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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Cleveland Clinic Signs 5-Year Contract With PathAI For Digital Pathology And AI

Cleveland Clinic plans to digitize 300,000 histology slides per year over the next five years with the help of PathAI (Boston, MA). They will then link this data to clinical and molecular test data to conduct translational research and further develop and improve PathAI's algorithms for cancer diagnostics.

Up until now, digitizing slides has been an expensive extra step that offered little benefit above the traditional microscope, according to Brian Rubin, MD, PhD, Chair of the Pathology and Laboratory Medicine Institute at Cleveland Clinic. "We want to build a comprehensive menu of AI tools that will make digital pathology overwhelmingly worthwhile for pathologists," says Rubin.
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MAWD Acquires Boyce & Bynum Pathology

MAWD Pathology (Lenexa, KS) acquired Boyce & Bynum Pathology Professional Services (BBPPS-Columbia, MO) for an undisclosed amount in early April. The deal makes MAWD one of the largest wholly physician-owned pathology practices in the nation.

MAWD and Boyce & Bynum at a Glance

	MAWD	*BBPPS*	*Total*
Employees	320	31	351
Pathologists	41	17	58
Hospital contracts	23	26	49
Year Founded	1969	1964	--

The combined MAWD and BBPPS will have over 350 employees, including 58 pathologists, with nearly 50 hospital contracts and freestanding histopathology and clinical labs in Kansas City, central Missouri and southeast Kansas.
Full details on page 2.

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MAWD Acquires Boyce & Bynum Pathology (*cont'd from page 1*)

Below is a summary of *LE's* discussion with Samuel Caughron, MD, President and CEO of MAWD, who is a board-certified molecular genetic pathologist.

Samuel Caughron, MD

How did the acquisition of BBPPS come about?
Boyce and Bynum sold its clinical lab business to Quest Diagnostics in early 2019. In 2021, BBPPS President Michael Curry, MD, PhD, reached out to inquire if MAWD could help with a pathologist shortage his group was anticipating. That opened the door for further conversations. Ultimately both groups saw the value of a combined pathologist-owned and managed practice and decided that an acquisition was the best path forward.

How will BBPPS operate as part of MAWD?
BBPPS will operate as a division of MAWD in central Missouri and BBPPS pathologists will continue to provide all current services. Dr. Curry will be President of the central Missouri division and take on a senior leadership position at the combined company.

What are the benefits of combining MAWD and BBPPS?
We expect to gain some cost savings, but that was not the primary driver. Really it came down to both groups believing we were stronger together in almost every aspect. Coming together offered a path to continue to promote access to state-of-the-art lab diagnostics for hospital and physician partners, including in smaller communities.

One clear benefit of having a combined group will be in pursuing growth opportunities, especially in the expansion of our molecular diagnostics services and expertise. The MAWD molecular lab offers a range of services, including individual cancer biomarkers (BRAF, EGFR, KRAS, etc.), next-gen sequencing for solid tumor profiling, myeloid neoplasms and BRCA 1/2 mutation analysis. But a lot of tests still leave the region going to national reference labs.

Having a larger combined group will allow us to support more molecular tests at MAWD and keep local pathologist expertise involved in molecular care. Some of the new tests we are working on include an expanded FISH menu as well as homologous recombination deficiency (HRD).

There are other benefits as well. We plan to combine and possibly expand our pathologists' assistant clinical rotation program. We also expect to expand our clinical trials testing business. With the acquisition, MAWD can bring more as a clinical trials partner with both expertise and broad access to Midwest patients from diverse rural and urban areas. Finally, and certainly not least importantly, the single group will improve professional staff recruitment/retention capabilities, pathologists' job satisfaction, security and provide enhanced career opportunities. Recruitment of quality pathologists may be the single greatest challenge facing pathology groups for the next several years.

What about digital pathology?
We have a whole-slide scanning capability, but are not yet doing a significant volume of digital pathology or any primary reads. We have not found the broad application that fits in our practice to lower costs or increase efficiency adequately to justify the cost. We keep an open mind but have watched other pathology labs go all-in with digital pathology only to back away from it later.

Applying AI algorithms to digitized slides could be an answer to increasing pathologist efficiency, but the technology is new and I believe there are yet unanswered liability questions.

For example, what happens if the AI wrongly says no cancer is present and the pathologist signs off on the case?

I have great hope that the combination of digital pathology and AI will improve pathologist efficiency, but think broad adoption is still way into the future.

