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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Is Alzheimer's Testing the Next Big Lab Market?

The FDA cleared the Alzheimer's drug Leqembi (lecanemab) in July 2023. The drug marked the first treatment for slowing Alzheimer's progression and cognitive decline to make it through the agency's traditional pathway. But Leqembi, which was developed by Eisai (Tokyo) and Biogen (Cambridge, MA), has fallen far short of its goals for patient prescriptions. That's partly because the current methods for diagnosing Alzheimer's—expensive brain imaging scans and invasive cerebral spinal fluid (CSF) tests—are acting as bottlenecks. However, new blood tests for Alzheimer's are being introduced that could give more patients access to treatment.
Full details on page 4.

Supreme Court Overturn of Chevron Could Tilt Odds in Favor of ACLA Lawsuit Win

The elimination of Chevron Deference gives U.S. courts more leeway in how they decide conflicts of statutory interpretation. Previously, courts were required to defer to a federal agency's reading of an ambiguous law or regulation.

The overturn of Chevron could boost the odds of success for ACLA's lawsuit challenging the FDA's authority to regulate laboratory-developed tests (LDTs).

More broadly, the end of Chevron could result in far higher Medicare payments for providers with greater coverage/access, and a bigger burden on government budgets, notes Kevin Caliendo, Managing Director at investment bank UBS (New York City).
Full analysis on page 8.

Quest to Buy Allina Health Outreach Lab Assets

Allina Health (Minneapolis, MN) has agreed to sell its outreach lab assets to Quest Diagnostics for an undisclosed sum. The transaction is expected to close by September 30. Allina Health is a nonprofit healthcare system that operates 12 hospitals and more than 90 clinics throughout Minnesota and western Wisconsin. Allina's outreach lab has an estimated >$20 million in annual revenue and is based at the 681-bed flagship Abbott Northwestern Hospital (Minneapolis).
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QUEST TO BUY ALLINA HEALTH OUTREACH LAB ASSETS (*cont'd from page 1*)
Hospital cost report data show that Allina's 12 hospitals had total laboratory department costs of $171 million (including hospital overhead costs) in 2022. Allina's outpatient laboratory charges totaled $337 million. Medicare CLFS payments to Allina totaled $1.5 million in 2022.

Quest will offer clinical lab testing services to approximately 50 of Allina's physician office clinics (with ~500 physicians, nurse practitioners and physician assistants), as well as independent outreach clients. Allina will maintain testing services at its urgent care centers and hospitals.

Acquired test volumes will be sent to Quest's regional lab in Wood Dale, Illinois—a northwestern suburb of Chicago located 400 miles from Minneapolis. Quest plans to offer jobs to approximately 200 Allina lab employees who will be affected by the sale.

Anatomic pathology services are provided to Allina by 37 pathologists, who are with Hospital Pathology Associates (Minneapolis), which is the largest pathology group in the Minneapolis area. The sale to Quest is focused on clinical lab outreach testing and is not expected to affect anatomic pathology services.

"This transaction will allow us to reinvest our non-profit resources to support our caring mission well into the future," according to Dominica Tallarico, Chief Operating officer for Allina.

Salary & Wage Pressure at Allina Health
Allina reported a $353 million operating loss in 2023, an 80% drop from the $196 million loss in 2022. Revenue increased by 5.5% to $5.2 billion in 2023, while expenses rose by 8.3% to $5.5 billion. Salaries and benefits increased by 6.9% to $3.4 billion and supply expenses rose 12.3% to $1.4 billion.

Allina's cost reduction efforts have included transitioning about 2,000 billing and IT employees to Optum, beginning May 5. Last year, Allina also laid off about 350 employees and implemented a hiring freeze for non-clinical jobs. Allina is aiming to post a "breakeven or positive operating margin in 2024."

