risk of developing cardiovascular conditions.

McNamara's Labs

In one case, defendant Jamie McNamara, 47, acquired a group of small independent labs in Texas and Louisiana, including LPS Toxicology Labs (dba Clarity Diagnostic Labs), S&A Sleep Solutions (dba Mercury Laboratory Services), Opteo Laboratory and Signify Laboratory. As alleged in court documents, orders for cardiovascular and cancer genetic tests were used by the defendant and others to submit more than $174 million in false and fraudulent claims to Medicare between November 2018 and July 2020. Of these submitted claims, Medicare reimbursed the McNamara's labs over $55 million. The indictment seeks forfeiture of more than $7 million in cash, three homes in Missouri, a yacht, a Tesla and other vehicles.

McNamara's Labs: Medicare Allowed Payments*



*Includes total Medicare Part B allowed amounts for LPS Toxicology, S&A Sleep Solutions, Opteo Laboratory and Signify Laboratory

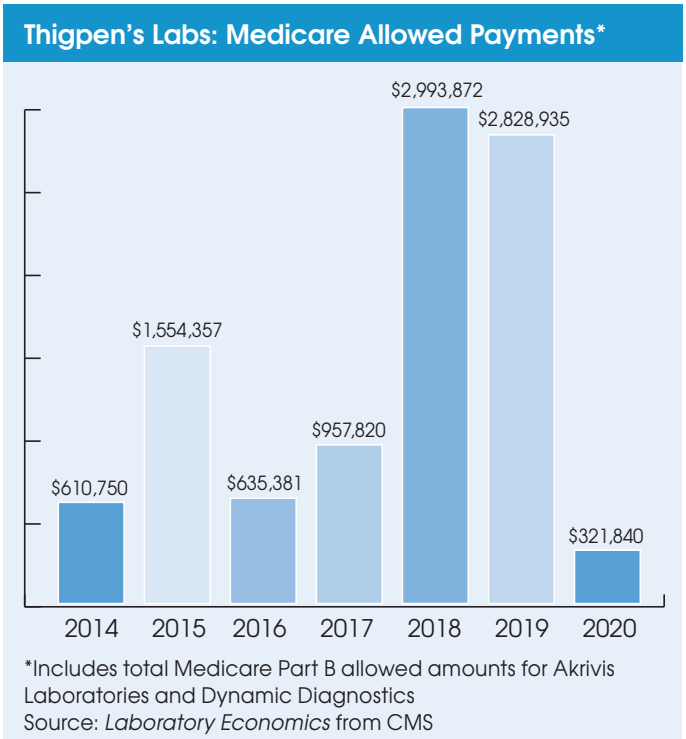
Source: *Laboratory Economics* from CMS

Akrivis Labs and Dynamic Diagnostics

Also involved in the crackdown was Christopher Thigpen, 48, of Hammond, LA, who was charged with a 12-count indictment for his role in a $54 million scheme to defraud Medicare between March 2014 and January 2021. Thigpen, through his lab companies, Akrivis Labs and Dynamic Diagnostics, is alleged to have submitted thousands of claims for definitive urine drug testing and genetic testing to Medicare that were not medically necessary and tainted by kickbacks, according to the DOJ. Of the $54 million of submitted claims, Medicare reimbursed Akrivis and Dynamic over $9.5 million.

National Telefraud Crackdown

The crackdown is a continuation of a nationwide coordinated effort to target telefraud, says Karen Lovitch, Chair of the Health Law Practice at Mintz (Washington, DC). This area continues to be a high priority for enforcement authorities, as evidenced by the publication of a Special Fraud Alert by the Health and Human Services Office of Inspector General on the same day that DOJ announced charges involving $1.2 billion in healthcare fraud.



"Cancer genetic testing has been at issue in many of the telefraud schemes uncovered over the past few years, so it was inevitable that new schemes would emerge," says Lovitch. "The type of testing might differ, but the allegations remain the same – the testing is allegedly being ordered for patients who do not need it, and Medicare does not permit the testing to be used as a general screening test, so it was not medically necessary."

Lovitch advises that clinical labs consider periodically auditing test orders to look for aberrant patterns, such as whether a particular provider is ordering a large volume of tests per day on a regular basis. Labs should also consider conducting formal or informal background checks of other labs with which they are doing business, she adds.