Have MAWD's test volumes recovered from the Pandemic lows?
Our non-Covid tests volumes are now at or higher than pre-Pandemic levels.

MAWD was quick to launch Covid-19 PCR testing [March 2020] and we have performed approximately 1.3 million tests to date. We have the capacity to perform more than 20,000 Covid-19 PCR tests per day.

Covid testing demand has recently waned. But I'm not convinced that we won't see yet another wave with increased demand for testing.

Cleveland Clinic Signs 5-Year Contract With PathAI (*cont'd from page 1*)

The staff at Cleveland Clinic's Pathology and Laboratory Medicine Institute includes 91 pathologists and an archive of more than 20 million glass slides. Cleveland Clinic pathologists read roughly one million new glass slides each year.

Rubin says that Cleveland Clinic has already been digitizing a small number of slides (5,000 to 10,000 annually) for some time. He notes that digital pathology has mostly been used for education and to provide clinical diagnostic reads for distant Cleveland Clinic hospitals in Florida and Abu Dhabi, United Arab Emirates.

The contract with PathAI involves a much bigger commitment toward digital pathology with AI. Under the agreement, Cleveland Clinic will get a small equity stake in PathAI, but no board seat.

Rubin says Cleveland Clinic will use a variety of whole-slide imaging systems, including high-thruput scanners from Roche, Philips and Leica.

Research and development of AI tools will focus on cancer diagnostics as well as histologic grading systems for chronic liver disease and inflammatory bowel disease. Data from digitized slide images will be analyzed along with molecular test results and patient treatment and outcome data. The goal is to develop a wide range of AI algorithms for both clinical diagnostics and immunotherapy selection, according to Andy Beck, MD, PhD, President of PathAI.

Rubin notes that change is difficult and most pathologists have bonded with their microscopes. "Digital pathology combined with a comprehensive suite of AI tools that solve as many problems as possible is what's needed," he says. Additional reimbursement that acknowledges the value of AI would also be helpful, adds Rubin.

Ultimately, Rubin sees a new pattern of practice that includes digitizing slides and applying AI algorithms overnight. A pathologist would then start his/her morning at the computer with all cases presorted and prioritized. Individual slides for each patient case would also be prioritized with regions of interest highlighted.

PathAI has raised a total of $255 million since being formed in 2016. Major backers include LabCorp, Kaiser Permanente, Merck and Bristol Meyers. PathAI is developing AI-based tools for breast cancer, uropathology, GI pathology and dermatopathology, as well as chronic liver disease. PathAI acquired Poplar Healthcare in August 2021. Poplar Healthcare is a full-service anatomic pathology lab with 350 employees, including 25 pathologists (see *LE*, August 2021).

Spotlight Interview With MolDx Director Gabriel Bien-Willner

The MolDX program was developed by Medicare in 2011 to establish coverage and reimbursement for molecular diagnostic tests. In 2018, Gabriel Bien-Willner, MD, PhD, took over as Medical Director of the program, which is run by Palmetto GBA, a Medicare administrative contractor (MAC) that covers Jurisdiction J (AL, GA, TN) and Jurisdiction M (NC, SC, VA, WV). Bien-Willner is a board-certified anatomic pathologist and molecular genetic pathologist. Throughout his career, he has been active in research, development and advancement of molecular diagnostic services, specifically next-generation sequencing. *Laboratory Economics* recently spoke with Dr. Bien-Willner about the MolDX program.

Gabriel Bien-Willner, MD, PhD

What are some changes you have made to the MolDX program since you took over?
When I joined the program in 2018 as an expert in the field, I set about making a series of substantive changes on multiple fronts. One is structural and procedural. Instead of making every policy decision as a one-off, we changed our processes to have much more structured, rigorous and reproducible procedures for how we write policy, how we do pricing and how we go about making edits. Another change was bringing in key subject matter expertise so that we could be much more specific in our technology assessments to write more effective policies, which also led to a change in our philosophy of how we write policy. Policies are no longer one-offs—they're all tied together with one logical framework. The third thing was to bring on additional resources. When I came on there was a small group of people, and now we have a much larger team of about 15.