Allina Health Outreach Laboratory Stats

Hospital Name	Location	Total Staffed Beds	Outpatient Charges for Laboratory for 2022	Medicare CLFS Payments for 2022	Total Estimated Outreach Testing Revenue
Abbott Northwestern Hospital	Minneapolis, MN	681	$141,524,412	$1,037,323	$10,255,677
Mercy Hospital	Coon Rapids, MN	479	56,399,193	164,136	2,925,009
United Hospital	Saint Paul, MN	391	45,287,580	143,442	2,403,014
Allina Health Faribault Med Ctr.	Faribault, MN	32	12,367,148	39,008	655,455
Owatonna Hospital	Owatonna, MN	39	11,176,447	34,140	587,163
Cambridge Medical Center	Cambridge, MN	54	10,332,414	31,335	541,764
Buffalo Hospital	Buffalo, MN	39	11,975,731	28,494	591,450
Allina Health United Hospital	Hastings, MN	42	7,495,026	16,422	363,581
Mercy Hospital - Unity Campus	Fridley, MN	164	11,001,613	0	421,307
Phillips Eye Institute	Minneapolis, MN	8	211,968	0	8,117
New Ulm Medical Center	New Ulm, MN	34	23,970,077	0	917,934
River Falls Area Hospital	River Falls, WI	25	5,181,735	0	198,435
Grand Total		1,988	$336,923,344	$1,494,300	$19,868,906

Source: LE Hospital Outreach Laboratory Database

Quest to Buy OhioHealth Outreach Lab Business

OhioHealth (Columbus) has agreed to sell certain assets of its outreach laboratory services business to Quest Diagnostics. The transaction is expected to close in the third quarter of the year. Financial terms of the agreement have not yet been disclosed.

OhioHealth will transition its outreach testing to Quest's regional laboratory in Pittsburgh when the deal closes. OhioHealth will continue to own and operate its hospital labs and provide services for inpatient and hospital-based outpatient care, and anatomic pathology services. Quest has extended offers of employment to most of the impacted OhioHealth employees.

OhioHealth includes a network of 15 hospitals, three joint-venture hospitals, one managed-affiliate hospital, and more than 200 ambulatory sites in central Ohio.

OhioHealth's main outreach lab is based at OhioHealth Riverside Methodist Hospital (Columbus), which has 789 beds and estimated annual clinical lab outreach testing revenue of $30-$50 million. The distance from Columbus to Pittsburgh is approximately 185 miles (~3 hours by car).

"Quest has the expertise and economies of scale to deliver meaningful cost savings in lab services, while our patients continue to access the high quality of care they have been accustomed to from OhioHealth," said Juanita Swickard, Interim Vice President, Shared Services, OhioHealth.

Financial Strength at OhioHealth

Unlike many other health systems that have recently sold their outreach labs, OhioHealth is profitable. OhioHealth reported an operating profit of $304 million in the fiscal year ended June 30, 2023, down from $342 million in fiscal 2022. Revenue increased by 6% to $5.7 billion in fiscal 2023.

Fitch Ratings has an AA+ bond rating on OhioHealth "reflecting the system's exceptionally strong credit profile as indicated by solid liquidity in excess of $7 billion, very favorable leverage metrics and reliably strong profitability."

Recent Hospital Lab Outreach Deals

Over the past 18 months, Quest and Labcorp have spent $800+ million to make 10 hospital outreach lab acquisitions. The biggest deal during this period was Quest's $275 million acquisition of the outreach lab business at NewYork-Presbyterian (New York City) in April 2023.

Date	*Buyer*	*Hospital Outreach Lab*	*Purchase Price*
Pending	Quest Diagnostics	OhioHealth outreach lab (Columbus, OH)	NA
Pending	Quest Diagnostics	Allina Health outreach lab (Minneapolis, MN)	NA
Apr-24	Labcorp	Providence California Medical Group Labs (Northern CA)	NA
Apr-24	Labcorp	Baystate Health outreach lab (Springfield, MA)	NA
Nov-23	Labcorp	Legacy Health outreach lab (Portland, OR)	$107.7
Sep-23	Labcorp	Tufts Medicine outreach lab (Boston, MA)	$157
Jun-23	Labcorp	Providence Oregon outreach lab (Portland)	$110
May-23	Labcorp	Jefferson Health outreach labs (Philadelphia)	$110.2
Apr-23	Quest Diagnostics	NewYork-Presbyterian outreach lab (New York City)	$275
Mar-23	Quest Diagnostics	Northern Light Health outreach lab (Bangor, ME)	$31

Source: *Laboratory Economics*

IS ALZHEIMER'S TESTING THE NEXT BIG LAB MARKET? (*cont'd from page 1*)
An estimated 6.9 million Americans aged 65 and older are currently living with Alzheimer's disease, according to the Alzheimer's Association (Chicago, IL). And an estimated 500,000 new cases of Alzheimer's will be diagnosed this year.