SALSA Bill To Fix PAMA Slowly Gaining Support

The Saving Access to Laboratory Services Act (S. 4449 and HR), which would provide a permanent fix to the lab reporting of private-payer data for determining CLFS rates, has been referred to the Senate Finance Committee, House Committee on Energy and Commerce, and House Committee on Ways and Means. The SALSA bills were initially introduced by Sens. Sherrod Brown (D-OH) and Richard Burr (R-NC) in the Senate and by five reps in the House in late June. The House bill has since gained support from two more members, Reps. G.K. Butterfield (D-NC) and Brian Fitzpatrick (R-PA). Without congressional intervention, more than 800 tests on the Medicare CLFS will receive up to 15% rate cuts effective January 1, 2023 (see *LE*, July 2023). Under the current schedule, labs are also required to report their private-payer data from the first half of 2019 to CMS in the first quarter of 2023

Invitae To Lay Off 1,000 Employees (*cont'd from page 1*)

Most of the layoffs will occur at Invitae's's headquarters and main laboratory in San Francisco and will affect scientists, software engineers, customer service reps and marketing staff. Invitae also operates CLIA-certified labs in Irvine, CA, Golden, CO, and Iselin, NJ. In addition, early last year Invitae announced plans to invest $115 million to open a 250,000-square-foot laboratory in Morrisville, NC. In connection with this new lab, Invitae signed a non-cancelable operating lease with a term extending through 2035.

Another big component of Invitae's restructuring will include the sale or wind-down of its test kit business. Invitae entered the kit business through its acquisition of ArcherDX for $2.3 billion in October 2020.

Invitae says it will now focus on its higher-margin, higher-growth opportunities in oncology, women's health, rare disease and pharmacogenomic testing. Invitae's most frequently ordered tests include BRCA 1&2 gene panels for determining risk of hereditary breast cancer, Lynch Syndrome gene panels for hereditary predisposition to colon and uterine cancer, and noninvasive prenatal testing (NIPT) for determining the risk that a fetus will be born with certain genetic abnormalities.

As of June 30, 2022, Invitae's balance sheet showed $737 million of cash and marketable securities. However, the company has a current cash burn rate of more than $600 million per year. The restructuring is expected to lower Invitae's annual cash burn rate to $225-$275 million by the end of 2023. After cost cutting, Invitae says it will have enough cash on hand to fund operations through the end of 2024.

In the six months ended June 30, 2022, Invitae reported a net loss of $2.705 billion, including asset impairment write-offs of $2.3 billion. Revenue grew by 20% to $253 million. The company's billable test volume increased by 22% to 666,000, while average revenue per billable test fell by 2% to $379.

Invitae was originally formed as a spin-off of Genomic Health (now owned by Exact Sciences) in 2010 and went public through an IPO in 2015. Invitae has accumulated total losses of $4.4 billion from its inception through June 30, 2022.

Invitae has $350 million of 2% convertible senior notes coming due September 1, 2024, and another $1.15 billion of 1.5% convertible senior notes coming due on April 1, 2028.

Invitae Mid-Year Financial Summary ($ in thousands)

Six months ended:	*6/30/22*	*6/30/21*	*% Chg*
Total revenue	$252,679	$210,772	19.9%
Net cash used in operations	-282,232	-218,845	NA
Net income	-2,705,320	24,294	NA
Diluted EPS	-$11.75	$0.11	NA
Cash & marketable securities	736,789	1,540,493	-52.2%
Billable test volume	666,000	546,000	22.0%
Avg. revenue per billable test	$379	$386	-1.8%

Source: Invitae Corp.

NeoGenomics Hires New Chief Executive

NeoGenomics (Fort Myers, FL) has hired Chris Smith as its Chief Executive and board member effective August 15. Smith, age 59, most recently served as CEO of Ortho Clinical Diagnostics. Mark Mallon had abruptly stepped down as NeoGenomics CEO and board member in late March (see *LE*, April 2022). Lynn Tetrault, Chair of the Board, had then served as interim CEO of NeoGenomics.

Labcorp Mid-Year 2022 Review

Labcorp (Burlington, NC) reported net income of $850 million for the six months ended June 30, 2022, down from $1.237 billion in the same period for 2021. Overall, Labcorp's reported half-year revenue fell by 5.1% to $7.597 billion.