Please comment on the huge growth in molecular diagnostics testing over the past 10 years.
It's good and bad. Just because it is growing doesn't mean it's growing for fraudulent reasons. It's an evolution of medicine. Especially in cancer, the explosion has been a positive thing. We now have technology that allows us to identify relevant alterations in genes. We want to cover services that have value. Our task is to reimburse for services that are reasonable and necessary. We do it with as much transparency as possible and ensure that all decisions we make are based on evidence. We know there are bad actors, but they are not a majority of providers. But those who do take advantage of the system play an outsize role in how money is spent. We have to strike a balance and determine who is providing quality services and who is not.

Have you experienced any pressure from Medicare to deny tests?
Absolutely not. There is no mechanism for that to occur. We have to protect the Medicare trust fund, but it's not by not spending money, it's by not spending money on services that are not reasonable and necessary.

How long does it take to make a coverage determination?
Right now, the turnaround time for coverage under an existing policy is about two months, although it could be less. If we don't need additional information, it might be a couple of weeks.

For new coverage policies, we now must follow the 21st Century Cures Act. Prior to that, we used to turn these determinations around in 9 to 12 months, but now the process is more complicated. The framework and the steps involved are more complex, policies are more complex and there are more stakeholders involved. We are now lucky to turn new coverage policies out in a 12-to-18-month window, if not longer.

We don't want it to take this long, but now we write more comprehensive policies called foundational policies. We don't cover tests from a specific vendor in these policies, we cover analytes measured. Any provider that measures a specific analyte can obtain coverage under a policy, provided they meet the analytical or clinical validity requirements set forth in the policy. It makes the wording and crafting of the policies more complex, but ultimately, it's better because the policies are broader in scope, allowing multiple providers to attain coverage without needing to have their own unique policies.

What advice do you have for laboratories that are seeking a determination?
First, make sure you have the expertise. If you are working on something new that has never been done before, talk to us early. We will explain the process to you. We will tell you how we will evaluate the evidence.

Can you address the evolution of Z codes and how they are being used now?
Because most of the tests the MolDX program evaluates are not FDA-cleared tests, but lab-developed tests, the DEX Z-Codes were developed as unique identifiers. They were initially developed by McKesson, which then sold them to Change Healthcare.

Palmetto GBA acquired the coding system from Change Healthcare in 2021. The MolDX program has evaluated over 20,000 tests using these codes, but now they are being utilized by other payers for the same or similar procedures.

When a doctor orders a molecular diagnostic test, doesn't that by itself indicate it is medically necessary?
No, it's the payer who determines what is reasonable and necessary. MACs are given the authority to make these determinations and we do this based on evidence. The providers' job is to get the appropriate medical care for their patient using their best judgment. Sometimes, what the provider and payer feel are reasonable and necessary align, but sometimes those perspectives differ. The provider that performs the service has the responsibility for billing that service to the payer. If a laboratory submits a claim, it is the lab's responsibility to ensure that the service is reasonable and necessary.

Under what circumstances is the use of an unlisted CPT code (for example, CPT 81479, unlisted molecular pathology procedure) justified and warranted?
The unlisted 81479 code is used when there is no other code that accurately describes the service rendered. There are a number of molecular pathology services that do not have specific codes, so the unlisted code would be appropriate. For MolDX or others utilizing Z codes, it's not an issue at all.

What are some common "no-no's" that you see molecular labs making when billing for their tests?
Not following the National Correct Coding Initiative guidance and stacking codes. Every service should be defined by one code. If you are running a gene panel, your one test should be billed with one code. If you perform multiple services, you will bill with multiple codes. [The American Medical Association officially retired the use of "stacking" codes in 2013.]

What are the red flags in billing for molecular tests that alert you to potential fraud?
Stacked codes is the first one. I don't want to discuss what we look for in terms of misbehavior because it's so variable. It's the Red Queen hypothesis – you put a stop to one bad actor with policies and edits, but other bad actors pop up. Bad actors have not too difficult a time figuring out how to take advantage of the system. Some of our policies have been written specifically to prevent abuse and fraud. For example, we have a policy saying repeat germline testing is not reasonable and necessary because the germline does not change. We had to write it because people were abusing the system.

What are your thoughts on the use of artificial intelligence in testing and the potential for a distinct CPT code and billing for AI programs?
Artificial intelligence doesn't really have a meaning to me. What we often see are algorithms trying to be passed off as unique services, but if they are part of another service, they should not be billed separately. No algorithm would ever be a laboratory service by itself.