The new Alzheimer's treatment Leqembi has a list price of $26,500 per year. In addition, the FDA recently cleared Eli Lilly's Alzheimer's drug Kisunla (donanemab), which has a list price of $32,000 per year. Both drugs are intravenous infusions that attack a protein (amyloid) that clumps into plaques in the brains of people with Alzheimer's. Both drugs slow disease progression (e.g., memory loss or other cognitive problems) but do not stop or reverse it.

In addition, at least nine pharmaceutical companies have clinical trials underway for new Alzheimer's drugs. Those in late-stage trials for oral pill treatments include BioVie (NE3107) and AB Science (masitinib).

But these drugs rely on PET scans and CSF tests to identify Alzheimer's patients for treatment. "The availability of more affordable and minimally invasive diagnostic tools will help support broad access for the management of Alzheimer's disease," according to Eisai's global Alzheimer's disease officer, Keisuke Naito.

New blood-based immunoassays that identify the proteins associated with Alzheimer's are likely to become the new standard for screening and monitoring the disease. The potential lab market could reach $500+ million per year. This estimate assumes 4 blood tests to identify and monitor each of the 500,000 new cases of Alzheimer's each year at an average reimbursement of $260 per test (for two protein markers per test).

At the June 25th Annual CLFS Meeting with CMS to address rate setting for new codes, ACLA requested a Medicare rate of $130 per Alzheimer's protein marker. Thus, a two-protein test (e.g., pTau181 & Abeta42) would be reimbursed $260. This level of reimbursement would match the Medicare rate of $260 for Fujirebio's FDA-cleared Lumipulse test. Coding and final rates will be announced by CMS later this year for an effective date of January 1, 2025.

There are currently at least six Alzheimer's lab tests on the market (see table). In addition, Danaher's Beckman Coulter is developing a blood test for its immunoassay analyzers. Beckman is expected to release a two-protein test (pTau217 & Abeta42) in RUO format later this year. Clinical data from the RUO test will be used to support an eventual FDA application.

Examples of Alzheimer's Lab Tests

Laboratory/ IVD Company	*Test Name*	*Sample Method*	*Status*	*Code*	*Medicare Rate*
Fujirebio	Lumipulse	CSF	FDA cleared	PLA 0358U	$260.50
Roche Diagnostics	Elecsys pTau181/ Abeta42 Ratio	CSF	FDA cleared	PLA 0445U	MAC priced
C2N Diagnostics (Washington University)	PrecivityAD	Blood	LDT	PLA 0412U	$339.00
Danaher Beckman	Access Immunoassay	Blood	Under development	NA	NA
Labcorp	ATN Profile	Blood	LDT	TBD	NA
Quanterix	LucentAD	Blood	LDT	TBD	NA
Quest Diagnostics	AD-Detect	Blood	LDT	PLA 0346U	$93.26

Source: *Laboratory Economics* from companies

Labcorp/Dynacare Workers Get 11% Wage Hike

Union workers at Dynacare Northwest (Seattle), a wholly-owned subsidiary of Labcorp, have ratified a new contract that gives lab employees an immediate average wage hike of 11% (effective early August) plus a cost-of-living adjustment (COLA) of 2% in 2025. In addition, all Labcorp/Dynacare union workers will get a $750 ratification bonus.

The new contract covers 710 Labcorp/Dynacare workers, including medical technologists (MTs), histotechnologists, medical lab technicians (MLTs), phlebotomists and couriers, who work at Swedish Health Services, which is the largest nonprofit health system in the Seattle area. Labcorp has held a contract to provide lab services, both onsite and reference, to Swedish since Labcorp acquired Dynacare in 2002.

The Labcorp/Dynacare workers, who are members of UFCW 3000, had threatened to strike if a new contract couldn't be negotiated (see *LE*, June 2024). Contract negotiations had been ongoing for more than a year.

"It was a tough fight, but we won some of the highest wage increases in Labcorp union history," according to Kyle Chrisman, a Labcorp phlebotomist who serves on the union bargaining committee.

UFCW 3000 – Labcorp New Contract Highlights

- Wage increases for all job classifications (averaging 11% in the first year)
- $750 contract ratification bonus
- 2% COLA in 2025
- Shortened the total number of years it takes to reach the top of the pay scale
- Healthcare & benefits expansion beginning January 1, 2025

UFCW 3000 charges its members between $192 and $900 in annual dues. The average member pays the union about $500 per year.