Looking specifically at Labcorp's lab testing business, revenue declined by 8.1% to $4.710 billion, including approximately 0.8% gained from acquisitions. On July 28, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

CRO Spin-off

The board of directors, executive leadership, and company name of the CRO business will be determined later as plans for the spin-off progress. With annual revenue of $3 billion and an estimated pretax profit margin of approximately 15%, analysts believe that Labcorp's CRO business could be valued at a range of $5.0 billion to $6.5 billion.

Adam Schechter will continue as Chairman and CEO of Labcorp, which will keep its core lab testing business and will retain two related pieces of its drug-development unit (clinical trials testing and early-stage development).

Covid-19 PCR Testing

Labcorp performed an average of 70,000 Covid PCR tests per day in 1Q22, which declined to 31,000 in 2Q22. Labcorp's average reimbursement per Covid PCR test is between $85 and $90. Labcorp's Covid testing revenue (PCR and antibody) totaled $795 million in the first half of 2022, down 43% from $1.391 billion in the same period last year.

Core Test Volume Trends

Labcorp's core testing revenue (excluding Covid testing) was up by 4.9% to $3.914 billion in the first half of 2022.

Hospital Lab Outreach Acquisitions

Most recently, Labcorp acquired the outreach assets of Prisma Health's hospital labs in South Carolina and completed its acquisition of assets from AtlantiCare in New Jersey. Labcorp has invested a total of $555 million for acquisitions so far this year.

Labcorp also announced an agreement to acquire the clinical lab outreach business of RWJBarnabas Health (West Orange, NJ). RWJBarnabas Health's largest hospitals include Robert Wood Johnson University Hospital New Brunswick (624 beds), Cooperman Barnabas Medical Center (557 beds) and Newark Beth Israel Medical Center (467 beds).

Earlier this year, Labcorp announced a comprehensive relationship with Ascension health system. Labcorp is buying select assets of Ascension's lab outreach business for $400 million (see *LE*, February 2022). Labcorp will also manage Ascension's hospital-based labs in 10 states (out of 19). The states covered in the agreement include Alabama, Florida, Kansas, Maryland, Michigan, New York, Oklahoma, Tennessee, Texas and Wisconsin.

Labcorp Mid-Year Financial Summary ($ millions)

Six months ended:	*6/30/2022*	*6/30/2021*	*% Chg*
Total revenue	$7,596.5	$8,002.2	-5.1%
LabCorp Diagnostics	4,709.5	5,123.3	-8.1%
Covance Drug Development	2,911.2	2,933.4	-0.8%
Operating cash flow	928.5	1,644.8	-43.5%
Capital expenditures	260.5	192.6	35.3%
Free cash flow	668.0	1,452.2	-54.0%
Net income	850.2	1,237.0	-31.3%
Diluted EPS	$9.11	$12.58	-27.6%
Est'd number of requisitions	89.8	93.4	-3.9%
Est'd revenue per requisition	$55.13	$57.55	-4.2%

Source: Labcorp and *Laboratory Economics'* estimates for requisitions

Quest Diagnostics Mid-Year 2022 Review

Quest Diagnostics (Madison, NJ) reported net income of $589 million for the six months ended June 30, 2022, down 47% from $1.1 billion in the same period for 2021. Overall, Quest's reported half-year revenue fell by 3.9% to $5.064 billion. Quest's first-half requisition volume was flat at an estimated 105.7 million reqs. Revenue per requisition decreased by 3.9% to an estimated $44.04 per req, driven in large part by a decline in Covid PCR testing. Here's a summary of some key topics discussed during the company's July 21 conference call with analysts:

Covid-19 Testing

Quest's Covid PCR test volumes in June and July averaged about 40,000 tests per day, excluding its joint venture Sonora Quest. Positivity rates have been increasing since March and approximately 25% of the PCR tests that Quest performed in the first two weeks of July were positive. The company forecasts that its daily Covid PCR testing volumes will range between 15,000 and 25,000 for the remainder of the year.

Core Testing Trends

Quest's overall core testing volumes (excluding Covid testing) grew by 5.1% to $3.971 billion in the first-half 2022. Its fastest-growing divisions were gene-based & esoteric testing, up 15.1% to $1.526 billion, and anatomic pathology, up 4.1% to $281 million.