In addition to Palmetto, which other MACs follow MolDX coverage decisions?
Noridian in Jurisdiction E (CA, HI, NV), CGS in Jurisdiction 15 (OH, KY) and WPS in Jurisdiction 5 (IA, KS, MO, NE) and Jurisdiction 8 (IN, MI).

LetsGetChecked To Acquire Veritas Genetics

Direct-to-consumer testing startup LetsGetChecked (Dublin, Ireland and New York City) has agreed to buy Veritas Genetics (Danvers, MA) and its subsidiary Veritas Intercontinental (Madrid, Spain) for an undisclosed amount.

Veritas Genetics was co-founded in 2014 by biotech entrepreneur George Church, PhD, a Harvard-trained biochemist who has helped start more than 20 companies.

Veritas operates a CAP-accredited lab in the Boston area that specializes in whole-genome sequencing. Its lead product is a laboratory-developed test that screens for risk of hereditary diseases in multiple categories including cancer, cardiovascular diseases and immune disorders. The test panel is marketed directly to consumers under the brand name myGenome. It was initially launched in 2018 at a price as low as $199. The current price of myGenome is $599.

LetsGetChecked at a Glance

Founder & CEO	Peter Foley
# Employees	730
Total capital raised	$263 million
Current valuation	$1 billion
Lead investors	Casdin Capital, HLM Venture Partners, Illumina Ventures, Optum Ventures

Source: LetsGetChecked

Veritas had raised more than $50 million from outside investors including Lilly Asia Ventures, Trustbridge Partners and Philab Holdings. However, in December 2019, Veritas announced that it was ceasing U.S. operations and laying off most of its employees due to its inability to raise more capital. In January 2020, Veritas reversed course and announced that it had obtained a loan and would resume U.S. operations. In addition, Veritas began pooled Covid-19 PCR testing after the Pandemic struck in early 2020.

Veritas Intercontinental is a spin-off of Veritas Genetics that is focused on the international market.

LetsGetChecked says that it will initially focus its marketing efforts for Veritas on a pharmacogenomic test panel that will help health plans and employers identify potential adverse drug reactions.

LetsGetChecked markets more than 30 test panels directly to consumers. The company was founded in 2015 by Irish entrepreneur Peter Foley.

Consumers can order tests via LetsGetChecked.com or through partner retailers, including CVS.com, Walmart.com and Amazon.com. Specimen collection kits are mailed to consumers for self-collected fingerstick blood samples. The kits include a BD Microcontainer blood tube and three lancets. The blood tubes require 600 uL of blood (approximately 10 drops of blood) and are shipped to a lab for testing. LetsGetChecked operates its own CAP-accredited lab in Monrovia, California, and the company also contracts with Northwell Health Labs in Long Island, NY.

Tests marketed by LetsGetChecked include an STD panel (chlamydia, gonorrhea, trichomoniasis, HIV and syphilis) for $149 and a lipid panel for $79. The company also sells a nasal swab Covid-19 PCR test for $109. LetsGetChecked has delivered more than three million test results to customers in the United States and Europe since being formed.

LetsGetChecked has raised a total of $263 million from private equity investors. Its last funding occurred in June 2021 and raised $150 million from a Series D round led by Casdin Capital. This valued LetsGetChecked at $1 billion.

Spotlight Interview With MyMedLab's Founder & CEO David Clymer

MyMedLab (Joplin, MO) is a privately held company focused on the direct-to-consumer market for lab testing. Annual revenue at MyMedLab is approximately $2 million and has been growing by approximately 20% per year for the past three years. *Laboratory Economics* recently spoke with Founder and CEO David Clymer.

David Clymer

When did you start MyMedLab?
After working at several different labs, I founded MyMedLab in 1993. Initially we provided specimen collection services to local companies for drug testing and health fair screenings.

In 2006, we switched gears by launching a website that allows consumers to directly order their own lab tests.

MyMedLab.com serves as the front end for test orders. We contract with traditional labs, including Quest Diagnostics and Great Plains Laboratory, for specimen collection and testing.

How does the test order process work?
Customers visit our website, select a specific test or test panel, enter a zip code and receive directions to a Quest patient service center for specimen collection. In addition, for certain tests, the contracted lab will ship a specimen collection kit directly to the consumer. Testing is performed at our contracted labs.

Consumers pay for their tests online by credit card during the order process.

Results are provided, generally within 72 hours, directly to the consumer through a personal health record maintained on our website.