Pathologist Compensation Reached $366K in 2023

Pathologists earned average compensation (salary & bonus) of $366,000 in 2023, according to the Medscape Physician Compensation Report for 2024. Over the past five years (2018-2023), pathologist compensation has risen by an average of 3.5% per year. Sixty-four percent of surveyed pathologists said that the most rewarding part of their job was "being good at what I do/finding answers, diagnoses." The most challenging part of a pathologist's job (cited by 29%) was "having so many rules and regulations." The latest Medscape Survey was completed by 7,000 physicians, including approximately 140 pathologists, between October 2023 and January 2024.

Average Physician Compensation by Specialty ($000)

Specialty	2023	2022	2021	2020	2019	2018	5-Year CAGR
Plastic Surgery	$536	$619	$576	$526	$479	$471	2.6%
Urology	$515	$506	$461	$427	$417	$408	4.8%
Gastroenterology	$512	$501	$453	$406	$419	$417	4.2%
Radiology	$498	$483	$437	$413	$427	$419	3.5%
Dermatology	$479	$443	$438	$411	$394	$419	2.7%
Pathology	$366	$339	$334	$316	$318	$308	3.5%
Family Medicine	$272	$255	$255	$236	$234	$231	3.3%

Source: Medscape Physician Compensation Reports for 2019-2024

Spotlight Interview with Ibex CEO Joseph Mossel

Ibex Medical Analytics (Tel Aviv, Israel and Brookline, MA) develops AI algorithms that help pathologists detect and grade cancer in prostate, breast and gastric biopsies. The company, which has more than 90 employees, was co-founded by two computer scientists, Joseph Mossel and Chaim Linhart, PhD, in 2016. This month we got in touch with CEO Mossel for an update on Ibex and the digital pathology & AI markets.

Joseph Mossel

How many lab clients does Ibex currently have?
A total of 50 organizations worldwide—the majority are based in Europe. Our U.S. lab clients include Alverno Labs, CorePlus (Puerto Rico), OSU Wexner Medical Center, PathGroup and UPMC.

Why are some European countries ahead of the U.S. in terms of digital pathology & AI adoption?
Countries like England, Belgium, France and the Nordic region are adopting digital pathology quicker because there is much more government support and funding there. And digitized slide images are required before AI algorithms can be applied.

What's the biggest obstacle to more adoption of digital pathology & AI in the U.S.?
Reimbursement is the biggest obstacle in the U.S. Without reimbursement, digital pathology requires a significant upfront investment in scanner hardware and has a shaky business case at best. AI tools can greatly increase accuracy and pathologist productivity, creating a return on investment, but you need the infrastructure of digital pathology to be there first.

What are the expected productivity gains for pathologists using AI tools?
Our platform can increase pathologist productivity by 50% to 100%. For example, we recently completed a study with Quest Diagnostics and Proscia Inc. that showed that our AI tools reduced pathologist reading times by 60%—pathologists were able to sign out 2.9 cases per hour instead of 1.2.

The study included 180 randomized prostate cases (including 4,366 H&E-stained slides from prostate core needle biopsies). Slides were digitized using Leica GT450 scanners at Quest's lab in Tampa. Digitized images and workflow were managed by Proscia's Concentriq Dx. Professional interpretations were performed by three board-certified pathologists with no previous experience with digital pathology or AI in clinical practice. Our AI increased pathologist productivity by red-flagging regions of interest with our heatmaps and by prefilling reports with measurements of core length and tumor length.

How do labs pay for Ibex's AI tools?
We use an annual subscription model, rather than per-click fees, to encourage labs and pathologists to utilize our AI for their entire pathology case volume.

What is the status/update on getting FDA clearance for Ibex's AI algorithms?
Our platform received the Breakthrough Device designation from the FDA in 2021 and we continue to work toward getting final clearance.

What differentiates one AI algorithm from a competing AI algorithm?
It's more than simply comparing one algorithm to another algorithm. The real differentiator is how well a particular clinical AI product integrates into the workflow at your laboratory.

How much money has Ibex raised to date?
A total of more than $100 million, including most recently a $55 million Series C round led by Octopus Ventures and 83North in October 2023.