Reimbursement Rates

"Over the last two years, Quest has renewed 12 national and large regional health plan contracts with price increases. We expect more renewals with price increases this year," according to James Davis, CEO-elect at Quest Diagnostics. However, Quest is still seeing pricing pressure for its hospital reference testing contracts and its client-bill business.

Acquisitions

On February 1, 2022, Quest acquired Pack Health (Birmingham, AL) in an all-cash transaction for $123 million, which consisted of $105 million plus contingent consideration estimated at $18 million. The contingent consideration is dependent upon Pack Health reaching certain revenue benchmarks. Pack Health employs certified health coaches who monitor and support individuals with chronic conditions through an online platform providing personalized content.

Quest Diagnostics Mid-Year Financial Summary ($ millions)

Six months ended:	6/30/2022	6/30/2021	% Chg
Total revenue	$5,064	$5,270	-3.9%
Routine clinical lab testing	2,164	2,182	-0.8%
Gene-based & esoteric testing	1,526	1,326	15.1%
Covid-19 testing	954	1,339	-28.8%
Anatomic pathology testing	281	270	4.1%
Other revenue	139	153	-9.2%
Operating cash flow	882	1,191	-25.9%
Capital expenditures	139	170	-18.2%
Free cash flow	743	1,021	-27.2%
Net income	589	1,100	-46.5%
Diluted EPS	$4.88	$8.38	-41.8%
Est'd number of requisitions	105.7	105.7	0.0%
Est'd revenue per requisition	$44.04	$48.40	-3.9%

*Other revenue includes life insurance testing and health information technology services (e.g., electronic health records, practice management and revenue cycle management)
Source: Quest Diagnostics and *Laboratory Economics'* estimates for requisitions

Labor Shortages

"Employee turnover in some job categories is impacting our ability to drive further productivity gains. However, these increased costs are in line with our expectations and are built into our guidance", according to Davis. Quest is seeing its greatest wage pressure for specimen processors and couriers.

America's Fastest-Growing Labs

Ispm Labs (Atlanta, GA) was the fastest-growing lab from 2017-2020, according to an *LE* analysis of newly released Medicare Part B Carrier allowed payment data. Ispm, which does business as Capstone Healthcare, received $29.8 million in Part B allowed payments in 2020, an increase of 205% per year from $1 million in 2017. Ispm specializes in Covid and toxicology testing.

Castle Biosciences (Phoenix, AZ) received $35 million in Part B allowed payments in 2020, an increase of 198% per year from $1.3 million in 2017. Castle specializes in gene expression profiling tests for cancer.

CareDx (Brisbane, CA) grew by 104% per year to reach $112 million in Part B allowed payments in 2020. CareDx specializes in DNA testing to gauge the risk of organ rejection for heart and kidney transplant patients.

Overall, some 3,000 independent labs saw their Medicare Part B Carrier allowed payments increase by 6.1% per year to $6.1 billion from 2017 to 2020.