Are test orders reviewed by a physician?
Yes. Test orders are reviewed either by our Chief Medical Officer, Craig Brandman, MD, or by a network of physicians affiliated with our contracted labs.

Does MyMedLab.com offer direct-to-consumer testing in all 50 states?
Our service is available in 45 states. It's not available in five states that have more restrictive regulations for consumer lab test ordering, which include Massachusetts, Maryland, New Jersey, New York and Rhode Island.

How many customers do you have and how do you attract new ones?
We have approximately 100,000 existing customers and a good portion of our business is repeat testing. Existing customers are especially appreciative of the history of test results that they can maintain on MyMedLab.com.

We add new customers primarily by word of mouth. We have tried online advertising on Google and Facebook, but have found that it mostly results in shoppers, not buyers, visiting our website.

Can you describe your typical customer and the tests they order?
Women aged 25 to 55. Among the most frequently ordered tests are thyroid stimulating hormone ($45), Vitamin D ($150), Mycotoxin test for mold exposure ($325) and Organic Acid Test ($325) for diet modification.

Our menu has approximately 300 tests in total. We have stayed away from offering certain tests that could cause panic if a positive result is recorded, including those for sexually transmitted diseases.

Does MyMedLab market other services?
Yes. About five years ago, we started offering a limited menu of supplements to complement our lab testing under the brand name Clymer Naturals. These include Vitamin D, CBD (for inflammation) and colostrum (for gut health).

Castle Biosciences To Buy AltheaDx For Up To $140 Million

Castle Biosciences (Friendswood, TX) has agreed to acquire AltheaDx (San Diego, CA) for $65 million in initial consideration consisting of $32.5 million in cash plus $32.5 million in stock. In addition, Castle could pay up to $75 million more in cash and stock if AltheaDx hits certain revenue targets over the next three years and gets expanded Medicare coverage for its IDgenetix test. The deal is expected to close this summer.

AltheaDx markets a laboratory-developed pharmacogenomic test under the brand name IDgenetix. The cheek-swab test analyzes a panel of 15 genes to help doctors make prescription recommendations for patients with depression. The test is performed at AltheaDx's CAP-accredited laboratory in San Diego. The Medicare program has covered IDgenetix since the fall of 2020 at a rate of $1,569 (CPT 81479: unlisted molecular pathology procedure).

AltheaDx, which has 40 employees, generated revenues of less than $1 million in 2021. Castle anticipates that AltheaDx will record $1-3 million of revenue in 2022.

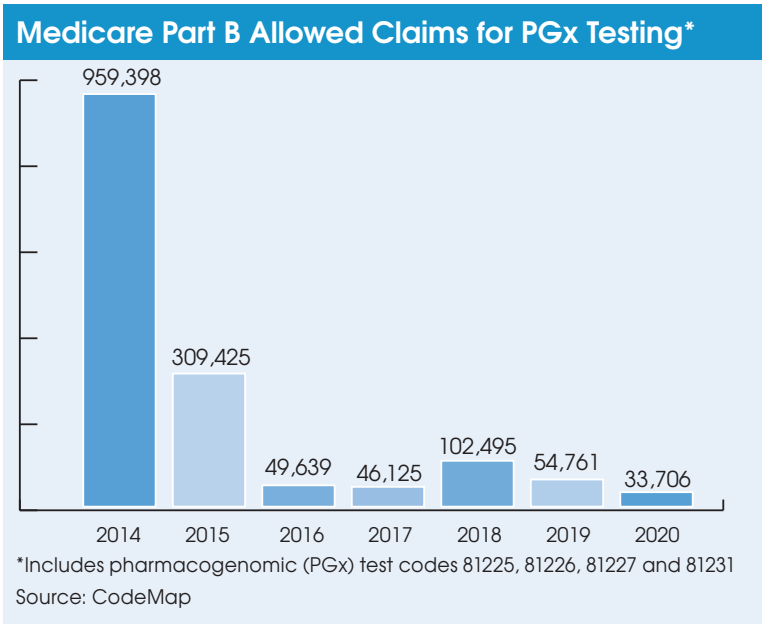
Privately-held AltheaDx's largest investors include Alma Life Sciences, Ally Bridge Group and WuXi Healthcare Ventures. AltheaDx filed for an initial public stock offering in December 2014, but shelved the proposed stock sale in early 2015.