Progress Report on HNL Lab Medicine's Transition to Digital Pathology

HNL Lab Medicine (Allentown, PA) is an independent lab that is majority owned by Lehigh Valley Health Network (LVHN). HNL has more than 1,100 employees, including 35 board-certified pathologists. It operates a full-service laboratory in Allentown and has more than 50 PSCs in Pennsylvania and New Jersey.

Sajjad Malik, MD

Last year, HNL announced plans to start scanning its surgical pathology slides and move toward digital interpretations (see *LE*, August 2023). HNL processes about 600,000 surgical pathology slides per year (excluding cytology and bone marrow biopsies).

Laboratory Economics recently interviewed Sajjad Malik, MD, Medical Director of Digital Pathology at HNL, for a progress update.

How many slide scanners has HNL installed?
We recently completed the installation of four Leica Aperio GT 450 scanners at our main lab in Allentown. Ultimately, we anticipate adding three more scanners. We're also using Proscia's Concentriq DX for image management and storage.

How is HNL validating digital pathology?
We're using CAP guidelines to validate the system. This includes concordance studies comparing pathologist interpretations using traditional microscope versus digitized images on 60 routine surgical cases and 20 complex cases requiring special stains or immunohistochemistry. Validation should be completed by early August.

Will you require your pathologists to perform digital pathology interpretations?
We're giving our pathologists the opportunity to transition to digital pathology at their own speed. Some of our pathologists are eager to switch to digital interpretations and others still like the feel of the microscope. Over time, digital pathology may allow our pathologists to work from home for part of the week. This may prove to be the biggest incentive to switch. Our goal is to have 50% of case volumes read digitally in 12 months and 100% within two years.

What has been the hardest part of moving to digital pathology?
The scanners require a large capital investment. In addition, our IT department spent a lot of time integrating the viewing system with our LIS.

What are some benefits you anticipate?
It's still early, but having digital pathology is already helping us recruit pathologists. The potential to work from home a few days a week is especially appealing.

We are also finding that multiple digital images on a computer monitor provide the pathologist with an immediate broad picture of a patient's case.

Pathologists are also able navigate from one case to the next case more quickly. In addition, sharing cases for second opinions can be done instantaneously.

What are your plans for incorporating AI tools?
We want to get it going, but first we need to get the majority of our pathologists comfortable with signing out cases digitally. We've begun some initial discussions with AI vendors about cost and workflow. I expect that we may integrate one or two AI algorithms in about a year or so.

WHAT THE CHEVRON DECISION MEANS FOR LABS (*cont'd from page 1*)

Sheila Walcoff

Laboratory Economics recently spoke with Sheila Walcoff, Esq., for an update on how the Chevron Decision could affect labs as well as other recent LDT regulation news. Walcoff is Founder and CEO of Goldbug Strategies (Gaithersburg, MD) which specializes in helping labs and IVD firms navigate FDA regulations. Key questions are answered below.

What does the Supreme Court's recent "Chevron Decision" mean for labs?
The Chevron doctrine required courts to defer to a federal agency's interpretation of the law when the law was ambiguous or silent on the matter in question, so long as the agency's interpretation was reasonable.

By overturning Chevron, the Supreme Court eliminated the requirement that judges defer first to the interpretation of the federal agency delegated to implement federal statutes. Nevertheless, the Supreme Court acknowledged that it is appropriate (and consistent with judicial precedent prior to the Chevron decision) for courts to give "due respect" to the interpretation of federal agencies, particularly if the issues require technical expertise beyond that which courts might possess.

One of the most important questions in the ACLA lawsuit is FDA's authority to apply medical device regulations "when the manufacturer of the [reagents, instruments, and systems] is a laboratory."

What are the key takeaways from the recent FDA Guidance: Laboratory Developed Tests: Small Entity Compliance Guide?
The Guidance (released on June 25) is a concise explanation of the new LDT requirements for labs of all sizes and a reminder that labs with sales of less than $100 million per year can qualify for substantially reduced FDA fees. Importantly, the Guidance reminds labs that the new Rule is in effect so "it is illegal to offer IVDs without complying with applicable requirements." Also, specimen collection kits used outside the lab are not "IVDs offered as LDTs," so labs that provide such kits are "medical device manufacturers" and FDA expects compliance with medical device rules (i.e., the LDT "phase out" period does not apply).