Top 25 Fastest-Growing Labs by Medicare Part B Carrier Allowed Payments*

Laboratory Name	Location	2020 Part B Allowed Amount	2017 Part B Allowed Amount	3-Year CAGR
Ispm Labs (dba Capstone Healthcare)	Atlanta, GA	$29,770,410	$1,049,281	205.0%
Castle Biosciences	Phoenix, AZ	35,026,069	1,329,530	197.6%
CareDx	Brisbane, CA	112,351,888	13,199,145	104.2%
Patients Choice Laboratories of Indiana	Indianapolis, IN	9,830,858	1,280,890	97.3%
Enigma Laboratory	Brooklyn, NY	10,997,893	1,460,591	96.0%
Mako Medical Laboratories	Raleigh, NC	31,287,532	4,380,675	92.6%
Ark Laboratory (now Helix Diagnostics)	Waterford, MI	7,214,587	1,167,194	83.5%
Gibson Diagnostic Labs	Irving, TX	7,335,194	1,193,489	83.2%
Labcorp	Rsrch Triangle Prk, NC	20,024,705	3,435,493	80.0%
Matias Clinical Laboratory	Baldwin Park, CA	8,789,958	1,567,197	77.7%
Caris MPI	Phoenix, AZ	54,580,145	10,489,722	73.3%
Invitae Corp.	San Francisco, CA	52,342,519	10,420,815	71.3%
Acutis Diagnostics	Hicksville, NY	17,765,785	3,716,478	68.5%
Orchard Laboratories Corp.	West Bloomfield, MI	6,656,523	1,627,570	59.9%
Genesis Laboratory Management	Oakhurst, NJ	8,918,556	2,238,782	58.5%
Mayo Collaborative Services	Rochester, MN	13,327,402	3,373,183	58.1%
Luminus Diagnostics	Tifton, GA	5,201,917	1,374,289	55.8%
Simple Laboratories	Harwood Heights, IL	4,796,662	1,335,640	53.1%
Abira Medical Laboratories	Langhorne, PA	14,126,876	4,167,639	50.2%
University of Washington	Seattle, WA	3,922,432	1,160,269	50.1%
Brookside Clinical Laboratory	Aston, PA	8,708,164	2,579,088	50.0%
Quest Diagnostics/Med Fusion	Lewisville, TX	10,774,614	3,390,241	47.0%
South Georgia Toxicology	Valdosta, GA	4,491,394	1,414,705	47.0%
Decipher Corp.	San Diego, CA	20,638,293	6,515,858	46.9%
Quest Diagnostics/Labtech Diagnostics	Anderson, SC	15,152,362	4,794,208	46.8%
Top 25 Total		514,032,737	88,661,971	79.7%
Grand Total for all 3,032 labs		$6,061,122,618	$5,068,940,152	6.1%

*The top 25 were calculated from all independent clinical labs that had Medicare Part B Carrier allowed payments of at least $1 million in 2017.

Source: *Laboratory Economics* from Medicare Part B Carrier utilization files, 2017 & 2020

Lab Stocks Down 37% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 37% year to date through August 12. In comparison, the S&P 500 Index has fallen by 10% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 60%; Myriad Genetics, 0%; and Psychemedics, down 5%. Labcorp is down 17% and Quest Diagnostics is off 19%.

Company (ticker)	Stock Price 8/12/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
ProPhase Labs (PRPH)	$11.49	$7.17	60%	$169	$131	1.3
Myriad Genetics (MYGN)	27.61	27.60	0%	2,040	672	3.0
Psychemedics (PMD)	6.65	$7.02	-5%	40	26	1.5
Enzo Biochem (ENZ)	2.67	3.21	-17%	119	112	1.1
Labcorp (LH)	259.42	314.21	-17%	28,770	15,715	1.8
Quest Diagnostics (DGX)	140.55	173.01	-19%	20,350	10,582	1.9
Castle Biosciences (CSTL)	33.94	42.87	-21%	627	110	5.7
Sonic Healthcare (SHL.AX)*	33.59	46.63	-28%	18,610	9,080	2.0
Veracyte (VCYT)	26.05	41.20	-37%	1,720	268	6.4
Natera (NTRA)	55.17	93.39	-41%	5,110	724	7.1
Exact Sciences (EXAS)	42.71	77.83	-45%	9,290	1,938	4.8
Sema4 Holdings (SMFR)	2.43	4.46	-46%	676	195	3.5
Guardant Health (GH)	54.18	100.02	-46%	5,680	408	13.9
Aspira Women's Hlth (AWH)	0.94	1.77	-47%	88	8	11.8
Opko Health (OPK)	2.52	4.81	-48%	2,020	1,426	1.4
Fulgent Genetics (FLGT)	52.41	100.59	-48%	696	925	0.8
CareDx (CDNA)	23.69	45.48	-48%	979	315	3.1
Biodesix (BDSX)	2.61	5.29	-51%	105	31	3.4
Exagen (XGN)	5.19	11.63	-55%	43	44	1.0
DermTech Inc. (DMTK)	6.80	15.80	-57%	55	14	3.9
NeoGenomics (NEO)	12.62	34.12	-63%	1,730	489	2.4
Invitae (NVTA)	5.37	15.27	-65%	2,290	486	4.7
Interpace Biosciences (IDXG)	2.44	$7.47	-67%	68	42	1.6
Biocept (BIOC)	1.17	3.62	-68%	5	63	0.1
Unweighted Averages			-37%	$101,281	$43,806	3.7

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from YFinance

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