Castle, which has 345 employees, is headquartered in Friendswood, Texas (near Houston) and operates CLIA-certified labs in Phoenix and Pittsburgh. Its lead testing product is DecisionDx-Melanoma, which analyzes 31 genes to predict metastatic risk in patients diagnosed with cutaneous (skin) melanoma. DecisionDx-Melanoma is an Advanced Diagnostic Laboratory Test (ADLT) that is reimbursed by Medicare at $7,193 (CPT 81529).

For the full year ended December 31, 2021, Castle reported a net loss of $31.3 million versus a net loss of $10.3 million in 2020; revenue increased by 50% to $94.1 million.

High Claims Denials for Pharmacogenomic Testing

To date, pharmacogenomic testing for medication selection has been a tough market for labs providing this service. The volume of allowed Medicare Part B carrier claims for four key codes used to bill for pharmacogenomic testing (aka cytochrome p450; CPT 81225, 81226, 81227 and 81231) declined from a combined total of 959,398 allowed claims in 2014 to 33,706 allowed claims in 2020, according to data from the coding and reimbursement firm CodeMap (Chicago, IL). Furthermore, CodeMap data show that denial rates for these pharmacogenomic testing codes ranged from an average of 26% (2014) to 85% (2019) over the seven-year period. This compares with average claims denials rates of less than 10% for most routine clinical lab tests.



Getlabs Raises $20 Million For At-Home Phlebotomy Service

Getlabs Inc. (Miami, FL) recently raised $20 million from a Series A financing round led by Emerson Collective and the Minderoo Foundation. Other investors included Tusk Venture Partners, Labcorp, Byers Capital, Anne Wojcicki (founder and CEO of 23andMe) and Susan Wojcicki (CEO of YouTube). Getlabs has now raised a total of $23 million since being formed in 2018.

Getlabs currently employs more than 100 full-time W-2 phlebotomists throughout the country who perform at-home blood draws for Labcorp, Quest Diagnostics and Sonora Quest. The service is paid out-of-pocket by telehealth patients by credit card. The cost ranges from $25 to $59 per blood draw. The price varies depending on the geographic market and the day and time of the service (e.g., weekends are more expensive). The fee covers Getlabs' phlebotomist salaries, supplies, and mileage. Lab testing fees are separate and paid to the lab by traditional insurance.

Getlabs launched the service in Phoenix in mid-2020, then expanded to Philadelphia and Dallas in early 2021. The company has since expanded to other major cities, including Atlanta, Boston, Chicago, Los Angeles, Miami, New York, etc.

Getlabs has served more than 50,000 patients to date.

The company plans to use the funding to hire more phlebotomists and continue expanding.

Getlabs was founded by its CEO Kyle Michelson, who previously founded Streamup, which was a live video streaming platform.

NeoGenomics Looking For A New CEO

On March 27, NeoGenomics (Fort Myers, FL) announced that Mark Mallon has stepped down as its Chief Executive and as a member of its board "effective immediately." Mallon had been with NeoGenomics for less than one year (see *LE*, April 2021).

NeoGenomics described the parting of the ways as mutual, stating that it wasn't due to "any disagreements about strategy with management or the board, inappropriate action by (the) CEO, or any violation of company policy or any accounting irregularity."

Mallon's departure comes as NeoGenomics has warned that its first-quarter results may be below the low end of its prior guidance of $118 to $120 million for revenue and -$12 to -$15 million for EBITDA. The larger-than-anticipated EBITDA loss was primarily driven by higher than expected costs. In addition, NeoGenomics has withdrawn its 2022 annual financial guidance issued in February.

The board has hired Russell Reynolds, a leading executive search firm, to help find Mallon's replacement. In the meantime, NeoGenomics' Board has appointed current Chair Lynn Tetrault as Executive Chair and established an Interim Office of the CEO.

ACLA Hires Van Meter As President

The American Clinical Laboratory Association (ACLA) has announced that Susan Van Meter is its next President. She replaces Julie Khani who resigned last November. Van Meter was previously the Executive Director of AdvaMedDx, the diagnostic division of the Advanced Medical Technology Association.

Changes At Enzo Could Pave The Way For A Sale

The annual meeting of shareholders of Enzo Biochem (New York City) held in early April resulted in a number of changes that could pave the way for a sale of the company's assets, including its Enzo Clinical Labs division.

A group of activist investors that own a combined 31% of Enzo has been pressuring the company to spin off its clinical lab business for more than two years. These investors include Harbert Fund Advisors (10.7% stake), Bradley Radoff (8.9%), James Wolf (6.7%) and Roumell Asset Management (5%).