What should labs that offer LDTs be doing right now? Is a "wait and see" approach appropriate?
Labs should not "wait and see" because, as the FDA highlights in the new Guidance, the LDT rule is in effect. Because the court did not enjoin FDA from implementing the Rule, compliance is required while the lawsuit winds its way through the U.S. court system. The first deadlines under the Rule could occur before there is a final decision since the federal government has already publicly announced its plan to appeal should ACLA prevail in the lower court.

The clock is already ticking, so labs should be initiating the following activities as soon as possible to help de-risk compliance:

1) For each LDT, develop and document intended use statements that include all FDA-required elements. This will enable labs to determine which aspects of the LDT Rule apply and by when.
2) Perform a quality system gap assessment to the new QMSR Rule and the LDT Rule. Labs should try to gap fill by revising existing laboratory policies and procedures to comply at a minimum with the Stage 1 adverse event reporting requirements, due no later than May 6, 2025.
3) For each LDT, start developing FDA compliant "labeling" to be ready for the May 6, 2026, deadline. This Stage 2 requirement carries the greatest risk to labs and includes much more information than many labs are anticipating.

Quest to Buy Canadian LifeLabs for $990 Million

Quest Diagnostics has agreed to acquire LifeLabs (Toronto, Canada) for CAN $1.35 billion (USD $990 million), including assumed debt (USD ~$300 million). The purchase price equates to a multiple of 1.4x LifeLabs' annual revenue of USD $710 million ($990M/$710M = 1.4x).

LifeLabs will retain its brand, its Toronto headquarters and its management after the deal is completed, which is expected by the end of the year. As part of Quest, the biggest synergies could come in the form of equipment/reagent purchasing with an estimated potential savings of $10 million per year, according to Kevin Caliendo, healthcare analyst at UBS.

Quest anticipates that the acquisition of LifeLabs will begin adding to its earnings within 12 months after the close.

Toronto-based pension fund Ontario Municipal Employees Retirement System (OMERS) is the current owner of LifeLabs. OMERS originally acquired LifeLabs, formerly known as MDS Diagnostic Services, for CAN $1.3 billion (USD $975 million) in 2007.

LifeLabs at a Glance

Headquarters	Toronto, Ontario
President & CEO	Charles Brown
# Employees	6,500
Annual test volume	112 million
Annual revenue	USD $710M
# Laboratories	16
# Patient collection centers	382

Source: LifeLabs and Quest Diagnostics

LifeLabs is the largest independent laboratory company in Canada (population: 39 million). LifeLabs operates 16 labs throughout Canada that perform a total of 112 million tests per year. Labcorp's Dynacare is the biggest Canadian competitor to LifeLabs.

LifeLabs' biggest client is the Ontario Ministry of Health, which administers healthcare services in Ontario. A comparison of lab test reimbursement shows that rates paid by Ministry of Health Ontario Health Insurance Plan (OHIP) are an average of 64% below Medicare CLFS rates (see table below).

Ontario/Canada vs. U.S. Lab Test Reimbursement Rates

Codes	Test Name	OHIP Rate*	Medicare CLFS Rate	Percentage Difference
L665/86140	C-Reactive Protein	$2.73	$5.18	-47%
L093/83036	Glycosylated Hemoglobin - HbA1c	5.33	9.71	-45%
L325/83525	Insulin	4.51	11.43	-61%
L733/G0145	Pap Test by Monolayer Cell Method	10.26	26.49	-61%
L445/85610	Prothrombin Time	1.96	4.29	-54%
L055/82465	Total Cholesterol	0.94	4.35	-78%
L340/84403	Total Testosterone	10.64	25.81	-59%
L341/84443	TSH (thyroid stimulating hormone)	2.63	16.80	-84%
L345/82607	Vitamin B12	2.63	15.08	-83%
L606/82306	Vitamin D 25-Hydroxy	8.57	29.60	-71%
Average				-64%

*Based on $1 Canadian dollar = $0.735 U.S. Dollar

Source: *Laboratory Economics* from Medicare CLFS and Ministry of Health Ontario Health Insurance Plan (OHIP) Laboratories and Diagnostics Branch

DermTech Files for Bankruptcy, Lays Off 20% of Staff

DermTech Inc. (San Diego, CA) filed for Chapter 11 protection on June 18 in the U.S. Bankruptcy Court for the District of Delaware.

DermTech intends to maintain its laboratory operations and continue processing orders for its DermTech Melanoma Test (DMT), while simultaneously conducting a process to sell substantially all of its assets.

DMT is a laboratory-developed test (LDT) that uses four skin patch stickers to non-invasively collect cells from a suspicious skin spot. The samples are then analyzed for the presence of genomic markers associated with melanoma at DermTech's CLIA-certified lab in southern California. The test has a 99% negative predictive value (NPV), meaning that with a negative test result, there is a 99% probability that the lesion is not melanoma. DMT is reimbursed by Medicare through a Proprietary Laboratory Analysis code (0089U) at $760.

In addition to the bankruptcy filing, DermTech laid off approximately 15 employees, or 20% of its workforce, in early June in an effort to preserve its cash.

DermTech has also entered into "retention agreements" that will pay its top executives one-time cash awards to keep them with the company through the end of the year. The company's CEO Bret Christensen will receive $510,000; CFO Kevin Sun ($349,350); Chief Commercial Officer Mark Aguillard ($200,000); and General Counsel Ray Akhavan ($330,650).

DermTech reported a net loss of $20 million in the three months ended March 31, 2024, versus a net loss of $31.3 million in the same period a year earlier; revenue was up 11% to $3.8 million. The company processed 15,360 billable tests in the latest quarter, down 14% from a year ago.

DermTech had cash and short-term securities of $39 million as of March 31, 2024. The company has accumulated losses totaling $444 million since being formed in 2017.

DermTech is being advised by Wilson Sonsini (San Diego), AlixPartners (New York City) and TD Cowen (New York City).

DermTech is the third publicly traded genetic testing company to file for bankruptcy in the past 12 months. Biocept Inc. (San Diego) filed for Chapter 7 bankruptcy liquidation on October 13, 2023. In addition, Invitae Corp. (San Francisco) filed for Chapter 11 bankruptcy protection on February 13, 2024 (see *LE*, February 2024).

DermTech Financial Results ($ millions)

Financial Highlights	*1Q2024*	*1Q2023*	*% Chg*
Revenue	$3.8	$3.5	11%
Sales & Marketing Expenses	7.8	15.4	-49%
Research & Development Expenses	3.3	4.4	-26%
General & Administrative Expenses	10.1	11.9	-15%
Total Operating Expenses	21.2	31.7	-33%
Net loss	20.0	31.3	-36%
Cash & Short-Term Securities	39.0	104.8	-63%
Total Debt	53.7	55.6	-3%
Accumulated Deficit	-$443.9	-$354.3	NA
Total Billable Tests	15,360	17,800	-14%

Source: DermTech Quarterly Financial Reports

The Top 25 Medi-Cal FFS Laboratories in 2023

California Medi-Cal fee-for-service (FFS) payments to labs and pathologists rose by 1.1% to reach $218.2 million in calendar-year 2023, according to data from the California Department of Health Care Services (DHCS). These FFS payments do not include lab expenses for Medi-Cal managed care plans, which are paid on a capitated basis and negotiate their own rates with their contracted providers. As of October 2023, Medi-Cal served 15.6 million members, including 14.1 million in managed care plans and 1.4 million in traditional fee-for-service.

The largest Medi-Cal lab provider is **Quest Diagnostics**, which received $24.1 million of Medi-Cal FFS payments in 2023, down slightly from 2022, according to data from the California DHCS.

The Genetic Disease Screening Program (GDSP) of the California Department of Public Health was the second largest, with $20 million, up 15.5% from $17.3 million in 2022. The Genetic Disease Screening Program provides prenatal and newborn testing services to Medi-Cal recipients.

Action Urgent Care Inc. (San Jose), which operates 14 urgent care clinics in the San Jose area, received $18.9 million in 2023.

H&M Molecular Diagnostics (San Diego), which specializes in PCR-based testing for Covid and other respiratory diseases, was the fastest-growing Medi-Cal lab. H&M received $8.7 million, up 346% from $1.9 million in 2022.