Proposals that Enzo shareholders voted to approve included:

- Enzo's board structure has been declassified so that all five of its directors will now be up for re-election each year. Previously Enzo's directors served three-year terms and re-elections were staggered.
- Shareholder votes on the approval of mergers, asset sales, and dissolution will now be subject to a simple majority approval. Enzo had previously required 66.7% shareholder approval.
- Enzo's new CEO, Hamid Erfanian, and private investor Bradley Radoff were added to Enzo's board. They replaced Rebecca Fischer and Dov Perlysky.

In related news, Enzo founder Elazar Rabbani, PhD, has been terminated from his position of Chief Scientific Officer effective April 21. Rabbani remains a board member. In addition, Barry Weiner, who is Rabbani's brother-in-law, has resigned as President of Enzo effective April 19.

Enzo's Latest Financial Results

Separately, Enzo reported a net loss of $5 million for the six months ended January 31, 2022 versus net income of $2.6 million for the same period a year earlier; total revenue increased by 1% to $60.6 million.

Enzo's Clinical Lab Division recorded a 4% revenue decline to $43.4 million in the latest six-month period. Revenues from Covid-19 testing represented 52% and 48% of Enzo's clinical lab revenue in the 2022 and 2021 periods, respectively. Overall assession volume for all of Enzo's testing services decreased by 7% in the latest six-month period. Enzo says that while its Covid-19 test volume increased, patient visits to doctor offices continued to decline due to patient hesitancy as a result of the pandemic.

Enzo operates a full-service clinical laboratory in Long Island, a network of over 30 patient service centers throughout New York, New Jersey and Connecticut, and two free-standing STAT labs in New York City and Connecticut.

How much is Enzo's Clinical Lab Division Worth?

Enzo's clinical lab business would likely attract interest from all four major commercial labs doing business in the New York City area, including Quest Diagnostics, Labcorp, OPKO's BioReference Labs and Sonic Healthcare USA, which owns Sunrise Medical Labs (Long Island, NY).

On the high end, Enzo's clinical lab business could be worth $217 million based on a multiple of 2.5x current annualized revenue of $87 million. On the low end, a multiple of 1.5x current annualized revenue would give it a value of $130 million. The tricky part is determining how much Covid-19 testing revenue will remain after the pandemic is declared officially over and associated volume and reimbursement decline.

Enzo's has a current stock market valuation of $141 million and an enterprise value of $129 million.

Publicly-Traded Lab Revenue Jumped 19% In 2021

On a combined basis, 24 publicly-traded labs reported a revenue increase of 19% to $30.8 billion in full-year 2021 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Among five national clinical labs (Quest Diagnostics, LabCorp, Sonic, BioReference and Enzo), combined revenue increased by 14% (after adjusting for acquisitions). Growth was fastest at Enzo Clinical Labs (New York, NY), which recorded a revenue gain of 81% to $87 million for its fiscal year ended July 31, 2021. Covid-19 testing accounted for nearly half (48%) of Enzo's lab testing revenue in fiscal year 2021.

Among 19 specialty and genetic testing labs, combined pro-forma revenue increased by 40%. Pro-forma revenue growth was fastest at ProPhase Labs (Garden City, NY), up 300% to $79 million. ProPhase operates a CLIA-certified lab in Long Island, NY (25,000 sq. ft.) and a second lab in northern New Jersey (4,000 sq. ft.). ProPhase's growth was driven by Covid-19 PCR, antigen and antibody testing.

Revenue Growth at 24 Publicly-Traded Lab Companies ($000)

Company	Full-Year 2021	Full-Year 2020	Reported Change	Pro Forma Change*
Quest Diagnostics (lab testing only)	$10,494,000	$9,139,000	14.8%	13.0%
LabCorp (lab testing only)	10,363,600	9,253,400	12.0%	10.9%
Sonic Healthcare USA[1]	1,745,100	1,300,600	34.2%	34.0%
Opko/Bio-Reference Labs	1,607,106	1,262,242	27.3%	27.3%
Enzo Clinical Labs (lab testing only)[2]	86,984	47,964	81.4%	81.4%
Total, 5 National/Clinical Labs	**$24,296,790**	**$21,003,206**	**15.7%**	**14.4%**
Exact Sciences	$1,767,087	$1,491,391	18.5%	17.0%
Fulgent Genetics	992,584	421,712	135.4%	123.0%
Myriad Genetics	690,600	557,100	24.0%	24.0%
Natera	625,486	391,005	60.0%	60.0%
NeoGenomics	484,329	444,448	9.0%	8.8%
Invitae Corp.	460,449	279,598	64.7%	64.7%
Guardant Health	373,653	286,730	30.3%	30.3%
CareDx	296,397	192,194	54.2%	54.2%
Veracyte	219,514	117,483	86.8%	86.8%
Sema4 Holdings	212,195	179,322	18.3%	18.3%
Castle Biosciences	94,085	62,649	50.2%	50.2%
ProPhase Labs	79,042	14,514	444.6%	300.0%
Biocept	61,249	27,461	123.0%	123.0%
Biodesix	54,506	45,557	19.6%	19.6%
Exagen Inc.	48,299	41,975	15.1%	15.1%
Interpace Biosciences	41,314	32,398	27.5%	27.5%
Psychemedics	24,909	21,360	16.6%	16.6%
Dermtech	11,838	5,885	101.2%	101.2%
Aspira Women's Health	6,812	4,651	46.5%	46.5%
Total, 19 Specialty/Genetic Labs	**6,544,348**	**4,617,433**	**41.7%**	**39.7%**
Grand Total, All 24 Lab Companies	**$30,841,138**	**$25,620,639**	**20.4%**	**18.9%**

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.
[1]Sonic Healthcare USA revenue is for the 12 months ended June 30, 2021 at constant exchange rate of 1 Australian Dollar equal to 0.70 U.S. Dollar. [2]Enzo's revenue is for lab services only for 12 months ended July 31, 2021.
Source: *Laboratory Economics* from company reports

Lab Stocks Down 33% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 33% year to date through April 14. In comparison, the S&P 500 Index has fallen by 8% so far this year. The top-performing lab stocks thus far in 2022 have been ProPhase Labs, up 16%; Psychemedics, down 8%; and Enzo Biochem, down 10%. Labcorp is down 14% and Quest Diagnostics is off 21%.

Company (ticker)	Stock Price 4/14/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
ProPhase Labs (PRPH)	$8.31	$7.17	16%	$121	3.1	NA
Psychemedics (PMD)	6.45	$7.02	-8%	$39	1.6	15.6
Enzo Biochem (ENZ)	2.88	3.21	-10%	129	1.1	NA
Exact Sciences (EXAS)	69.61	77.83	-11%	13,541	7.7	NA
Myriad Genetics (MYGN)	23.98	27.60	-13%	1,671	2.4	NA
Labcorp (LH)	269.04	314.21	-14%	30,008	1.9	7.4
Quest Diagnostics (DGX)	135.92	173.01	-21%	20,255	1.9	7.1
CareDx (CDNA)	35.41	45.48	-22%	1,689	5.7	NA
Sonic Healthcare (SHL.AX)*	35.52	46.63	-24%	19,654	2.2	8.2
DermTech Inc. (DMTK)	11.95	15.80	-24%	139	11.8	NA
Guardant Health (GH)	71.99	100.02	-28%	7,918	21.2	NA
Opko Health (OPK)	3.34	4.81	-31%	2,396	1.4	34.0
Castle Biosciences (CSTL)	25.94	42.87	-39%	338	3.6	NA
Veracyte (VCYT)	24.15	41.20	-41%	1,689	7.7	NA
Sema4 Holdings (SMFR)	2.61	4.46	-41%	272	1.3	NA
Aspira Women's Hlth (AWH)	1.02	1.77	-42%	81	11.9	NA
Interpace Biosciences (IDXG)	4.24	$7.47	-43%	73	1.8	NA
Fulgent Genetics (FLGT)	56.13	100.59	-44%	1,353	1.4	2.0
Exagen (XGN)	6.31	11.63	-46%	32	0.7	NA
Biocept (BIOC)	1.83	3.62	-49%	18	0.3	4.9
Invitae (NVTA)	6.50	15.27	-57%	2,163	4.7	NA
Natera (NTRA)	39.52	93.39	-58%	3,256	5.2	NA
NeoGenomics (NEO)	12.31	34.12	-64%	1,624	3.4	NA
Biodesix (BDSX)	1.61	5.29	-70%	38	0.7	NA
Unweighted Averages			-33%	$108,498	4.3	11.3

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from company reports and Capital IQ

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