Top 25 Medi-Cal FFS Laboratories in CY 2023

Laboratory	*CY 2023 Reimbursements Paid (FFS Only)*	*CY 2022 Reimbursements Paid (FFS Only)*	*% Chg*
Quest Diagnostics	$24,087,235	$24,144,246	-0.2%
CDPH Genetic Disease Branch	19,956,575	17,277,356	15.5%
Action Urgent Care Inc.	18,853,080	NA	NA
Planned Parenthood	18,808,488	18,533,472	1.5%
LabCorp	8,829,791	8,620,266	2.4%
H&M Molecular Diagnostics	8,668,309	1,944,840	345.7%
Gentech Laboratories	7,079,203	NA	NA
Regents of the University of CA/UCLA Outreach	4,401,182	4,362,512	0.9%
Natera Inc.	3,786,517	1,914,701	97.8%
Childrens Hospital of Los Angeles	3,545,543	3,631,416	-2.4%
Dignity Health	2,574,498	2,416,578	6.5%
Santa Clara Medical Center	2,369,579	2,141,774	10.6%
Latara Enterprise (dba Foundation Laboratory)	2,113,566	2,519,603	-16.1%
Primex Clinical Labs	2,027,159	2,873,337	-29.4%
City of Hope Helford	1,936,181	1,693,498	14.3%
Rady Children's Hospital	1,804,442	2,262,335	-20.2%
Billiontoone Inc.	1,629,442	NA	NA
Avellino Lab USA	1,536,115	NA	NA
Hazel Hawkins Memorial Hospital	1,515,056	1,493,089	1.5%
Family Planning Associates	1,480,238	1,318,292	12.3%
Loma Linda University	1,466,005	1,525,638	-3.9%
CHLAMG-Pathology	1,457,930	1,275,576	14.3%
Alameda Health System	1,279,787	1,164,840	9.9%
Biological Laboratory Inc.	1,265,526	1,440,884	-12.2%
County of San Bernardino	1,189,664	1,281,839	-7.2%
Total for Top 25 Labs	$143,661,111	$103,836,092	38.4%
Grand Total, all Medi-Cal Labs	**$218,173,815**	**$215,862,931**	**1.1%**

Source: California Dept. of Health Care Services

Lab Stocks Up 27% So Far In 2024

Twenty-five lab stocks have risen by an unweighted average of 27% year to date through July 12. In comparison, the S&P 500 Index is up 18% year to date. Only eight lab stocks have gained, while 17 have declined. The top-performing lab stock thus far in 2024 is GeneDx, up 1,093%. Quest Diagnostics is up 5% and Labcorp is down 9%.

Company (ticker)	Stock Price 7/12/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$32.80	$2.75	1093%	$863	$222	3.9
Natera (NTRA)	111.60	62.64	78%	13,260	1,209	11.0
Myriad Genetics (MYGN)	26.42	19.14	38%	2,430	774	3.1
CareDx (CDNA)	15.91	12.00	33%	647	275	2.4
Guardant Health (GH)	31.07	27.05	15%	4,050	604	6.7
Tempus AI (TEM)	39.76	37.00	7%	8,080	562	14.4
Quest Diagnostics (DGX)	144.11	137.88	5%	21,000	9,287	2.3
Interpace Biosciences (IDXG)	1.09	1.08	1%	59	41	1.5
Exagen (XGN)	1.93	1.99	-3%	30	56	0.5
Biodesix (BDSX)	1.69	1.84	-8%	296	55	5.4
NeoGenomics (NEO)	14.79	16.18	-9%	2,110	611	3.5
Opko Health (OPK)	1.38	1.51	-9%	1,310	800	1.6
Labcorp (LH)	206.17	227.29	-9%	23,340	12,300	1.9
Castle Biosciences (CSTL)	18.55	21.58	-14%	298	251	1.2
Veracyte (VCYT)	22.75	27.51	-17%	1,540	376	4.1
Sonic Healthcare (SHL.AX)*	26.30	32.08	-18%	16,000	8,377	1.9
Psychemedics (PMD)	2.37	2.96	-20%	14	22	0.7
ProPhase Labs (PRPH)	3.30	4.52	-27%	85	29	3.0
Fulgent Genetics (FLGT)	20.95	28.91	-28%	-209	288	NA
Exact Sciences (EXAS)	46.36	73.98	-37%	10,480	2,535	4.1
23andMe (ME)	0.48	0.91	-47%	97	220	0.4
Aspira Women's Hlth (AWH)	1.61	4.08	-61%	21	9	2.4
DermTech Inc. (DMTKQ)	0.05	1.75	-97%	17	16	1.1
Biocept (BIOCQ)	0.00	0.04	-100%	5.0	1	3.5
Invitae (NVTAQ)	0.00	0.63	-100%	1,250	482	2.6
Totals & Averages			27%	$107,073	$39,397	2.7

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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